Regulatory Analysis Template

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Agency Name Health & Human Services (HHS) **Rule #** Chapter 441-8

Iowa Code Section Authorizing Rule 217.23

State or Federal Law(s) Implemented by the Rule N/A aside from the authorizing statute.

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This chapter defines reimbursement of small claims procedures for department employees. It serves to ensure department employees can be reimbursed for damage to personal items incurred through service to HHS clients in a timely and efficient manner.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

N/A

    - Classes of persons that will benefit from the proposed rule:

HHS employees, primarily facilities and field staff.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred

- Quantitative description of impact:

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5 Year Total
Costs Total Reimbursement* Total Claims	$2,570 18	$2,085 19	$6,430 47	$3,452 25	$1,109 7	$15,646 116
Benefits Increased Employee Trust	Intangible	Intangible	Intangible	Intangible	Intangible	

*All monetary values have been rounded to the nearest dollar.

YTD as of 6/6/2023: 3 claims have been approved for a total of $652.

- Qualitative description of impact:

The nominal cost to reimburse employees for damaged personal property justifies the benefits of retaining and supporting the department's facility and field staff workforce. Reimbursing employees for damaged personal items when in service to HHS clients helps to maintain an adequate workforce to support the critical needs of Iowans served by the Department.

3. Costs to the state
   - Implementation and enforcement costs borne by the agency or any other agency:

In addition to the table above, HHS incurs personnel costs for those team members tasked with processing claims for reimbursement. However, due to the small number of claims submitted for review, costs are absorbed into current HHS employee costs.

   - Anticipated effect on state revenues:

None identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The costs and the benefits of the proposed rule and inaction are largely the same due to the authorizing statute. The only difference between the proposed rule and inaction is the added benefit of flexibility and a more streamlined process for HHS employees to submit and process claims under the proposed rule.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

Iowa Code Section 217.23 requires the department to promulgate rules on reimbursement processes. Aside from streamlining internal processes via this exercise, the department is not authorized to establish less costly alternatives.

6. Alternative methods considered by the agency

- Description of any alternative methods that were seriously considered by the agency:

N/A

- Reasons why they were rejected in favor of the proposed rule:

N/A

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:

CHAPTER 8
PAYMENT OF SMALL CLAIMS

441—8.1(217) Authorization to reimburse. The department will follow Iowa Code section 217.23(2) when reimbursing employees for personal items damaged or destroyed by clients of the department during the employee's tour of duty. The claimant shall provide the department with a detailed written account of the incident, including an estimated cost of repair or replacement.

This rule is intended to implement Iowa Code section 217.23.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** IAC 441-11, 641-179

Iowa Code Section Authorizing Rule 8A.504

State or Federal Law(s) Implemented by the Rule Iowa Code sections 217.34, 234.12, 239B.14, and 249A.5.

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10:00am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

These chapters define debt offset procedures for the legacy departments of public health (641-179) and human services (441-11). Debt offset is intended to recoup overpayment or other debt owed to the department. HHS impacted programs include but are not limited to: Supplemental Nutrition Assistance Program, Family Investment Program, Medicaid, Promise Jobs, Child Care Assistance.

Through the debt offset program, money is collected from individuals or entities having been identified as receiving an overpayment or otherwise owing funds to the department. Repayment may include withholding part or all of federal or state tax refunds or other state payments owed to the debtor. Money collected is credited back to the program(s) making the claim.

Regulatory Analysis Template

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

Individuals or entities having been identified as receiving an overpayment or otherwise owing funds to the department.

    - Classes of persons that will benefit from the proposed rule:

Other persons who depend and utilize HHS program funds.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Over the last five fiscal years, Iowa HHS has cumulatively collected $4.2 million in recoupment under the debt offset program, with an average of $839,000 recovered each year (median $859,000). Money collected is used for additional service delivery or program development. *Note: Debt offsets collected by programs moved out of HHS in the government reorganization have not been included in this analysis.*

Identified Impacts*

	SFY2018	SFY2019	SFY2020	SFY2021	SFY2022	5 Year Total
Costs HHS Implementation Service Delivery	($1,210,000) ($665,000)	($1,363,000) ($1,045,000)	($1,298,000) ($906,000)	($1,283,000) ($859,000)	($1,387,000) ($718,000)	($6,541,000) ($4,193,000)
Benefits Recouped Debts Increased Public Trust	$665,000 Intangible	$1,045,000 Intangible	$906,000 Intangible	$859,000 Intangible	$718,000 Intangible	$4,193,000 Intangible
Net Value	($1,210,000)	($1,363,000)	($1,298,000)	($1,283,000)	($1,387,000)	($6,541,000)

*All monetary figures have been rounded to the nearest thousandth.

    - Qualitative description of impact:

By recouping the overpaid funds, programs will have more funds to offer other participants enrolled in their programs.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for those team members tasked with completing the debt offset procedure, as well as technology expenses.

The Iowa Department of Revenue (IDR) oversees the debt offset procedure for executive branch agencies; this was previously managed by the Department of Administrative Services (DAS). The Department of Inspections, Appeals, and Licensure (DIAL) provides investigation and customer service support for HHS debt collections. Implementation costs borne by these agencies have not been included in this analysis.

- Anticipated effect on state revenues:

Though the cost benefit analysis shows a negative financial outcome, recoupment ensures publicly funded services are implemented as intended by the Iowa legislature and in compliance with state and federal regulations. This leads to public trust in HHS systems and programs. Further, collection of moneys owed the department confers a public benefit through use of returned funds to support qualifying service recipients and/or public program development.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

HHS is implementing the debt offset program according to the parameters detailed in Iowa Code and the procedure described in Iowa Administrative Code by the IDR (previously DAS).

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

N/A

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

N/A

- Reasons why they were rejected in favor of the proposed rule:

In the combined department, HHS does not require multiple debt offset rule chapters. The department seeks to repeal the legacy public health chapter and re-promulgate all necessary rules under the legacy human services chapter, 441-11.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.

- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Regulatory Analysis Template

Text of Proposed Rule: CHAPTER 11
COLLECTION OF DEBT

441—11.1(217) Definitions.

"Current" means that amount which is due and owing within the previous 12 months from the date of submission to the department of administrative services or that amount which is due and owing from the date the repayment agreement or court order is implemented, if less than 12 months, before the date of submission to the department of administrative services.

"Current repayment" means that payment of the cumulative sum due and owing in accordance with a repayment agreement or court order for the preceding 12 months or the date of the order or agreement if the order or agreement is more recent.

"Debtor" means a current or former recipient of public assistance that has been determined by the department to be responsible for the repayment of a particular debt. For supplemental nutrition assistance program (SNAP), "debtor" shall include all adult members of the SNAP household participating at the time the SNAP overpayment or program violation occurred and shall include nonrecipients found guilty of violating SNAP rules by committing an act such as, but not limited to, trafficking. For child care assistance, "debtor" may include the current or former provider or current or former recipient of child care assistance. For Medicaid, "debtor" shall include any current or former Medicaid member, or the parents of a current or former Medicaid member who was under the age of 21 when the parents completed the application and had responsibility for reporting changes, who received services or benefits as a result of client or agency error or administrative overpayment or who owes a debt of unpaid premium payments for medical assistance.

"Public assistance" means family investment program, SNAP, Medicaid, state supplementary assistance, PROMISE JOBS, child care assistance, refugee cash assistance, and Hawki program.

"Repayment agreement" means an agreement entered into voluntarily between the department and the debtor for the repayment of debts and detailed on a form issued by the department. *"Written notification*" means the notification sent to a debtor by the department on a form issued by the department.

441—11.2(217) Establishment of claim.

11.2(1) *Accounts.* The department will maintain an account for each debt that has occurred containing the following information:

a. A debtor name and account number.
b. Program in which the debt occurred.
c. Date the debt was discovered.
d. Inclusive dates of the debt.
e. Total dollar amount of each debt.
f. Primary cause of the debt.
g. Any transaction applied to this debt.

11.2(2) *Notice of debt.* A claim is established when the first written notice of the debt is issued to the household

11.2(3) *Change in debt.* An additional written notification of debt will be issued if a change occurs in the amount or period of the debt.

11.2(4) *Collection action.* No collection action will be initiated on:

a. A debt for which no notice of debt has been issued to the household.
b. A debt that is in appeal status.
c. A debt that is in suspended status due to an exception to policy.

441—11.3(217) Application of payment. Payment will be applied only to debts subject to collection pursuant to subrule 11.2(4).

11.3(1) *Application of payment to a single program area.*

a. If there is more than one debt in a program, payment will be applied:

(1) First to all debts which have an agreement in chronological order of discovery, and

(2) Then to debts which do not have an agreement in chronological order of discovery until all debts have been paid in full or the full payment amount has been exhausted.

b. For SNAP, payment will be applied first to all debts with an agreement and then to debts without an agreement. Within those two groupings, payment will be applied in the following order:

(1) First to state-only debts in chronological order of discovery,

(2) Then to intentional program violation (IPV) debts in chronological order of discovery,

(3) Then to inadvertent household error (IHE) debts in chronological order of discovery, and

(4) Then to agency error debts in chronological order of discovery.

11.3(2) *Application of payment to multiple program areas.* If there are debts in more than one program area of public assistance, payments received will be applied to those program areas as indicated by the mode of repayment (SNAP benefits, FIP benefits) or as indicated by the client at the time of payment.

11.3(3) *Application of undesignated cash payment.* If an undesignated cash payment is received, it will be applied to each program area proportionally based on the cumulative balance of all debts in all program areas combined.

441—11.4(217) Setoff against state income tax refund, rebate, or other state payments, including, for example, state employee wages.

11.4(1) *Criteria for setoff.*

a. A claim against a debtor may be made by the department for public assistance debts when:

(1) A debtor has failed to negotiate a repayment agreement for that program area of public assistance, or

(2) A repayment agreement is not current, and

(3) The cumulative balance of the applicable debts in 11.4(1)*"a"*(1) and (2) exceeds $50.

b. A claim against a debtor will not be made by the department for debts when:

(1) The debt is in suspended status due to an exception to policy or is in an appeal status, or

(2) The debt is being recovered through grant or benefit reduction.

11.4(2) *Frequency of submission.* The department will submit to the department of administrative services twice each month a list of those debtors who have a debt meeting the criteria in subrule 11.4(1).

11.4(3) *Pre-setoff notice.* The department will mail written notification to a debtor to inform the debtor of the amount the department intends to claim and apply to debts in each program when:

a. The department is notified by the department of administrative services that the debtor is entitled to a state income tax refund, rebate, or other state payment;

b. The department makes claim against the debtor.

11.4(4) *Method for division of joint payments.* When either spouse wishes to request a division of a jointly or commonly owned right to payment, a written request shall be submitted to the department within 15 days after the written notification is mailed. When the request is received within the 15-day limit, the spouse's proportionate share of a jointly or commonly owned right to payment, as determined by the department of administrative services, shall be released by the department of administrative services unless:

a. Other claims are made on that portion of the jointly or commonly owned right to payment, or

b. That spouse was also a member of the same household and the spouse's income and resources were or should have been considered in the calculation of public assistance.

11.4(5) *Appeal rights.* When a debtor wishes to contest the claim of the department, a written request shall be submitted to the department within 15 days after the written notification is mailed. When the request is received within the 15-day limit, a hearing will be granted pursuant to rules in 441—Chapter 7.

a. If the department is upheld in the final decision, the setoff process will continue and the refund, rebate, or other state payment will be applied to the appropriate delinquent debts.

b. If the department is reversed in the final decision, the debtor's refund, rebate, or other state payment shall be released to the debtor by the department of administrative services.

11.4(6) *Debt setoff.* If the department has not received a request for an appeal hearing or a request for division of a jointly or commonly owned right to payment within 15 days after the date the written notification

is mailed, the department will notify a debtor of the final decision regarding the claim by mail.

11.4(7) *Application of setoff.* The department will apply any setoff received from the department of administrative services as a result of this rule to the debtor's debts as indicated on the written notification mailed to the debtor and in accordance with rule 441—11.3(217).

Any amount remaining after the setoff shall be released back to the individual.

441—11.5(234) Setoff against federal income tax refund or other federal payments, including, for example, federal employee wages.

11.5(1) *Criteria for setoff.*

a. Debtors not participating in SNAP shall be subject to collection action through the treasury offset program (TOP) which includes, but is not limited to, federal salary offset and federal tax refund offset.

(1) Debtors shall be referred to TOP if they are delinquent in repaying their SNAP debt and there is a claim or combination of claims with an unpaid balance which exceeds $25.

(2) No claim which is less than three months old or more than ten years old as of January 31 of the offset year shall be referred. Exception: Claims which have had a final judgment entered are not subject to the ten-year time limit.

(3) Debtors are delinquent in repaying their SNAP debt if:

1. A repayment agreement has not been signed and 120 days have elapsed since the due date of the demand letter as defined in 441—subrule 65.21(4) minus any days the claim was not subject to collection action because of an appeal.

2. A repayment agreement has been signed but the debtor has failed to make the agreed-upon payments and has failed to make up the missed payments. The debtor shall be referred to TOP when 120 days have elapsed since the first of the month following the month that the debtor failed to make the agreed-upon payment and has not subsequently made up the missed payment.

b. A claim against an individual will not be referred to TOP by the department of inspections, appeals, and licensure (DIAL) for debts when:

(1) The debt is in suspended status due to an exception to policy or is in an appeal status, or

(2) The debt is being recovered through benefit reduction.

11.5(2) *Setoff under TOP.* DIAL shall, by December 1 of each year, submit a notification of liability for delinquent claims to the Department of the Treasury.

11.5(3) *Pre-setoff notice.* DIAL shall notify a debtor identifying the amount the department intends to refer to TOP for offset.

11.5(4) *Offset fee.* For each offset that the Treasury Department effects against an individual referred to TOP, Treasury will charge the individual a fee.

11.5(5) *Appeal rights.* When an individual wishes to contest the delinquent status of a claim as identified by DIAL, a written request shall be submitted to DIAL within 60 days of the date of the pre-offset notice. When the request is received within the 60-day limit, a review shall be granted.

DIAL shall determine if the claim is past due and legally enforceable and shall notify the individual in writing of the decision.

11.5(6) *Application of setoff.* DIAL shall apply any setoff received as a result of this rule to the individual's SNAP debts.

Any amount remaining after the setoff shall be released back to the individual.

These rules are intended to implement Iowa Code sections 217.34, 234.12, 239B.14, and 249A.5.

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** IAC 441-13

Iowa Code Section Authorizing Rule 234.12, 237A.12, 239B.4, 249A.4, 514I.4

State or Federal Law(s) Implemented by the Rule NA

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This chapter defines HHS methods and procedures to review public assistance program eligibility determinations made by Department staff. These quality control measures are designed to ensure HHS implements these programs in accordance with Iowa Code and federal regulations and in an efficient and effective manner. HHS impacted programs include: Supplemental Nutrition Assistance Program, Family Investment Program, Medical Assistance, Child Care Assistance.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

None

- Classes of persons that will benefit from the proposed rule:

Program recipients will benefit from quality control measures that ensure accuracy of eligibility determinations.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred

- Quantitative description of impact:

The following are actuals incurred in the fiscal years shown.

	SFY2023	SFY2024	SFY2025	SFY2026	SFY2027	5 Year Total
Costs HHS Implementation	($1,672,00)	($1,819,000)	($1,947,000)	($1,950,000)	($1,911,000)	($9,299,000)
Benefits Improved HHS Services Increased Public Trust	Qualitative Intangible	Qualitative Intangible	Qualitative Intangible	Qualitative Intangible	Qualitative Intangible	Qualitative Intangible
Net Value	($1,672,000)	($1,819,000)	($1,947,000)	($1,950,000)	($1,911,000)	($9,299,000)

Identified Impacts**All monetary figures have been rounded to the nearest thousandth.

- **Qualitative description of impact:**

Improved quality control measures for Iowans seeking these services.

3. **Costs to the state**
   - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for those team members tasked with completing the quality control procedure. These costs are reflected in the table above as "HHS Implementation".

   - Anticipated effect on state revenues:

N/A

4. **Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction**

Though the cost benefit analysis shows a negative financial outcome, quality control measures ensure publicly funded services are implemented as intended by the Iowa legislature and in compliance with state and federal regulations. Review findings also assist HHS in making quality improvements to the processes and procedures that support how HHS team members determine eligibility for public assistance programs. This leads to efficient and effective provision of public services and an increased public trust in HHS systems and programs.

5. **Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule**

No less costly or intrusive methods were identified.

6. **Alternative methods considered by the agency**
   - **Description of any alternative methods that were seriously considered by the agency:**

N/A

   - Reasons why they were rejected in favor of the proposed rule:

HHS is implementing the quality control program according to the parameters detailed in Iowa Code and federal regulations.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:CHAPTER 13
PROGRAM EVALUATION

441—13.1(234,239B,249A,514I) Definitions.

"Active case" means a case that was receiving assistance for the month of review.

"Case record" means the record used to establish a client's eligibility.

"Client" means a current or former applicant or recipient of the family investment program (FIP), Supplemental Nutrition Assistance Program (SNAP), child care assistance program, or medical assistance program.

"Field investigation" means a contact involving the public or other agencies to obtain information about the client's circumstances for the appropriate month of review.

"Medical assistance programs" means those programs funded by Medicaid or the Children's Health Insurance Program (CHIP).

"Month of review" means the specific calendar or fiscal month for which the assistance under review is received.

"Negative case" means a case that was terminated or denied assistance in the month of review.

"Public assistance programs" means those programs involving federal funds, i.e., family investment program (FIP), Supplemental Nutrition Assistance Program (SNAP), child care assistance program, and medical assistance program.

"Random sample" means a systematic (or every nth unit) sample drawn monthly for which each item in the universe has an equal probability of being selected. Sample size is determined by federal guidelines or state corrective action needs.

"State policies" means the rules and regulations used by the department to administer the family investment program (FIP), Supplemental Nutrition Assistance Program (SNAP), child care assistance program, and medical assistance program.

This rule is intended to implement Iowa Code sections 234.12, 239B.4, 249A.4 and 514I.4.

441—13.2(234,239B,249A,514I) Review of public assistance records by the department.

13.2(1) Authorized representatives of the department shall have the right to review case records to determine the following:

a. If the client has provided complete, correct and accurate information to the department to be used in the determination of the assistance benefits.

b. If the department has correctly administered the state policies in determination of assistance for the public assistance programs.

c. Whether overpayments or underpayments have been made correctly to the public assistance client during the month of review.

d. If there is indication of fraudulent practice or abuse of the public assistance programs by either the client or department.

13.2(2) All pertinent case records within the department may be used by the reviewer to assist in substantiating an accurate reflection as to the correctness of the assistance received by the client.

This rule is intended to implement Iowa Code sections 234.12, 239B.4, 249A.4 and 514I.4.

441—13.3(234,239B,249A,514I) Cases to be reviewed. Any active or negative public assistance case may be reviewed at any time at the discretion of the department to:

13.3(1) Ensure federal and state requirements for quality control are met.

13.3(2) Detect error prone case issues to assist in corrective action.

13.3(3) Maintain public assistance program integrity.

This rule is intended to implement Iowa Code sections 234.6, 234.12, 239B.4, 249A.4, and 514I.4.

441—13.4(234,239B,249A,514I) Notification of review. On positive case actions, clients will be notified, either orally or in writing, that their case has been selected for review when contact is required by federal guidelines, or when contact is allowed and additional information is required to complete the review. The client will be contacted in a negative case only if a discrepancy exists that cannot be resolved from the case record and contact is allowed by federal guidelines.

This rule is intended to implement Iowa Code sections 234.6, 234.12, 239B.4, 249A.4, and 514I.4.

441—13.5(234,239B,249A,514I) Review procedure. The department will select the appropriate method of conducting the review.

13.5(1) A random sampling of active and negative case actions will be used to determine the case records to be studied.

13.5(2) The case record will be analyzed for discrepancies and correct application of policies and procedures and will be used as the basis for a field investigation.

13.5(3) Client interviews are required as follows:

a. Personal interviews are required on all active SNAP reviews.

b. An appointment letter may be sent to the client by the department to schedule or confirm the appointment date, time and location.

c. Client contacts are only required in negative case reviews when there is a discrepancy that cannot be resolved from the case record.

13.5(4) Collateral contacts are made whenever the client is unable to furnish information needed or the reviewer needs additional information to establish the correctness of eligibility and payment but only when allowed by federal guidelines. Verification to confirm the accuracy of statements or information may be obtained by documentary evidence or a contact with a third party.

a. The client shall release specific information whenever necessary to verify information essential to the determination of eligibility and payment.

b. Should the client refuse to authorize the department to contact an informant to verify information that is necessary for the completion of the review, collateral contacts will still be made through use of the general release statement contained in the financial support application or the review/recertification eligibility document.

This rule is intended to implement Iowa Code sections 234.6, 234.12, 239B.4, 249A.4, and 514I.4.

441—13.6(234) Failure to cooperate. Client cooperation with quality control is a program eligibility requirement as set forth in rule 441—65.3(234). When quality control determines that a client has refused to cooperate with the review process, the client is no longer eligible for the program benefits and will not be eligible for the program benefits until the client has cooperated.

This rule is intended to implement Iowa Code section 234.12.

441—13.7(234,239B,249A,514I) Report of findings. The quality control review findings are used by the department in the following ways:

13.7(1) To take the appropriate case action where an overpayment or underpayment has been found in a client's case record.

13.7(2) To identify error-prone program issues to be used in planning a department corrective action plan.

13.7(3) To determine the error rate used to establish state agency liability.

This rule is intended to implement Iowa Code sections 234.12, 239B.4, 249A.4, and 514I.4.

441—13.8(234,237A,239B,249A,514I) Federal review. A sample of cases may also be reviewed by the applicable federal agency to determine the correctness of the department's action or of the department's review of the case.

This rule is intended to implement Iowa Code sections 234.12, 237A.12, 239B.4, 249A.4, and 514I.4.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 441-122

Iowa Code Section Authorizing Rule 256I

State or Federal Law(s) Implemented by the Rule IC 256I

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location:https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter sets forth oversight measures of the department in relation to the Early Childhood Iowa area boards to ensure sound fiscal management of Early Childhood Iowa funds. The department reviews internal controls managing disbursement of funding, approves and signs agreements between the area boards and the state, requires a regular audit of funds managed by each area board, and ensures area boards have liability insurance and a contract-monitoring schedule for their funded programs.

Sound fiscal oversight of Early Childhood Iowa area boards works to ensure these boards operate optimally, allowing boards to successfully improve efficiency and effectiveness of early care services provided to families.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

Early Childhood Iowa area boards.

- Classes of persons that will benefit from the proposed rule:

Parents accessing early care services supported by an Early Childhood Iowa area board.
Communities utilizing an Early Childhood Iowa board to improve the efficiency and effectiveness of early care services provided to families.
Children served by such early care services.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
   - Quantitative description of impact:

Figures below are actuals incurred in the fiscal years shown.

Identified Impacts*

	SFY2023	SFY2024	SFY2025	3 Year Total
Costs				
State Agency Implementation	$371,000	$376,000	$417,000	$1,164,000
Area Board Audits	$14,000	$22,000	$15,000	$51,000
Benefits				
Increased Public Trust	Intangible	Intangible	Intangible	Intangible
Improved Early Care Services	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	-$385,000	-$398,000	-$432,000	-$1,215,000

*All monetary figures have been rounded to the nearest thousandth.

   - Qualitative description of impact:

State agency team members provide on-going technical assistance and oversight of each local board's operating procedures, the local board's contract audits, community needs assessment reviews and local designation meetings, and reviews of reports submitted within IowaGrants.gov.

Local boards operate under sound fiscal policies, using programmatic data metrics aligned with their local investments, and pay for an annual official audit by a firm of their choice**.**

Early Childhood Iowa areas boards must comply with fiscal oversight measures by reporting in IowaGrants via a mid-year financial report, budget, and annual report with fiscal verification from their fiscal agent; including conducting regular financial audits of funds managed by the board.

3. Costs to the state
   - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for team members to provide fiscal oversight of Early Childhood Iowa area boards; prior to FY2024 these team members reported to the Department of Management. Costs to the state agency have included a range of 2.5 FTE to 2.25 FTE, travel, and office space expenses across the fiscal years shown. These costs are reflected in the table above as "State Agency Implementation".

   - Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a known three-year total net value of -$1,215,000, averaging $405,000 per year, to oversee improved early care services in those areas covered by an Early Childhood Iowa area board. Eliminating fiscal oversight measures as defined in this rule chapter may diminish the quality of operations of area boards, thus impacting the area board's ability to improve early care services to the same degree the board might when operating under sound fiscal practices. An area board using funds fraudulently or in contradiction to the requirements of Iowa Code may diminish public trust in the Early Childhood Iowa program and the department.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS implements fiscal oversight of the Early Childhood Iowa area boards in accordance to requirements of Iowa Code. This rule chapter does not ascribe department duties or implementation elements in addition to those directly defined in Code.

    - Reasons why they were rejected in favor of the proposed rule:

N/A

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Regulatory Analysis Template

Text of Proposed Rule:

Item 1. Rescind 441—Chapter 122 and adopt the following **new** chapter in lieu thereof:

CHAPTER 122
FISCAL OVERSIGHT OF THE EARLY CHILDHOOD IOWA INITIATIVE

441—122.1(256I) Definitions. For the purpose of these rules, the following definitions apply:

"Agreement" means a contract between the area boards, state board, department, and state agencies to which funding is allocated.

"Audit" means a financial review by area boards of early childhood Iowa funds. Area boards that receive federal funds shall complete an audit of the funds. The audit must be a single audit if the area board received a total of federal funds from all funding sources in excess of the threshold defined in 2 CFR 200.501(b) as amended to December 31, 2023. Area boards that are not required to conduct a single audit under 2 CFR 200.501(b), as amended to December 31, 2023, may coordinate with the fiscal agent to conduct the required audit. The audit requirements shall be found in the online toolkit available on the department website.

"Early childhood Iowa area board" or *"area board"* means the same as defined in Iowa Code section 256I.1.

"Early childhood Iowa state board" or *"state board"* means the same as defined in Iowa Code section 256I.1.

441—122.2(256I) Fiscal oversight.

122.2(1) In consultation with the state board, the department has adopted policies to oversee the fiscal responsibilities of area boards.

122.2(2) The department will:

a. Review the internal controls of all disbursements of early childhood Iowa funding;

b. Approve the process for issuing agreements with area boards;

c. Approve and sign all agreements between the area boards and the state for the purposes of Iowa Code chapter 256I;

d. Develop a policy for the disbursement of funds;

e. Require an audit, conducted by an independent agency, of the early childhood Iowa funds managed by area boards. The minimum requirements and frequency of audits for the area boards shall be determined and approved by the state board;

f. Ensure that all area boards secure liability insurance;

g. Require that area boards submit a contract-monitoring schedule for their funded programs.

These rules are intended to implement Iowa Code sections 256I.1 to 256I.12.

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** IAC 441-200

Iowa Code Section Authorizing Rule IAC 232.119

State or Federal Law(s) Implemented by the Rule IAC 600

Title IV-E of the Social Security Act (42 US Code sections 670 through 679b) provides for federal funding for foster care and adoption assistance.

The Howard Metzenbaum Multiethnic Placement Act of 1994 (MEPA), 42 U.S.C.A. 51151, as amended by the Interethnic Adoption Provision of 1996 (IEP)

Public Law, 95-608, Indian Child Welfare Act of 1978, Policy Sec. 4(4), 101(a), (b), and (c), 102(a), 102(d), 103(a), 105(b), 201.

Public Law 96-272, the Adoption Assistance and Child Welfare Act of 1980.

Public Law 100-294, the Child Abuse Prevention, Adoption, and Family Services Act of 1988.

Public Law 105-89, the Adoption and Safe Families Act of 1997 (ASFA), PL 108-145, the Adoption Promotion Act of 2003.

Public Law 109-239, the Safe and Timely Interstate Placement of Foster Children Act of 2006.

Public Law 109-248 - Adam Walsh Child Protection and Safety Act of 2006

Public Law 109-288 - Child and Family Services Improvement Act of 2006

Public Law 110-351 - Fostering Connections to Success and Increasing Adoptions Act of 2008

Public Law 111-320 - CAPTA Reauthorization Act of 2010

Public Law 112-34 - Child and Family Services Improvement and Innovation Act of 2011

Public Law 113-183, Preventing Sex Trafficking and Strengthening Families Act of 2014

Public Law 114-95, Every Student Succeeds Act of 2015

Public Law 114-22 - Justice for Victims of Trafficking Act of 2015

Public Law 115-123 - Bipartisan Budget Act of 2018 (also Family First Prevention Services Act)

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter structures adoption services to be provided by HHS to place eligible children in adoptive arrangements that are safe, high quality, and in the best interest of the child. HHS accepts applications for adoption of children with special needs; application for adoption of a child without special needs is referred to a private child-placing agency, though exception may be made for relatives of children under the guardianship of HHS.

Applicants applying to HHS to adopt must participate in a preplacement assessment and home visit. A child will not be placed in an adoptive home until parental rights of the child's birth parents have been terminated. Preference is given to placing children from the same birth family together. A relative or other adult with a significant relationship with the child is given priority consideration. Foster parents will be given consideration for a child in their care.

HHS conducts activities designed to prepare the family and the child to make the transition to adoptive placement, including conducting transitional visits between the adoptive family and the child before placement in the home. Additionally, HHS makes monthly supervision visits from the time the child is placed with the family until finalization of the adoption occurs. The department will not release identifying information from sealed adoption records unless approved to do so by the Director for purposes of treatment or research.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
   - Classes of persons that will bear the costs of the proposed rule:

None identified

   - Classes of persons that will benefit from the proposed rule:

Families seeking adoption, and the children that will be adopted.

Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred

   - Quantitative description of impact:

Figures below are actuals incurred in the fiscal years shown.

Identified Impacts*

	SFY2023	SFY2024	SFY2025	SFY2026	SFY2027	5 Year Total
Costs						

HHS Implementation	($123,000)	($131,000)	($136,000)	($138,000)	($142,000)	($670,000)
Benefits Improved Outcomes for Adopted Children	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	($123,000)	($131,000)	($136,000)	($138,000)	($142,000)	($670,000)

*All monetary figures have been rounded to the nearest thousandth.

Improved outcomes are realized when children experience timely, stable, and permanent adoptive placements. Per federal regulation, this is measured through timely adoption within 24 months of removal. In 2022, 58% of children served by the department seeking adoptive placement met this metric. This is up from 50% in 2018.

- Qualitative description of impact:

Permanency in the form of adoption is important for children to develop healthy secure relationships and serves to reduce the potential stressors that arise from being displaced multiple times. Youth who experience minimized placement changes are more likely to experience fewer school changes, less trauma and distress, decreased mental health complications, less behavioral problems, increased probabilities for academic achievement, and a lasting positive relationship with an adult.

Costs to the state

- Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for team members to support the adoption program. These costs are reflected in the table above as "HHS Implementation". Other service delivery costs incurred by the adoption program are reflected in the cost benefit analysis for chapters 441-203 and 441-204 and are not reflected here.

- Anticipated effect on state revenues:

N/A

Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a net value of -$670,000 over the five years studied and improved outcomes for children in adoptive care. Eliminating adoption services provided by HHS is likely to reduce the number of adoptive arrangements available to qualified children seeking adoption. Without the assessment and home visit services detailed in this rule adoptive relationships may be more likely to fail. A lack of available, quality, adoptive relationships increases the likelihood of adverse impact to the child.

Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

No less costly or intrusive methods exist.

Alternative methods considered by the agency

- Description of any alternative methods that were seriously considered by the agency:

N/A

- Reasons why they were rejected in favor of the proposed rule:

HHS implements adoption services in accordance with requirements of Iowa Code and federal regulations; overall, HHS implements the program as directed and has little flexibility in determining program elements. Activity in this rule chapter seeks to place eligible children under the guardianship of HHS in adoptive arrangements that are safe, high quality, and in the best interest of the child. The pre and post adoption services offered to the child and adoptive family under this rule chapter reinforce and ensure stable and safe placements. A less intrusive method has not been identified to achieve the purpose of this rule.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:

TITLE XVI
ALTERNATIVE LIVING

CHAPTER 200
ADOPTION SERVICES

[Prior to 7/1/83, Social Services[770] Ch 139]
[Previously appeared as Ch 139—renumbered IAB 2/29/84]
[Prior to 2/11/87, Human Services[498]]

441—200.1(600) Definitions.

"Adoption" means a legal and social process through which a child becomes a member of a family into which the child was not born. Adoption provides the child the same rights, privileges and duties as a birth child.

"*Adoption selection***"** means the process of making adoption placement decisions. The adoption selection committee team, tasked with making the final adoption placement decision, is made up of department of health and human service professionals. These professionals are brought together to review the child(ren)'s needs and the family's abilities to meet those needs, to make the best adoption match available and to ensure compliance with applicable adoption laws.

"*Adoption selection committee team***"** means department staff members designated to assist in the adoption selection process. The adoption selection committee team consists of the adoption supervisor and a minimum of two adoption workers. The social work administrator (SWA) may elect to be part of the team if there is more than one family seeking to adopt the child and the SWA may select additional department staff to serve as members of the Team on a case-by-case basis.

"Adoption service" means a service directed towards children who are legally available for adoption, the birth family, prospective adoptive family, and adoptive family.

"Adoptive family" means an approved person or persons who have a child placed in their home and are being supervised prior to finalizing the adoption; or who have a child in their home who is legally adopted and entitled to the same benefits as a child born into the family.

"Adoptive home study" includes an assessment of the family's parental attributes and a written report stating approval or nonapproval of the family for adoptive placement of a child or children.

"Child study" includes a written description of the child including strengths and needs; medical, mental, social, educational, placement and court history; a description of the child's relationships with the birth family, foster family, and significant others; a summary of the child's understanding and feeling about adoption and recommendations as to the type of family that can best meet the child's needs.

"Court-ordered studies" means home studies ordered by a judge for the purpose of determining custody of a child or placement of a child for the purpose of adoption.

"*Department*" means the Iowa department of health and human services and includes the local offices of the department.

"Family-centered services" means services and other support intended to safely maintain a child with the child's family or with an adult relative, to safely and in a timely manner return a child to the home of the child's parent or relative, or to promote achievement of concurrent planning goals by identifying and helping the child secure placement for adoption, with a guardian, or with other alternative permanent family connections. Family-centered services include services adapted to the individual needs of a family regarding the specific services and other support provided to the child's family and the intensity and duration of service delivery and services intended to preserve a child's connections to the child's neighborhood, community, and family and to improve the overall capacity of the child's family to provide for the needs of the children in the family.

"Foster family adoption" means the adoption of a child by a licensed foster family who has cared for the child.

"Guardianship record" means a case record regarding a child, established and retained by the department, when the department is named guardian of the child by court order. The purpose of the guardianship record is to collect and maintain information about the child and the birth family, legal documents, and other information that will assist in fulfilling the responsibility of guardian.

"Life book" means a compilation of information about the child, including birth information, photographs of the child; placement history, including dates of placement, names of caretakers, reasons for leaving the placement; relationships; school reports; social, medical, mental health developmental history; awards received, important events, letters from significant persons, and other information that the child wishes to include. The life book will assist the child in dealing with separation and loss issues and provide background and genealogy data.

"Placement services" includes the activities and travel necessary to plan and carry out the placement of a child or children into the adoptive family.

"Postadoption services" includes those services that an adoptive family may access after the adoption is finalized to assist the family in coping with and resolving problems within the family.

"Postplacement services" includes the supervision, support and intervention necessary prior to finalization to assist in maintaining the adoptive placement.

"Preadoptive family" means an approved adoptive family with a child placed in the home for adoption whose adoption has not been finalized.

"Preparation of child" includes activities necessary to ready the child for placement into an adoptive family.

"Preparation of family" includes the activities necessary to assist the family in adding an adoptive child as a new member of their family.

"Preplacement visits" means contacts, activities, and visits between the child and adoptive family prior to the adoptive placement.

"Procedendo" means an order issued by the Iowa Supreme Court returning jurisdiction to the district court after a final appellate decision regarding an appeal.

"Recruitment and retention contractor" or *"contractor"* means the entity that contracts with the department statewide to recruit foster and adoptive parents, complete home studies, and perform activities to support and encourage retention of foster and adoptive parents, or any of its subcontractors.

"Relative" means an individual related to a child within the fourth degree of consanguinity or affinity, by marriage, or through adoption.

"Selection of family" means reviewing approved home studies to match a family's strengths with a specific child's needs.

"Child with special needs" means a child who meets one or more of the criteria set forth at 441—201.3(1).

441—200.3(600) Application. Persons wishing to apply to adopt a child through the department shall complete an Application for Adoption form. An application for adoption shall only be accepted for children who are under the guardianship of the department.

200.3(1) *Limitations.* The department and its contractor shall accept only applications for adoption of a special needs child. The department shall refer adoption applications for children without special needs to private child-placing agencies. Exceptions to this rule may be made for:

a. Relatives of a child under the guardianship of the department; or

b. Foster parents with whom the child has a significant relationship.

200.3(2) *Procedures.* Before a home study is completed, applicants shall:

a. Complete the Application for Adoption form, and

b. Ensure that the Physician's Report for Foster and Adoptive Parents form is completed by the applicant's family physician.

441—200.4(600) Adoption services. Adoption services shall include adoptive home study, preparation of child, selection of family, preparation of family, preplacement visits, placement services, and postplacement services.

200.4(1) *Adoptive home study.* For applicants who apply to the department to adopt, the contractor shall prepare an adoptive home study through the following activities:

a. Family assessment. The family assessment shall include a minimum of two face-to-face interviews with the applicants and at least one face-to-face interview with each member of the household. At least one of the interviews shall take place at the applicant's home. The assessment of the prospective adoptive family shall include an evaluation of the family's ability to parent a special needs child or children including the following:

(1) Motivation for adoption and whether the family has biological, adopted or children in foster care currently placed in the home.

(2) Family's and extended family's attitude toward accepting an adopted child and plans for discussing adoption with the child.

(3) The attitude toward adoption of other people involved with the family in a significant way.

(4) Emotional maturity; marital history, including verification of marriages and divorces; assessment of marital relationship; and compatibility of the adoptive parents.

(5) Ability to cope with problems, stress, frustrations, crises, separation, and loss.

(6) Medical, mental, and emotional conditions that may affect the applicant's ability to parent a child, treatment history, status of treatment, and the evaluation of the treatment. Applicants and all household members must disclose any past or current mental health or substance abuse issues, or both. The department may require further documentation, evaluation, or both, to determine the suitability of the home.

(7) Willingness to accept a child who has medical problems (such as a child who is at risk for a communicable disease), intellectual disabilities, or emotional or behavioral problems. Ability to provide for the child's physical, medical, and emotional needs and commit to support a child's overall well-being.

(8) Description of biological children and previously adopted children, if any, including their attitudes toward adoption, relationship with others, and school performance.

(9) Capacity to give and receive affection.

(10) Statements from three references provided by the family and additional references the contractor may wish to contact.

(11) Attitudes of the adoptive applicants toward the birth parents and the reasons the child is available for adoption.

(12) Financial information, including the family's ability to provide for a child.

(13) Disciplinary practices that will be used.

(14) History of abuse involving family members, including how the abuse was addressed and how that history impacts the applicant's ability to be an adoptive parent.

(15) Assessment of, commitment to, and capacity to maintain other significant relationships.

(16) Recommendations for the number, age, sex, characteristics, and special needs of a child or children the family can best parent.

(17) The family's ability to anticipate and understand the special needs of an adopted child as the child gets older and how the family will manage those needs.

b. Record checks. Record checks are required for each applicant and for anyone who is 14 years of age or older living in the home of the applicant to determine whether any of those persons have founded child abuse reports, dependent adult abuse reports or criminal convictions or have been placed on the sex offender registry.

(1) The records of the applicants shall be checked:

1. On the Iowa central abuse registry using the Request for Child Abuse Information form;
2. By the Iowa division of criminal investigation, using the HHS Criminal History Record Check Form B;
3. On the Iowa sex offender registry;
4. On the child abuse registry of any state where the applicant has lived during the five years prior to the issuance of the investigative report; and
5. For a national criminal history through fingerprinting or another biometric identification-based process accepted by the federal government.

(2) The records of persons aged 14 or older living in the home of the applicant shall be checked:

1. On the Iowa central abuse registry using the Request for Child Abuse Information form;
2. By the Iowa division of criminal investigation, using the HHS Criminal History Record Check Form B; and
3. On the Iowa sex offender registry.

(3) Out-of-state child abuse checks, dependent adult abuse checks and national criminal history checks may be completed on any adult living in the home of the applicant if the department has reason to do so.

(4) The department shall not approve a prospective applicant and shall not perform an evaluation if the applicant or anyone living in the home of the applicant has been convicted of a felony offense as set forth in Iowa Code section 600.8(2)*"b."*

(5) The department shall not approve a prospective applicant and shall not perform an evaluation if the applicant or anyone living in the home of the applicant has committed a crime in a state other than Iowa that would be a forcible felony if the crime would have been committed in Iowa, as set forth in Iowa Code section 600.8(2)*"b."*

c. Evaluation of record.

(1) If the applicant or anyone living in the home has a record of founded child abuse, dependent adult abuse, a criminal conviction, or placement on the sex offender registry, the applicant shall not be approved to adopt unless an evaluation determines that the abuse or criminal conviction does not warrant prohibition of approval.

(2) The evaluation shall be conducted according to procedures in 441—113.13(2) and 113.13(3) for applications for adoption through the department or procedures in 441—paragraph 108.9(4)*"e"* for applications for adoption through a child-placing agency.

d. Written report. The contractor shall prepare a written report of the family assessment, known as the adoptive home study, which shall be used to make recommendations on appropriate placement.

(1) The department shall notify the family of the decision using the Adoption Notice of Decision form.

(2) If the department does not approve the home study, the reasons shall be stated on the notice.

(3) The department shall provide the family a copy of the adoptive home study with the notification of approval or denial.

e. Preplacement assessment and home study update. A preplacement assessment and home study update is required if the adoptive home study was written more than two years previously, in accordance with Iowa Code section 600.8. The preplacement assessment and home study update shall be conducted by completion of the following:

(1) The child abuse, dependent adult abuse and criminal record checks shall be repeated, except for fingerprinting. If there are any founded abuses or convictions of crimes that were not evaluated in the previous home study, they shall be evaluated using the process set forth in paragraph 200.4(1)*"c."*

(2) One face-to-face visit shall be conducted with the approved adoptive family.

(3) The information in the approved adoptive home study shall be reassessed.

(4) An updated written report of the reassessment and adoptive home study shall be written, dated, signed by the worker and supervisor for the contractor, and a copy provided to the adoptive family.

(5) Families who are dually licensed to provide foster family care shall have their adoption approval date align with their foster home licensing date.

f. Procedure for foster parent adoptions. When a licensed foster parent applies for approval as an adoptive home, home study activities that have been completed within the previous year as part of a licensing study pursuant to 441—Chapter 113 need not be repeated.

g. Annual visits to the adoptive family home. The contractor shall complete a minimum of one visit each year in the homes of families approved to adopt.

(1) The visit shall not be waived.

(2) When a person aged 14 or older moves into the home, the agency shall perform checks on the Iowa central abuse registry, by the division of criminal investigation, and on the sex offender registry. The record check evaluation process shall be completed if the person has a criminal conviction or founded abuse report or is on the sex offender registry.

(3) Findings and observations of the visit shall be documented and provided to the department when the update is submitted.

(4) The department shall be notified within 30 days of any deficiencies noted or other concerns discovered that require corrective action.

200.4(2) *Preparation of child.* The department shall conduct specific activities designed to enable a child to make the transition to an adoptive placement or refer the child to the family-centered services contractor or other professionals. The activities shall include, but not be limited to:

a. Counseling regarding issues of separation, loss, grief, guilt, anger and adjustment to an adoptive family.

b. Assisting in the preparation or update of a life book.

c. Provision of age-appropriate information regarding community resources available, such as children's support groups, to assist the child in the transition and integration into the adoptive family.

d. Any appropriate evaluations or testing.

200.4(3) A*doption selection process.* When the department is appointed guardian of a child(ren) following the termination of parental rights, the department has both the duty and the authority to select an adoptive placement for that child(ren). To fulfill this duty, the department must hold a conference during which the department selects an adoptive family for an identified child(ren). At the conference, known as an adoption selection staffing, each interested family with an approved adoption or interstate compact home study will be considered. The adoption selection committee will determine which family will be able to best meet the needs of the child(ren) going forward. The adoption selection process will value the best interest of the child(ren) above all else.

a. The selection committee will consider placement priority as outlined in Iowa Code section 232.117, and will consider the following:

(1) The adoptive family selected for a child or sibling group must be based on a thorough assessment of each child's current and potential developmental, medical, emotional, and educational needs.

(2) The child(ren)'s need for family connections will be prioritized. Separation of siblings should be avoided. When separation is necessary to protect the safety and well-being of one or more children in the sibling group, all reasonable efforts must be made to select a placement likely to maintain contact between siblings if such contact is in the best interests of each sibling.

(3) The adoptive family selected will be able to nurture and accept the child(ren) as a fully integrated member(s) of the family.

(4) Race, color, or national origin may not be considered in placement selections except when an Indian child is being placed pursuant to Iowa Code section 232.7 or Iowa Code chapter 232B.

(5) Placement decisions shall be made consistent with the best interests and special needs of the child, including the adoptive family's capacity and commitment to holistically supporting the child's development and well-being.

(6) A relative who is within the fourth degree of consanguinity shall be given consideration for selection as the adoptive family for a child who is legally available for adoption if the child has a significant relationship with the relative or the child is aged 14 or older and elects adoption by the relative.

(7) Foster parents shall be given consideration for selection as the adoptive family for a child in the foster parents' care who is legally available for adoption if the child has been in the foster parents' care for six months

or longer or the child has a significant relationship with the family.

a. The adoption selection committee team should strive to complete the adoption selection process in 60 days or less absent special circumstances.

b. Upon reaching a decision, the adoption selection committee team staff will notify families of the decision made by adoption selection committee team and will send placement notification to the family not selected within two business days of the date all parties were initially notified, using the *Adoption Notice of Decision* form.

c. The Selection of an adoptive family is not an appealable issue, as a child continues to be under the guardianship of the department until an adoption is finalized.

200.4(4) *Preparation of family.* The contractor and the department shall conduct activities designed to enhance the family's readiness to accept the child or children into the family and strengthen the family's commitment to adopt. A referral may be made for family-centered services if needed. The activities shall include, but not be limited to:

a. Completion of required preservice training and the self-study course, "Universal Precautions in Foster and Adoptive Family Homes," before placement of a child. These training requirements apply to families who are adopting special needs children who are under the guardianship of the department.

(1) Relatives who have cared for a related child for at least six months and who have been selected to adopt that related child may have their participation in the preservice training waived by the service area manager or designee.

(2) The department may waive the preservice training requirement in whole or in part when the department finds that:

1. The applicant has completed relevant training or has a combination of relevant training and experience that is an acceptable equivalent to all or a portion of the required preservice training; or

2. There is good cause for the waiver based upon the circumstances of the child and the applicant.

(3) Applicants must retake the preservice training if the adoption approval process is not completed within 24 months after the preservice training is initially completed.

b. Discussion with family members regarding problems resulting from a child's separation, loss, grief, and anger due to the loss of the birth parents.

c. Provision of background information on the child and birth family, including a child study that includes experiences such as foster and adoption placements and other pertinent information and the child's life book.

d. Provision of information regarding the child's special needs and behavior patterns.

e. Provision of a description of the child's medical needs, including whether or not the child has a communicable disease.

f. Discussion of the impact that adding a new member or members to the family may have on all current family members.

g. Explanation of the state's subsidized adoption program.

h. Provision of information regarding the community resources that are available to assist the family, such as parent support groups, community supports including Medicaid funded supports and post adoption supports.

200.4(5) *Preplacement visits.* The department shall plan, conduct and assess the transitional visits between the adoptive family and the child or children before the adoptive placement of the child in the home.

200.4(6) *Placement services.* Placement services include the activities necessary to plan and carry out the placement of a child or children into the adoptive family.

Before placement of a child, the Agreement of Placement for Adoption form, shall be signed by all parties.

200.4(7) *Postplacement services.* An adoptive family is eligible for postplacement services from the time a child is placed with the family until finalization of the adoption occurs. The department shall supervise the placement, provide ongoing support to the child and family, perform crisis intervention, and complete required reports. Assistance with behavioral interventions to strengthen the placement and prevent disruption may be provided through family-centered services.

a. Postplacement supervision shall focus on the following areas:

(1) Integration and interaction of the child or children with the family.

(2) Changes in the family functioning which may be due to the child's placement.

(3) Social and emotional adjustment of the child or children.

(4) Child's growth and development since placement with the adoptive family.

(5) Changes and adjustments that have been made in the family since the child's placement.

(6) Family's method of dealing with testing behaviors and discipline.

(7) Behavioral evidence of the degree of bonding that is taking place and the degree to which the child is becoming a permanent member of the adoptive family.

(8) School adjustment of a child who is attending a school.

(9) The behavioral needs of the child.

(10) The psychological and mental health needs of the child.

(11) Services and supports that will assist the child and family in the future.

b. At a minimum, the department shall make monthly home visits until the adoption is final. If the family is experiencing problems, the department shall make as many visits as are necessary to assess and support the placement.

c. The department shall prepare a written report based on the postplacement visits with recommendations regarding the finalization of the adoption and submit the report to the court before the hearing to consider granting a decree of adoption.

200.4(8) *Postadoption services.* The department's contractor shall provide postadoption services to families that are eligible for the department's adoption subsidy program in accordance with the contract. The goal of these services is to prevent adoption dissolution. The family may obtain additional support through community resources or support groups.

441—200.5(600) Termination of parental rights. The department shall not place a child in an approved adoptive home until parental rights of the child's birth parents have been terminated and guardianship assigned to the department. This would not apply to families and children participating in tribal customary adoption. If one or both birth parents are deceased, the worker shall provide the court with verification of the birth parents' death and the death shall be stated in the guardianship order. When the termination of parental rights is appealed by a birth parent, an adoptive placement may be made if the adoptive parents sign an adoptive placement agreement that includes an acknowledgment of the conditions of the placement should termination be overturned. However, the adoption may not be finalized until the appeal is withdrawn or a final decision regarding the appeal is reached and a procedendo issued.

441—200.6(600) Interstate placements. Interstate placement of a child into Iowa, or out of Iowa, shall follow interstate placement of child procedures in accordance with Iowa Code sections 232.158 through 232.166.

441—200.7(600) Requests for home studies.

200.7(1) *Court-ordered.* Court-ordered home studies for adoption of a child or children under the authority of the department shall be completed by the department's contractor.

200.7(2) *Interstate compact.* Requests for an adoptive home study through the interstate compact process shall be completed by the department's contractor.

441—200.8(600) Reasons for denial. An individual or family shall be denied approval of an adoptive home study for any of the following reasons unless an evaluation determines that denial is improper:

200.8(1) *Founded child abuse report or dependent adult abuse report*

200.8(2) *Criminal conviction.*

200.8(3) *Documented concerns.* Concerns may be documented in one or more of the following areas:

a. Motivation to adopt.

b. Child-rearing ability and practices.

c. Emotional stability.

d. Physical or mental health.

e. Interpersonal relationships.

f. Finances.

g. Marital relationship.

h. Other areas that may impact the applicant's ability to meet the needs of a child both at present and in the future.

200.8(4) *Substance abuse.* Verified substance use or abuse that prevents the family from adequately caring for the child shall mean denial of approval.

200.8(5) *Lack of cooperation.* If the individual or family fails to cooperate in providing the information needed to complete the preplacement assessment or home study, the application shall be denied.

200.8(6) *Appeals.* Prospective adoptive families may appeal denial of approval of their home study.

441—200.9(600) Removal of child from preadoptive family. When the department determines that it is in the child's best interest to be removed from a preadoptive family, a Letter of Removal form shall be mailed to the family prior to removal. Removal of a child from a preadoptive family is not an appealable action.

441—200.10(600) Consents. A request for consent to the adoption shall be submitted to the guardian for a child who is under the guardianship of the department and for whom finalizing an adoption is recommended. If the adoption is in the best interest of the child, the department shall sign a Consent to Adoption form, prior to a court hearing finalizing the adoption.

A consent to adopt may be rescinded by the department, by signing a Rescinding the Consent to Adoption form for any of the following reasons:

1. At the request of the adoptive family.
2. A founded child abuse report, dependent adult abuse report, accusation of child abuse, or dependent adult abuse pending determination of the report.
3. Conviction of a crime, or accusation of a crime, pending a court decision regarding the crime.
4. At the request of a child who is aged 14 or over and has reversed the decision regarding the adoption.
5. Other verified indications that the adoption is not in the best interest of the child.

441—200.11(600) Requests for access to information for research or treatment.

200.11(1) *Requests.* Any person seeking access to the department's sealed adoption records for the purpose or purposes set forth in Iowa Code section 600.16(1)*"c"* or Iowa Code section 600.24(2) shall submit a request in writing to the department. Each request shall contain sufficient facts to establish that the information sought is necessary for conducting a legitimate medical research project, or for treating a patient in a medical facility.

200.11(2) *Process.* Upon receipt of a request for information sought in conducting a research project, the director or a designee shall review the request for information and make a decision to approve, or deny, the request based on the research to be conducted, the benefits of the research, the methodology, and the confidentiality measures to be followed. Upon a request for information for treating a patient in a medical facility, a decision regarding approval or denial shall be made by the director or designee based on the written information provided by a physician or the medical facility, making the request. Requester shall be notified in writing of approval or denial and if denied, reasons for denial given.

441—200.12(600) Requests for information for purposes other than research or treatment. Requests for information from department adoption records for purposes other than research or treatment shall be made on the department's website.

200.12(1) The department shall not release identifying information from sealed adoption records. Adult adoptees, adoptive parents, birth parents, siblings or descendants of an adopted person, or legal representatives of any of the above shall be provided:

a. An adoption packet containing a sample affidavit for filing with the court,
b. Directions for filing the affidavit,
c. A list of county clerks of court,
d. The address of the bureau of vital statistics, and
e. Instructions on how to obtain the name of the Iowa county where the adoption was finalized, if necessary.

200.12(2) An adopted person who was a resident of the Annie Wittenmeyer Home (Iowa Soldier's and Sailor's Home) may receive nonidentifying information from Annie Wittenmeyer records if the information is available.

These rules are intended to implement Iowa Code chapter 600.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 441-201

Iowa Code Section Authorizing Rule 600.17 to 600.23

State or Federal Law(s) Implemented by the Rule Iowa Code sections 600.17 to 600.23

Title IV-E of the Social Security Act (42 US Code sections 670 through 679b) provides for federal funding for foster care and adoption assistance.

The Howard Metzenbaum Multiethnic Placement Act of 1994 (MEPA), 42 U.S.C.A. 51151, as amended by the Interethnic Adoption Provision of 1996 (IEP)

Public Law, 95-608, Indian Child Welfare Act of 1978, Policy Sec. 4(4), 101(a), (b), and (c), 102(a), 102(d), 103(a), 105(b), 201.

Public Law 96-272, the Adoption Assistance and Child Welfare Act of 1980.

Public Law 100-294, the Child Abuse Prevention, Adoption, and Family Services Act of 1988.

Public Law 105-89, the Adoption and Safe Families Act of 1997 (ASFA), PL 108-145, the Adoption Promotion Act of 2003.

Public Law 109-239, the Safe and Timely Interstate Placement of Foster Children Act of 2006.

Public Law 109-248 - Adam Walsh Child Protection and Safety Act of 2006

Public Law 109-288 - Child and Family Services Improvement Act of 2006

Public Law 110-351 - Fostering Connections to Success and Increasing Adoptions Act of 2008

Public Law 111-320 - CAPTA Reauthorization Act of 2010

Public Law 112-34 - Child and Family Services Improvement and Innovation Act of 2011

Public Law 113-183, Preventing Sex Trafficking and Strengthening Families Act of 2014

Public Law 114-95, Every Student Succeeds Act of 2015

Public Law 114-22 - Justice for Victims of Trafficking Act of 2015

Public Law 115-123 - Bipartisan Budget Act of 2018 (also Family First Prevention Services Act)

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Regulatory Analysis Template

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter seeks to increase access to adoptive arrangements for children with special needs, older children, and children otherwise hard to place in an adoptive home by implementing a subsidized adoption program. This program provides financial assistance to interested adoptive parents capable of providing suitable care but lacking in necessary economic resources.

To be eligible, a child under the guardianship of HHS must have been determined by a qualified health care professional to have met the definition of special needs included in this rule, or be aged five or over, or be a member of a sibling group of three or more children who are placed in the same adoptive home. A child in the guardianship of a licensed child-placing agency may be eligible for subsidy if the child is eligible to receive SSI based on a diagnosed disability or if the child has received a federally funded adoption subsidy in a prior adoption.

Subsidy payments to approved adoptive parents may include:

- Special Services Assistance: Compensation for medical, dental, therapeutic, educational, or other similar service or appliance required by an adopted child by reason of a disability.
- Monthly Maintenance Assistance: Monthly payment to assist with room, board, clothing, and spending money. The maximum monthly payment rate is pursuant to the foster family care maintenance rates.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

N/A

    - Classes of persons that will benefit from the proposed rule:

Adoptive parents of eligible children.
Children in a subsidized adoption.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Figures below are actuals incurred in the fiscal years shown.
Identified Impacts*

Regulatory Analysis Template

	SFY2018	SFY2019	SFY2020	SFY2021	SFY2022	5 Year Total
Costs Adoption Subsidy Payment	($75,241,000)	($75,736,000)	($77,291,000)	($77,957,000)	($77,680,000)	($383,905,000)
Benefits Federal Title IV-E Funding Improved Outcomes for Adopted Children	$35,369,000 Qualitative	$37,093,000 Qualitative	$41,359,000 Qualitative	$44,998,000 Qualitative	$45,726,000 Qualitative	$204,545,000 Qualitative
Net Value	($39,872,000)	($38,643,000)	($35,932,000)	($32,959,000)	($31,954,000)	($179,360,000)

*All monetary figures have been rounded to the nearest thousandth.

- Qualitative description of impact:

The amount of subsidy is negotiated between HHS and the qualified adoptive parent(s) based on the needs of the child and circumstances of the adoptive family. In SFY2022 10,600 children received an adoption subsidy payment. The rule chapter requires that other services available to meet the needs of an eligible child that are free of charge be explored and used prior to spending subsidy funds.

3. Costs to the state
   - Implementation and enforcement costs borne by the agency or any other agency:

Any implementation costs incurred by HHS for operation of the adoption program are reflected in the cost benefit analysis for chapter 441-200 and are not reflected here.

Federal funds received through the Title IV-E Federal Payments for Adoption Assistance Program are used to assist in funding subsidized adoptions. The federal participation rate varies; in SFY22 Iowa's participation rate was 86.26%. This is up from 80.88% in SFY2018. These funds are reflected in the table above as "Federal Title IV-E Funding".

   - Anticipated effect on state revenues:

Subsidy payments are provided out of Federal Title IV-E of the Social Security Act funds as well as state appropriated funds for the use of adoption subsidy payments These costs are reflected in the table above as "Adoption Subsidy Payments". Subsidy payments are a combination of both the federal and state funding sources.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a net value of $31,954,000 and improved outcomes for children in subsidized adoptive care. Eliminating the subsidy is likely to reduce the number of guardianship arrangements available to children in need, which has the potential to shift children eligible for guardianship into more restrictive care arrangements, thus increasing the likelihood of adverse impact to the child. Additionally, more restrictive care arrangements could result in the state paying more for care of an eligible child than would be paid in form of a subsidy under this rule chapter.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

Activity in this rule chapter seeks to increase access to adoptive arrangements for eligible children through use of a subsidy. Subsidy rates are set at an equivalent value to what a family would receive to provide family foster care. These subsides encourage the adoption of children from Iowa's foster care system and minimize financial obstacles to adoption. Reducing this rate would likely result in reduced children being adopted into permanent families. A consequence of fewer adoptions could be additional financial and capacity burdens to Iowa's foster care system.
To limit the impact on state revenues, the rule chapter requires that other services available to meet the needs of an eligible child that are free of charge be explored and used prior to spending subsidy funds.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS implements the subsidy program in accordance to requirements of Iowa Code and federal regulations. The Department follows both the federal and state requirements and guidelines in this rule chapter.

- Reasons why they were rejected in favor of the proposed rule:

N/A

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:

CHAPTER 201
SUBSIDIZED ADOPTIONS

441—201.1(600) Administration. The department shall administer the subsidized adoption program, in conformance with the legal requirements for adoption.

441—201.2(600) Definitions.
"Child" means a person who has not attained age 18, or a person with a physical or mental disability who has not attained age 21.

"Escrow account" means an interest-bearing account in a bank or savings and loan association which is maintained by the department in the name of a particular child.

"Maintenance subsidy" means a monthly payment to assist the family in meeting the living expenses and expenses related to the care of a child with special needs in covering the cost of room, board, clothing, and spending money. The child will also be eligible for medical assistance pursuant to 441—Chapter 75.

"Nonrecurring expenses" means reasonable and necessary adoption fees, court costs, attorney fees and other expenses which are directly related to the legal adoption of a child with special needs. These shall be limited to attorney fees, court filing fees and other court costs.

"Physician" means a licensed medical or osteopathic doctor as defined in rule 441—77.1(249A).

"Presubsidy" means payment for maintenance or special services for a child with special needs who is placed in an adoptive home and who meets all eligibility criteria for maintenance subsidy but whose adoption is not finalized.

"Qualified intellectual disability professional" means a person who has at least one year of experience working directly with persons with an intellectual disability or other developmental disabilities and who is one of the following:

1. A doctor of medicine or osteopathy.
2. A registered nurse.
3. A person who holds at least a bachelor's degree in a human services field including, but not limited to, social work, sociology, special education, rehabilitation counseling, or psychology.

"Qualified mental health professional" means a person who meets all the following conditions:

1. Holds a master's degree in a mental health field including, but not limited to, psychology, counseling and guidance, or psychiatric nursing and social work; or is a doctor of medicine or osteopathic medicine; and
2. Holds a current Iowa license when required by the Iowa professional licensure laws for persons practicing as a psychiatrist, a psychologist, a marital and family therapist, a mental health counselor, an advanced registered nurse practitioner, a psychiatric nurse, or a social worker; and
3. Has at least two years of postdegree experience supervised by a mental health professional in assessing mental health problems, mental illness, and services needs and in providing mental health services.

"Special services subsidy" means payment to a provider or reimbursement to the parent for medical, dental, therapeutic, or other services, equipment or appliances required by a child to meet the child's identified special needs.

441—201.3(600) Conditions of eligibility or ineligibility.

201.3(1) The child is eligible for subsidy when the department or a private agency has documented that it has been unable to place the child in an appropriate adoptive home without a subsidy and the child is determined to be a child with special needs based on one or more of the following reasons:

a. The child has a medically diagnosed disability, as determined by a physician, an advanced registered nurse practitioner or a physician assistant, which substantially limits one or more major life activities, requires ongoing professional treatment, impacts the child's ability to perform daily living skills, and is expected to last 12 months or longer.

b. The child has been determined by a qualified intellectual disability professional to be intellectually disabled.

c. The child has been determined by a qualified professional to be at high risk of developing a qualifying medical, mental, or emotional condition as defined in this subrule. A child in this group is eligible for subsidy of nonrecurring expenses only.

d. The child has been diagnosed by a qualified mental health professional to have a psychiatric condition which impairs the child's mental, intellectual, or social functioning, and for which the child requires ongoing professional services.

e. The child has been diagnosed by a qualified 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 significantly interferes with the child's intellectual, social and personal adjustment and which requires ongoing treatment.

f. The child is aged five or over.

g. The child is a member of a sibling group of three or more children who are placed in the same adoptive home.

201.3(2) A child who enters the United States from another country on the basis of a visa classifying the child as an orphan, in accordance with the Immigration and Naturalization Act as amended to December 31, 2023, for the purpose of adoption by a specific United States family is not eligible for subsidized adoption maintenance payments, medical assistance, or special services except for nonrecurring expenses.

201.3(3) Adverse eligibility determinations by the department may be appealed according to rules in 441—Chapter 7.

201.3(4) The department shall review the subsidy agreement when the child reaches the age of 17½ to determine whether the child is eligible to receive subsidy to the age of 21 due to the child's physical, intellectual, or mental health disability.

a. The disability shall be diagnosed by a physician, a qualified mental health professional, or a qualified intellectual disability professional.

b. The diagnosis shall be current within one year prior to the child's eighteenth birthday.

c. The child's parents shall provide documentation of the child's disability.

441—201.4(600) Application. Application for presubsidy or subsidy for a child with special needs in the guardianship of the department shall be made at the time of the adoptive placement of the child, or at any time in the adoptive process before finalization of the adoption.

201.4(1) The prospective adoptive family residing in Iowa who has been studied and approved for adoptive placement or a family residing outside of the state of Iowa studied and approved by a governmental child-placing agency or a licensed child-placing agency in that state, may apply for subsidy for an eligible Iowa child.

201.4(2) Withdrawal of the subsidy application shall be reported to the department immediately.

201.4(3) The effective date for the Adoption Subsidy Agreement will be the date the agreement is signed by the adoptive parents and the department, which may be the date the child is placed in the adoptive home or any date up to and including the date the adoption is finalized. The agreement shall state the amount of the presubsidy or subsidy, the frequency and duration of payments and the conditions under which the agreement may be terminated.

201.4(4) An application for subsidy cannot be taken after the child is adopted except when there are facts relevant to a child's eligibility that were not presented before the finalizing of the adoption.

a. Upon receiving verification that the child was eligible before the child's adoption, the department may conduct an administrative review of the facts and may determine the child an eligible child with special needs. Eligibility will be effective after the Application for Subsidy is completed and the Adoption Subsidy Agreement form is signed by all parties.

b. Requests for determination after the adoption is finalized shall be forwarded with verification of eligibility to the department. The department shall conduct an administrative review of eligibility factors and render a written decision within 30 days of receipt of request and verification materials unless additional verification is requested. If additional verification is requested, a decision shall be reached within 30 days of receipt of additional verification materials.

201.4(5) A child in the guardianship of a licensed child-placing agency may be eligible for adoption subsidy when one of the following conditions is met:

a. The child receives or is eligible to receive SSI based on a diagnosed disability, or

b. The child received federally funded adoption subsidy in a prior adoption.

441—201.5(600) Negotiation of amount of presubsidy or subsidy.

201.5(1) The amount of presubsidy or subsidy shall be negotiated between the department and the adoptive parents and shall be based upon the needs of the child and the circumstances of the family.

a. Each time negotiations are completed, the Adoption Subsidy Agreement shall be completed.

b. The adoption Subsidy Agreement shall be completed and retained in an inactive case record for future reference when:

(1) A child is eligible for subsidy but the child or family does not currently need assistance; or

(2) The child is at risk of being determined a child with special needs according to paragraph 201.3(1)*"a," "b," "d,"* or *"e"* in the future.

201.5(2) Other services available to the family free of charge to meet the needs of the child, such as other federal, state, and local governmental and private assistance programs, shall be explored and used before the expenditure of subsidy funds. Unearned income of the child shall be verified by documentation provided to the department worker by the family from the source of the income.

201.5(3) A maintenance subsidy may be no less than $10 per month.

201.5(4) An adoptive family may request a review of the subsidy agreement when there is a change in the family's circumstances or the needs of the child.

201.5(5) Maintenance subsidy shall continue under the same rules if the adoptive family moves outside of the state of Iowa.

201.5(6) The maximum monthly maintenance payment for a child in subsidized adoption shall be made pursuant to the foster family care maintenance rates according to the age and special needs of the child as found at 441—156.6(234).

441—201.6(600) Types of subsidy.

201.6(1) *Special services only.*

a. Reimbursement to the family or direct payment to a provider may be made for the following special services needed to meet the needs of the child.

(1) Outpatient counseling or therapy services. Reimbursement for outpatient individual or family services may be provided from a non-Medicaid provider only with approval from the department and when one of the following applies:

1. The services are not available from a Medicaid provider within a reasonable distance from the family.
2. The child and the family were already receiving therapy or counseling from a non-Medicaid provider and it would not be in the child's best interest to disrupt the services.
3. Available Medicaid providers lack experience in working with foster, adoptive, or blended families.

Reimbursement to non-Medicaid providers shall be limited to the Medicaid rate.

(2) Expenses for transportation, lodging, or per diem related to preplacement visits, not to exceed $2000 per family.

(3) Medical services not covered by the Medicaid program when the child, either alone or with the family, resides outside the state of Iowa and that state's Medicaid does not cover a needed service, or a provider enrolled with Iowa Medicaid cannot be secured. An adoption subsidy payment shall not supplement the Medicaid payment rate to a Medicaid provider or a non-Medicaid provider.

(4) An additional premium amount as a result of adding the child to the family's health insurance group.

(5) Medical transportation, food and lodging not covered by Medicaid when the child is receiving specialized care in a facility 50 miles or farther from the family home, when the family is participating in services and to facilitate reunification with the child.

(6) Supplies and equipment as required by the child's special needs and unavailable through other resources.

1. When the siblings in a sibling group of three or more are placed together, a one-time-only payment can be made, not to exceed $500 per child, to reimburse the family for expenses related to accommodating the needs of the sibling group.
2. When home modifications have been authorized to accommodate a child's special needs and the family later sells the house, the family shall repay the department an amount equal to the increase in the equity value of the home attributable to the modifications.

(7) Nonrecurring expenses. Payment for nonrecurring expenses is generally limited to a total of $1000 per child for attorney fees, court costs and other related legal expenses. Nonrecurring expenses may be paid

when the adoptive family has negotiated an Adoption Subsidy Agreement, or an Agreement to Future Adoption Subsidy.

(8) Funeral benefits at the amount allowed for a foster child in accordance with 441—156.

b. The need for special services shall be documented in the Adoption Subsidy Agreement. The family shall provide documentation of expenses to the department.

c. Any single special service and any special service delivered over a 12-month period costing $500 or more shall have prior approval from the central office adoption program manager prior to expending program funds.

d. For all Medicaid covered services the department shall reimburse at the same rate and duration as Medicaid as set forth in rule 441—79.1(249A).

201.6(2) *Maintenance only.* A monthly payment to assist with room, board, clothing and spending money may be provided, as determined under rule 441—201(600). The child will also be eligible for medical assistance pursuant to 441—Chapter 75.

201.6(3) *Maintenance and special services.* For children with special needs, a special services subsidy may also be included when a maintenance subsidy is provided.

441—201.7(600) Determination of ongoing subsidy eligibility and suspension of subsidy payments.

201.7(1) Eligibility for continuation of adoption subsidy shall be evaluated when the department has reasonable cause to suspect the adoptive parent is not providing financial support or is no longer legally responsible for the child. This includes, but is not limited to, the following circumstances:

a. The child is placed in out-of-home care.

b. A person alleges the parents are not providing financial support to the child.

c. A person other than the parent is awarded legal custody of the child.

d. A person other than the parent is appointed as the guardian of the child.

e. The child has applied for food assistance or other benefits.

f. The child has not resided with the parent for the past 30 consecutive days.

g. The parent is incarcerated.

h. The parent is awaiting trial for criminal charges related to harm caused to a child in the home.

201.7(2) The department will contact the child's parents via letter, telephone, or electronic or other means and document such efforts.

201.7(3) The child's parents shall provide documentation of support, including receipts, to the department upon request.

201.7(4) Upon completion of the department's evaluation of the child's continued eligibility for adoption subsidy, the department will issue a written notice to the parents documenting required ongoing actions by the parents, including an expectation of continued cooperation by the parents to provide documentation of ongoing support to the child at the request of the department.

201.7(5) The department shall suspend adoption subsidy payments if the parents refuse to cooperate or if the department is unable to determine whether the parents are providing financial support or are legally responsible for the child.

201.7(6) Through a Notice of Decision, the department shall terminate the Adoption Subsidy Agreement upon a finding that the child is not being financially supported.

201.7(7) When the child has resided out of the parental home for 30 consecutive days, the department will request a renegotiation of the Adoption Subsidy Agreement with the parents to reduce or suspend payments as agreed to by the parents.

441—201.8(600) Termination of subsidy. Subsidy will terminate when any of the following occur:

201.8(1) The adoptive child no longer meets the definition of child in rule 441—201.1(600).

201.8(2) The child marries.

201.8(3) The adoptive parents are no longer using the maintenance payments to support the child.

201.8(4) Death of the child, or death of the parents of the child (one in a single-parent family and both in a two-parent family).

201.8(5) Upon conclusion of the terms of the agreement.

201.8(6) Upon request of the adoptive parents.

201.8(7) The adoptive parents are no longer legally responsible for the child.

201.8(8) The child enlists in the military.

441—201.9(600) Reinstatement of subsidy. Reinstatement of subsidy will be made when the subsidy was terminated because of reasons in 201.8(3), 201.8(6), or 201.8(7) and the reason for termination no longer exists.

441—201.10(600) New application. New applications will be taken at any time, but processed only so long as funds are available. Maintenance and special services already approved will continue.

441—201.11(600) Medical assistance based on residency. Children with special needs eligible for any type of subsidy are entitled to medical assistance as defined in 441—Chapter 75. The funding source for medical assistance is based on the following criteria:

201.11(1) IV-E-eligible children:

a. IV-E-eligible children residing in Iowa from Iowa and from other states shall receive medical assistance from Iowa.

b. IV-E-eligible children from Iowa residing in another state shall receive medical assistance from the family's state of residence, even though medical assistance available in the family's state of residence may vary from Iowa's medical assistance.

201.11(2) Non-IV-E-eligible children:

a. Non-IV-E-eligible children from Iowa residing in Iowa shall be covered by Iowa's medical assistance.

b. Non-IV-E-eligible children from Iowa residing in another state shall be covered by Iowa's medical assistance unless eligible for benefits from the other state pursuant to a program funded under Title XIX of the federal Social Security Act as amended to December 31, 2023.

c. Non-IV-E-eligible children from another state residing in Iowa shall be covered by Iowa's medical assistance if all the following conditions are met:

(1) The child is under the age of 21.

(2) The child is residing in Iowa in a private home with the child's adoptive parent or parents.

(3) Another state is currently paying an adoption subsidy for the child pursuant to an adoption assistance agreement in effect for the child with that state.

(4) The state paying the adoption subsidy is a member of the interstate compact on adoption and medical assistance (ICAMA).

(5) The state paying the adoption subsidy provides medical assistance benefits pursuant to a program funded under Title XIX of the Social Security Act, under the optional group at Section 1902(a)(10)(A)(ii)(VIII) of the Act as amended to December 31, 2023, to children residing in that state (at least until age 18) for whom there is a state adoption assistance agreement in effect with the state of Iowa other than under Title IV-E of the Social Security Act.

201.11(3) When an Iowa child receives medical assistance from another state, Iowa shall discontinue paying any medical costs the month following the move unless additional time is necessary for a timely notice of decision to be provided to the family. An exception shall be made when the initial Iowa subsidy agreement provides for services not covered by the other states.

441—201.12(600) Presubsidy recovery. The department will recover the cost of presubsidy maintenance and special services provided by the department as follows:

201.12(1) Funds will be applied to the cost of presubsidy maintenance and special services from the unearned income of the child.

201.12(2) The department will serve as payee to receive the child's unearned income. The income will be placed in an account and be applied toward the cost of the child's current care with the remainder placed in an escrow account.

201.12(3) When a child has funds in escrow these funds may be used by the department to meet the current needs of the child not covered by the presubsidy payments and not prohibited by the source of the funds.

201.12(4) When the child leaves presubsidy care, funds in the escrow shall be paid to the adoptive parents, or to the child if the child has attained the age of majority.

These rules are intended to implement Iowa Code sections 600.17 to 600.23.

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** IAC 441-203

Iowa Code Section Authorizing Rule IAC 232.119

State or Federal Law(s) Implemented by the Rule: Iowa Code section 232.119.

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10:00am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter seeks to increase access to adoptive arrangements by creating the Iowa Adoption Exchange, a streamlined system of matching children available for adoption with potential adoptive homes. Matches are managed through a computerized statewide exchange system.

Children under the guardianship of HHS for whom an adoptive home is not available are entered on the exchange within 60 or 90 days of receipt of termination of parental rights. Children under the guardianship of a licensed child-placing agency whose parental rights have been terminated may be registered on the exchange at any time. Approved families wishing to adopt are entered on the exchange by HHS or a licensed child-placing agency.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
   - Classes of persons that will bear the costs of the proposed rule:

N/A

   - Classes of persons that will benefit from the proposed rule:

Iowa families and children seeking adoption.

Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred

- Quantitative description of impact:

Figures below are actuals incurred in the fiscal years shown.

Identified Impacts*

	SFY2018	SFY2019	SFY2020	SFY2021	SFY2022	5 Year Total
Costs None Identified						
Benefits Improved Outcomes for Adopted Children	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	$0	$0	$0	$0	$0	$0

*All monetary figures have been rounded to the nearest thousandth.

- Qualitative description of impact:

The adoption exchange seeks to find loving adoptive families for often the longest-waiting children in the foster care system. Over the last five state fiscal years, 5,400 adoptions have occurred out of Iowa's child welfare/foster care system, averaging over 1,000 each year. The adoption exchange helps to support adoption finalization in Iowa.

Costs to the state

- Implementation and enforcement costs borne by the agency or any other agency:

N/A

- Anticipated effect on state revenues:

N/A

Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows improved outcomes for children in adoptive care. Eliminating the exchange is likely to reduce the number of adoptive arrangements available to qualified children seeking adoption. A lack of available adoptive relationships increases the likelihood of adverse impact to the child.

Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

There are no other alternative methods that can accomplish the intended benefit.

Alternative methods considered by the agency

- Description of any alternative methods that were seriously considered by the agency:

HHS implements the Adoption Exchange in accordance with requirements of Iowa Code.

- Reasons why they were rejected in favor of the proposed rule:

N/A

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:

CHAPTER 203
IOWA ADOPTION EXCHANGE

441—203.1(232) Definitions.

"Children who are difficult to place" means children as defined in 441—201.3(1), children under state guardianship for whom an adoptive home is not available within 90 days after termination and children as part of a sibling group of more than three children.

"Iowa adoption exchange system (exchange system)" is a computerized system established to facilitate the adoptive placement of children by matching children legally available for adoption and approved families desiring to adopt a child who is difficult to place.

*"Recruitment, Retention, Support and Training (RRTS) Contract"*means the State's contractor(s) responsible for activities related to licensing foster families and approving adoptive families; providing support services to foster and preadoptive families; conducting preservice and in-service training; and assistance in matching children in need of foster home care.

441—203.2(232) Children to be registered on the exchange system. All children who are difficult to place shall be registered on the exchange system within 60 days of receipt of the termination of parental rights court order unless a deferral is granted by the adoption program manager.

203.2(1) Licensed child-placing agencies shall register a child whose parental rights have been terminated and who is under their guardianship using one of the following methods:

a. If the agency is registering less than four children a calendar year, the agency shall submit the Waiting Child Enrollment form to the department.

b. If the agency registers more than three children in a calendar year the agency shall access the exchange system and enter the child's name and data.

441—203.3(232) Families to be registered on the exchange system. Approved families wishing to adopt a child who is difficult to place shall be registered on the exchange system by the department.

203.3(1) Licensed child-placing agencies and certified adoption investigators shall register an approved family on the exchange using one of the following methods:

a. If the licensed child-placing agency is registering less than four families a calendar year the agency shall submit the Exchange Referral of Family form to the department.

b. If the licensed child-placing agency registers more than three children in a calendar year, the agency shall access the exchange system and enter the family's name and data.

c. Certified adoption investigators shall submit the Exchange Referral of Family form, to the department.

441—203.4(232) Matching process. Using the computerized exchange system, the department and licensed child-placing agencies shall search for approved families to meet the needs of the available children. The child's and family's workers shall be contacted for additional information needed to make an informed decision concerning possible adoptive placements.

These rules are intended to implement Iowa Code section 232.119.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** IAC 441-204

Iowa Code Section Authorizing Rule IAC 234.6

State or Federal Law(s) Implemented by the Rule

Fostering Connections to Success and Increasing Adoptions Act of 2008

Iowa Code sections 232.117, 234.6, and 249A.4

Iowa Code section §232.104(2)(d)(2) 232.104(6), 232D and 633.552

1999 Iowa Acts, Chapter 203, section 15, subsection 9

2006 Iowa Acts, House File 2734, section 17, subsection 10

Social Security Act sections 472 and 473(d)(3)

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10:00am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter seeks to increase access to guardianship arrangements by implementing a subsidized guardianship program to provide financial assistance to guardians of eligible children who are in foster care but are not able to be adopted and are not able to return home. Eligible children include those aged ten years or older or part of a sibling group with a child aged ten years or older, who have been previously under the custody of the department, with a documented permanency goal of guardianship or another planned permanent arrangement.

Prospective guardians must be licensed, have a significant relationship with the child, and seek a long-term commitment.

Payments to approved guardians may include:

- Monthly maintenance payments with the maximum monthly rate made pursuant to the foster family care maintenance rates.
- Guardianship subsidy at a rate negotiated with HHS, not to exceed the state's current daily basic foster care rate plus any eligible daily special needs allowance or sibling allowance.
- Reimbursement for non-recurring expenses necessary to finalize a guardianship up to $2,000.
- Reimbursement for special services for the child such as outpatient medical care, travel expenses for family therapy, or equipment required to accommodate a special need.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

Legally responsible parents may incur a support debt under the child support recovery program for foster care payments made. Subsidy payments are considered foster care payments for purpose of child support recovery. This is reflected in the table above as "Child Support Debt Incurred".

    - Classes of persons that will benefit from the proposed rule:

Guardians of eligible children who are in foster care but are not able to be adopted and are not able to return home.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Figures below are actuals incurred in the fiscal years shown.

Identified Impacts*

	SFY2023	SFY2024	SFY2025	3 Year Total
Costs Subsidy Payments to Guardians	($53,000)	($299,000)	($570,000)	($858,000)
Benefits Child Support Debt Incurred	Unknown	Unknown	Unknown	Unknown
Federal Title IV-E Funding	$13,000	$58,000	$121,000	$163,000
Improved Outcomes for Children under Guardianship	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	($40,000)	($241,000)	($449,000)	($695,000)

*All monetary figures have been rounded to the nearest thousandth.

- Qualitative description of impact:

The amount of subsidy is negotiated between HHS and the qualified guardian based on the needs of the child and circumstances of the family providing guardianship. Guardianship is a safe alternative to adoption, providing permanency for the youth without requiring formal termination of parental rights. HHS has continued to increase the number of children in the subsidized guardianship program since its inception in 2019. In SFY2023 139 children received a guardianship subsidy payment. The rule chapter requires that other services available to meet the needs of an eligible child that are free of charge be explored and used prior to spending subsidy funds.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

Any implementation costs incurred by HHS for operation of the adoption program are reflected in the cost benefit analysis for chapter 441-200 and are not reflected here.

Federal funds received through the Title IV-E Federal Payments for Adoption Assistance Program are used to assist in funding subsidized guardianships. The federal participation rate varies; in SFY22 Iowa's participation rate was 21.51%. These funds are reflected in the table above as "Federal Title IV-E Funding".

- Anticipated effect on state revenues:

N/A

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a net value of -$695,000 over the three fiscal years studied and improved outcomes for children in subsidized guardianship care. These costs may also be offset by support debt under the child support recovery program. The alternative to a child exiting the child welfare system through the subsidized guardianship program is the child remaining in the child welfare system. Should a child remain in the child welfare system, the state would incur costs to maintain a child in need of assistance case which may continue until the child reaches the age of 18.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

HHS implements the subsidy program in accordance with requirements of Iowa Code and federal regulations; overall, HHS implements the program as directed and has little flexibility in determining program elements. HHS does maintain flexibility in identifying children eligible for guardianship subsidy assistance.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:
    - Reasons why they were rejected in favor of the proposed rule:

HHS has defined eligible children as those aged ten years or older or part of a sibling group with a child aged ten years or older, who have been previously under the custody of the department. HHS believes the eligibility criteria described in this rule chapter is at the level necessary to provide for safe and stable guardianship arrangements for children in need of guardianship. Alternative approaches might include expanding or reducing the eligibility criteria detailed here.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:

CHAPTER 204
SUBSIDIZED GUARDIANSHIP PROGRAM

441—204.1(234) Definitions.

"Child" means either a person less than 18 years of age or a person 18, 19, or 20 years of age who meets one or more of the following conditions:

1. Is in full-time attendance at an accredited school pursuing a course of study leading to a high school diploma.
2. Is attending an instructional program leading to a high school equivalency diploma.
3. Has been identified by the director of special education of the area education agency as a child requiring special education as defined in Iowa Code section 256B.2(1).

"Guardianship subsidy" means a monthly payment to assist in covering the cost of room, board, clothing, and spending money for the child.

"Nonrecurring expenses" means reasonable and necessary guardianship fees, court costs, attorney fees, and other expenses that are directly related to finalizing the legal guardianship of a child. These expenses shall be limited to attorney fees, court filing fees and other court costs.

"Relative" means a person to whom a child is related by blood, marriage, or adoption, or a person who has a significant, committed, positive relationship with the child.

"Sibling group" means at least two children who are whole or half-siblings. A sibling group may include adopted children who have a common parent.

441—204.2(234) Eligibility.

204.2(1) *General conditions of eligibility.* The guardian named in a permanency order under Iowa Code section 232.104(2)*"d"*(1) or Iowa Code chapter 232D for a child who was previously in the custody of the department is eligible for subsidy when all of the following conditions exist:

a. The child has a documented permanency goal of:

(1) Guardianship; or

(2) Another planned permanent living arrangement.

b. The child is either:

(1) Ten years of age or older and consents to the guardianship; or

(2) Part of a sibling group with a child aged ten or older.

c. The child has lived in continuous foster family care with the prospective guardian for the six months before initiation of the guardianship subsidy.

d. The prospective guardian is a licensed relative foster parent who has a significant relationship with the child and demonstrates a willingness to make a long-term commitment to the child's care.

(1) The guardian shall be a relative as defined in this chapter.

(2) Placement with that guardian must be in the best interest of the child. The best-interest determination must be documented in the case file.

e. A child who is part of a sibling group with a child ten years of age or older may be eligible for subsidy if all criteria are met. The following conditions for the younger sibling shall also be met:

(1) The sibling is placed as a foster child in the same prospective guardian home.

(2) The guardian and the department agree it is appropriate for guardianship to be granted for the sibling.

204.2(2) *Residency.* The subsidized guardianship applicant or recipient need not reside in Iowa.

204.2(3) *Unearned income.* The family or the guardian shall provide to the department documentation from the source of the child's unearned income.

204.2(4) *Other services.* Other services available to meet the needs of the child that are free of charge, such as federal, state, and local governmental programs, or private assistance programs, shall be explored and used prior to the expenditure of subsidized guardianship funds.

441—204.3(234) Application. Applications for the subsidized guardianship program may be made at any county office of the department.

204.3(1) *Application forms.* Application for a subsidized guardianship shall be made on the approved department form.

204.3(2) *Eligibility determination.* The determination of whether a child meets the eligibility requirements is made by the department. The proposed guardian shall be notified in writing of the decision of the department regarding the child's eligibility for the program and the amount of subsidy to be provided.

204.3(3) *Effective date.* The effective date of the guardianship subsidy payment shall be the date the guardianship order is signed if all other conditions of eligibility are met.

204.3(4) *Redetermination.* The department shall review the child's eligibility, the needs of the child and the child's unearned income every 12 months. Reviews may be done more often if needed due to the child's need for special services, revision of the subsidy amount because of the child's age, or a request for review by the guardian.

204.3(5) *Determination of eligibility after age 18.* The department shall review the subsidy agreement when the child reaches the age of 17½ to determine whether the child is eligible to receive subsidy to the age of 21 to complete high school or equivalency or due to the child's physical, intellectual, or mental health disability.

a. A disability shall be diagnosed by a physician, a qualified mental health professional or a qualified intellectual disability professional.

b. The diagnosed disability shall be current within one year prior to the child's eighteenth birthday.

c. Documentation of the child's diagnosed disability shall be provided by the child's guardian to the department.

d. Upon the child's reaching the age of 18, the subsidy may continue until the child completes courses leading to a high school diploma or equivalency or reaches the age of 21. Documentation of school enrollment and completion shall be provided by the child's guardian.

441—204.4(234) Negotiation of amount of subsidy.

204.4(1) *Subsidy agreement.* The amount of subsidy shall be negotiated between the department and the guardian and shall be based upon the needs of the child and the circumstances of the family.

204.4(2) *Amount of subsidy.* Each time negotiations are completed, the department and the guardian shall complete and sign a new Guardianship Subsidy Agreement.

a. The maximum monthly maintenance payment for a child in subsidized guardianship shall be made pursuant to the foster family care maintenance rates according to the age and special needs of the child as found in 441—156.6.

(1) The rate for the guardianship subsidy shall not exceed the state's current daily basic foster care rate plus any daily special needs allowance or sibling allowance for which the child is eligible, as found in 441—156.6.

(2) Reserved

b. If the subsidized guardianship payment is less than the maximum amount allowed, the guardian may request an increase if there is a substantial change in the child's needs and circumstances that requires additional resources.

c. Guardianship payments shall continue if the guardian dies or becomes incapacitated and has named a successor guardian in the Guardianship Subsidy Agreement or in any amendments to the agreement.

204.4(3) *Placement outside of home.* If a child needs to be placed out of the guardian's home and the plan is for the child to return to the guardian within six months, a partial subsidy amount may be negotiated.

204.4(4) *Nonrecurring expenses.* The nonrecurring expenses necessary to finalize a guardianship shall not exceed $2,000.

204.4(5) *Special services.*

a. Reimbursement to the guardian family or direct payment made to a provider is limited to the following services.

(1) Outpatient individual or family services provided from a non-Medicaid provider only with approval from the department and when one of the following applies:

1. The services are not available from a Medicaid provider within a reasonable distance from the family.
2. The child and the family were receiving therapy or counseling from a non-Medicaid provider and it would not be in the child's best interest to disrupt the services.
3. Available Medicaid providers lack experience in working with foster, adopted, or blended families.

(2) Travel-related expenses including transportation, meals and lodging not covered by Medicaid for visitation or family therapy when the child is receiving Medicaid-paid services out of the home.

(3) Supplies and equipment as required by the child's special needs and unavailable through other resources.

(4) Funeral benefits at the amount allowed for a foster child in accordance with 441—156.8(234).

b. Any single special service and any special service delivered over a 12-month period costing $500 or more shall have prior approval from the department prior to expending program funds.

c. For all Medicaid-covered services, the department shall reimburse at the same rate and duration as Medicaid as set forth in 441—79.1(249A).

441—204.5(234) Parental liability. These subsidy payments are considered foster care payments for purposes of child support recovery and as such create a support debt for the legally responsible parent or parents.

441—204.6(234) Determination of ongoing subsidy eligibility and suspension of subsidy payments.

204.6(1) Eligibility for continuation of guardianship subsidy shall be evaluated when the department has good cause to suspect the guardian is not providing financial support or is no longer legally responsible for the child. Good cause includes, but is not limited to, the following circumstances:

a. The child is placed in out-of-home care under Iowa Code chapter 232.
b. A person alleges the guardian is not providing financial support to the child.
c. A person other than the guardian is awarded legal custody of the child.
d. A person other than the guardian is appointed as the guardian of the child.
e. The child has applied for food assistance or other benefits.
f. The child has not resided with the guardian for the past 30 consecutive days.
g. The guardian is incarcerated.
h. The guardian is awaiting trial for criminal charges related to harm caused to a child in the home.

204.6(2) The department will contact the child's guardian via letter, telephone, or electronic or other means and document such efforts if an evaluation is determined to be necessary.

204.6(3) If such an evaluation occurs, the child's guardian shall provide documentation of support, including receipts, to the department upon request.

204.6(4) Upon completion of the department's evaluation of the child's continued eligibility for guardianship subsidy, the department will issue a written notice to the guardian documenting required ongoing actions by the guardian, including an expectation of continued cooperation by

the guardian to provide documentation of ongoing support to the child at the request of the department.

204.6(5) The department shall suspend guardianship subsidy payments if the guardian refuses to cooperate with any department evaluation designed to determine legal responsibility for the child or to determine whether the guardian is providing financial support for the child.

204.6(6) Through a Notice of Decision, the department will notify the guardian that the guardianship subsidy payment will be suspended, modified, or terminated.

204.6(7) When the child has resided out of the guardian's home for 30 consecutive days, the department shall request a renegotiation of the Guardianship Subsidy Agreement with the guardian to reduce or suspend payments as agreed to by the guardian.

441—204.7(234) Termination of subsidy. A Guardianship Subsidy Agreement remains in effect until the subsidy is terminated. The subsidy shall terminate when any of the following occur, and a notice shall be sent which states the reason for the termination:

1. The child reaches the age of 18, unless the department determines that the subsidy may continue until the child reaches the age of 21 as specified by subrule 204.3(5).
2. The child marries or enlists in the military.
3. The child no longer lives with the guardian, except for placement outside the home as limited by subrule 204.4(3).
4. The relationship ends due to the death of the child.
5. The terms of the Guardianship Subsidy Agreement are concluded.
6. The guardian requests that the guardianship payment cease.
7. The department has determined the guardian is not providing financial support to the child.
8. The guardian fails to abide by the terms of the Guardianship Subsidy Agreement.
9. The guardianship case is terminated by court order.
10. The department funds for subsidized guardianship are no longer available
11. Due to incapacity, the guardian can no longer discharge the responsibilities necessary to protect and care for the child, the guardianship has been or will be vacated, and a successor guardian was not named in the *Guardianship Subsidy Agreement.*
12. The death of the guardian when a successor guardian is not named in the *Guardian Subsidy Agreement* (one in a single-parent family or both in a two-parent family).

441—204.8(234) Reinstatement of subsidy. Reinstatement of the subsidy shall be made when the subsidy was terminated at the guardian's request and the guardian has requested reinstatement.

441—204.9(234) Appeals. The guardian may appeal adverse determinations pursuant to 441—Chapter 7.

441—204.10(234) Medical assistance. Children eligible for subsidy are entitled to medical assistance as defined in 441—Chapter 75. When an Iowa child receives medical assistance from another state, Iowa shall discontinue paying any medical costs the month following the move unless additional time is necessary for a timely notice of decision to be provided to the guardian.

The funding source for medical assistance is based on the following criteria:

1. Children from Iowa residing in Iowa shall be covered by Iowa's medical assistance.
2. Children from Iowa residing in another state shall receive medical assistance from the state of residence if eligible. Iowa shall provide medical assistance for children not eligible in

their state of residence. Medical assistance available in the family's state of residence may vary from Iowa's medical assistance.

3. Children from another state residing in Iowa shall continue to be covered by the other state's medical assistance unless the state has adopted the adoption assistance interstate compact and a contract between Iowa and the other state exists.

These rules are intended to implement Iowa Code section 234.6 and 2006 Iowa Acts, House File 2734, section 17, subsection 11.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 641-1

Iowa Code Section Authorizing Rule 139A.2, 139A.3, 139A.3A, 139A.4, 139A.21, 139A.31, 139A.33, 136A

State or Federal Law(s) Implemented by the Rule 135, 139A, 137

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name
Joe Campos

Address
Joe.campos@idph.iowa.gov

Email and/or phone number
515-304-0963

Purpose and summary of proposed rule:

This rule chapter provides for disease investigation and disease control through preventive measures including but not limited to quarantine and isolation. This chapter captures reportable communicable and noncommunicable diseases, cancers, and farm related injuries.

The rule chapter defines procedure for members of the public to comply with the reporting requirements for the categories listed above, including:

- Who is required to report.
- When to report.
- What needs to be reported.
- How to report.

The rule chapter provides for cancer surveillance, which allows for evaluation of trends over time and evaluation of potential cancer clusters, as well as helping Iowa hospitals to monitor and improve the quality and comprehensiveness of their cancer care. Having administrative rules that allow the Iowa Cancer Registry to maintain their contract with the National Cancer

Institute (NCI) funded Surveillance, Epidemiology and End Results (SEER) Program allows the State of Iowa to maintain a high quality registry at a very low cost to the State.

It also provides for congenital and inherited disorder surveillance to compile, evaluate, retain, and disseminate information on the occurrence, prevalence, causes, treatment, and prevention of congenital disorders. Congenital disorders shall be considered reportable conditions in accordance with rules adopted by the department and shall be abstracted and maintained by the registry.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

The public does not incur any cost via implementation of this rule.

- Classes of persons that will benefit from the proposed rule:

Individuals or families near persons with communicable diseases. Communities in which persons with reportable communicable diseases reside. Individuals with congenital and inherited disorders.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Estimated figures below are projections based on past program performance as included in the Red Tape Rule Report for this chapter.

Identified Impacts*

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5 Year Total
Costs HHS Implementation	$1,238,000	$1,238,000	$1,238,000	$1,238,000	$1,238,000	$6,190,000
Benefits Improved Public Health & Safety	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	Indeterminate	Indeterminate	Indeterminate	Indeterminate	Indeterminate	Indeterminate

*All monetary figures have been rounded to the nearest thousandth.

State general fund allocations support only a portion of the HHS implementation costs for Chapter 1. The state general fund allocation has remained static. Federal grant funds provide approximately $6.5million dollars in annual funding in support of Chapter 1 implementation. Federal government issues supplemental grant awards to support the response to outbreaks that impact the nation (e.g. COVID-19 and Mpox). These supplemental awards are in addition to the annual grant support.

- Qualitative description of impact:

Public health surveillance is foundational to public health practice. It aids in understanding diseases and their spread to determine appropriate actions to control outbreaks. If this rule chapter did not exist, it would limit the ability of public health officials to monitor, control, and prevent these reportable diseases and conditions. An inability to assess the incidence and impact of reportable conditions on Iowans would prevent us from conducting disease investigation, contact tracing, and connecting affected individuals with recommended testing and treatment. Ultimately, disease transmission would increase, as would sequelae of untreated STIs (including chronic pelvic pain, pelvic inflammatory disease, vision and hearing problems, and death).

In addition, if this rule did not exist, there would not be the ability to access the incidence, contributing factors, and impact to families of congenital and inherited disorders. There would be not data to inform prevention or treatment efforts for congenital and inherited disorders.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs to support the procedures described in this rule chapter. These costs are reflected in the table above as "HHS Implementation."

    - Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The general fund dollars, supplemented largely by federal funding sources, supports a net value in improved public health and safety. If this rule chapter didn't exist, it is very likely that the disease burden would increase, leading to increased absences from school and work which could have an impact on the economy. If the department were no longer able to isolate and/or quarantine individuals that either have a communicable disease or are at risk for developing and spreading a communicable disease it would have a significant impact on morbidity and mortality across the state.

Iowa HHS would not be able to implement programs and activities authorized and required by Iowa Code Chapter 136A, and would be unable to initiate, conduct and supervise screening and health care activities in order to detect and predict congenital and inherited disorders. Iowa HHS would also not be able to assure the availability of and access to quality genetic and genomic services for Iowans.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

HHS is implementing an isolation and quarantine process and reporting for certain diseases and conditions in accordance with Iowa Code. A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS implements isolation and quarantine measures in accordance to requirements of Iowa Code. The Department does have flexibility in setting parameters for process and investigation cooperation, as well as the reporting structure for communicable and noncommunicable diseases and conditions. The department also has some flexibility in the communicable and noncommunicable diseases and conditions required to be reported pursuant to authority in Iowa Code. No alternative methods have been seriously considered as HHS believes these are the most effective for both cost and maintenance of public health.

    - Reasons why they were rejected in favor of the proposed rule:

HHS believes the parameters established in this rule chapter for education, testing, and vaccination are at a level necessary to protect public health and safety.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

NA

Text of Proposed Rule:

Regulatory Analysis Template

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

641—1.1(139A) Definitions. For the purpose of these rules, the following definitions will apply:

"AIDS" means the same as defined in Iowa Code chapter 141A.

"Area quarantine" means the same as defined in Iowa Code chapter 139A.

"Business" means the same as defined in Iowa Code chapter 139A.

"Care provider" means the same as defined in Iowa Code chapter 139A.

"Case" means an individual who has confirmatory evidence of disease.

"Clinical laboratory" means any laboratory performing analyses on specimens taken from the body of a person in order to assess that person's health status.

"Communicable disease" means the same as defined in Iowa Code chapter 139A.

"Congenital or inherited disorder" means any congenital disorder as defined in Iowa Code chapter 136A or any inherited disorder as defined in Iowa Code chapter 136A.

"Disease surveillance" means the ongoing, systematic collection, analysis, and interpretation of health-related data essential for planning, implementation, and evaluation of public health programs and practices.

"Exposure" means contact with an agent in a manner that could cause disease or infection.

"HBV" means the same as Iowa Code chapter 139A.

"Health care facility" means the same as Iowa Code chapter 139A.

"Health care provider" means the same as defined in Iowa Code chapter 139A.

"HIV" means the same as defined in Iowa Code chapter 141A.

"Hospital" means the same as defined in Iowa Code chapter 135B.

"IDSS" means the Iowa disease surveillance system, a secure electronic statewide disease reporting and surveillance system.

"Infectious disease" means a disease caused by the entrance into the body of organisms, including but not limited to bacteria, protozoans, fungi, prions, or viruses which grow and multiply.

"Infectious tuberculosis" means pulmonary or laryngeal tuberculosis as evidenced by:

1. Isolation of M. tuberculosis complex (positive culture) from a clinical specimen or positive nucleic acid amplification test, or
2. Both radiographic evidence of tuberculosis, such as an abnormal chest X-ray, CT, PET or MRI scan, and clinical evidence, such as a positive skin test or whole blood assay test for tuberculosis infection, coughing, sputum production, fever, or other symptoms compatible with infectious tuberculosis that lead a health care provider to diagnose infectious tuberculosis according to currently acceptable standards of medical practice and to initiate treatment for tuberculosis.

"Investigation" means an inquiry conducted to determine the specific source, mode of transmission, and cause of a disease or suspected disease occurrence and to determine the specific incidence, prevalence, and extent of the disease in the affected or general population. "Investigation" may also include the application of scientific methods and analysis to institute appropriate control measures.

"Isolation" means the same as defined in Iowa Code chapter 139A.

"Local board" means the same as defined in Iowa Code chapter 139A.

"Local department" means the same as defined in Iowa Code chapter 139A.

"Placard" means the same as Iowa Code chapter 139A.

"Poison control or poison information center" means any organization or program which has as one of its primary objectives the provision of toxicologic and pharmacologic information and referral services to the public and to health care providers (other than pharmacists) in response to inquiries about actual or potential poisonings.

"Public health disaster" means an incident as defined in Iowa Code section 135.140.

"Quarantinable disease" means any communicable disease that presents a risk of serious harm to public health and that may require isolation or quarantine to prevent its spread. "Quarantinable disease"

includes but is not limited to cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, novel influenza, and severe acute respiratory syndrome (SARS).

"Quarantine" means the same as defined in Iowa Code chapter 139A.

"Reportable cancers" means those cancers included in the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) Program.

"Reportable disease" means means any disease or condition approved by the state epidemiologist or medical director and designated by this chapter. .

"Sexually transmitted disease or infection" or *"STI"* means a disease or infection as identified by this chapter that is transmitted through sexual practices. "Sexually transmitted disease or infection" includes, but is not limited to, acquired immunodeficiency syndrome (AIDS), chlamydia, gonorrhea, hepatitis B, hepatitis C, human immunodeficiency virus (HIV), human papillomavirus, and syphilis.

"Suspected case" means an individual that presents with clinical signs or symptoms indicative of a reportable or quarantinable disease.

"Toxic agent" means any noxious substance in solid, liquid or gaseous form capable of producing illness in humans including, but not limited to, pesticides as defined in Iowa Code chapter 206, heavy metals, organic and inorganic dusts and organic solvents. Airborne toxic agents may be in the form of dusts, fumes, vapors, mists, gases or smoke.

641—1.2(139A) Authority. The director is the principal officer of the state to administer disease, poisoning and condition, and incident reporting and control. The Iowa Cancer Registry, administered by the Department of Epidemiology of the College of Public Health at the University of Iowa, is a public health authority for purposes of collecting cancer data in accordance with this chapter.

641—1.3(139A,141A) Reportable communicable and infectious diseases, poisonings or conditions, and cancers. Reportable communicable and infectious diseases, poisonings and conditions under this chapter are those listed in Appendices A and B.. The director may also designate any disease, poisoning or condition or syndrome temporarily reportable for the purpose of a special investigation.

1.3(1) *Cancer.* Pursuant to Public Law 92-218 and Public Law 102-515, each occurrence of a reportable cancer that is diagnosed or treated in an Iowa resident or occurs in a nonresident who is diagnosed or treated in an Iowa facility shall be reported to the Iowa Cancer Registry.

1.3(2) *Congenital and inherited disorders.* Each occurrence of a congenital and inherited disorder that is diagnosed or treated in an Iowa resident or occurs in a nonresident who is diagnosed or treated in an Iowa facility is a reportable condition pursuant to Iowa Code chapter 136A, and records of these congenital and inherited disorders shall be abstracted and maintained in a central registry. Congenital and inherited disorder surveillance shall be performed to determine the occurrence and trends of congenital and inherited disorders, to conduct thorough and complete epidemiological surveys, to assist in the planning for and provision of services to children with congenital and inherited disorders and their families, and to identify environmental and genetic risk factors for congenital and inherited disorders.

641—1.4(135,139A) Reporting requirements.

1.4(1) *Who is required to report.*

a. Communicable and infectious diseases, and poisonings.

(1) Health care providers, hospitals, and clinical laboratories and other health care facilities are required to report cases of reportable diseases, poisonings and conditions. Health care providers and hospitals are exempted from reporting communicable and infectious disease laboratory results and blood lead testing if the healthcare provider or hospital ensures that the laboratory performing the analysis provides a report containing the required information to the department.

(2) School nurses are required to report suspected cases of a reportable disease, poisoning or condition occurring among the children supervised.

(4) Poison control and poison information centers are required to report inquiries about cases of a reportable disease, poisoning or condition received by them.

(5) Medical examiners are required to report their investigatory findings of any death which was caused

by or otherwise involved a reportable disease, poisoning or condition.

(6) Occupational nurses are required to report cases of reportable diseases, poisonings and conditions.

(7) Hospitals, health care providers and clinical laboratories outside the state of Iowa shall immediately report any confirmed or suspected case of a reportable disease, poisoning or condition in an Iowa resident.

b. Reportable cancers. Health care providers, hospitals, clinical laboratories and health care facilities involved in the diagnosis, care or treatment of individuals with a reportable cancer.

c. Congenital and inherited disorders. Health care providers, clinics, clinical laboratories and other health care facilities are required to report cases of a congenital or inherited disorder.

1.4(2) *What to report.* Each report will contain all information as listed in Iowa Code chapter 139A, in addition to:

a. For communicable and infectious diseases:

(1) The name of the reportable disease.

(2) The treatment provided for the reportable disease.

b. For poisonings:

(1) The analytical result.

(2) In the case of blood lead testing, whether the sample is a capillary or venous blood sample.

(3) For conditions not identified by a laboratory analysis, the date that the condition was diagnosed.

(4) In the case of occupational conditions, the name of the patient's employer.

c. For reportable cancers:

(1) Follow-up data.

(2) Demographic, diagnostic, prognostic, treatment, and other medical information.

d. For congenital and inherited conditions:

(1) Follow-up data.

(2) Demographic, diagnostic, treatment and other medical information.

(3) Tissue samples may also be submitted.

1.4(3) *How to report.* Information on when and how to report any of the diseases, conditions, or injuries included in this chapter can be found in Appendices A and B.

a. Immediate reporting by telephone of diseases identified as immediately reportable. A health care provider and a public, private, or hospital clinical laboratory will immediately report any confirmed or suspect case of a disease identified in Appendix A as immediately reportable to the department.

b. Other diseases that carry serious consequences or spread rapidly. A health care facility, health care provider and a public, private, or hospital clinical laboratory will immediately report any confirmed or suspected case of a common source epidemic or disease outbreak of unusual numbers.

c. Reporting to other public health authorities. The department may authorize hospitals, health care providers or clinical laboratories outside the state of Iowa to report any confirmed or suspect case of a reportable disease, poisoning, or condition to another public health authority for the purpose of facilitating a report to the department.

d. Cancers. The department has delegated to the Iowa Cancer Registry the responsibility for collecting cancer data.

(1) Those required to report shall submit required data to the Iowa Cancer Registry monthly, in an electronic format specified by the Iowa Cancer Registry. Those required to report may employ registrars with Iowa Cancer registry-approved training, or contract with the Iowa Cancer Registry or an outside vendor to submit reportable cancer cases and required data elements to the Iowa Cancer Registry.

(2) As needed for SEER surveillance activities, the Iowa Cancer Registry shall have remote electronic access, where available, or physical access to all cancer-relevant medical records.

e. Congenital and inherited disorders. The department has delegated to the Iowa Registry for Congenital and Inherited Disorders the responsibility to maintain a central registry for congenital and inherited disorders. The Iowa Registry for Congenital and Inherited Disorders shall:

(1) Prior to collecting the data from health care providers, hospitals, clinics, clinical laboratories and other health care facilities, work with the reporting facility to develop a process for abstracting records which is agreeable to the reporting facility.

(2) Develop and distribute reporting forms where applicable.

(3) Develop an abstracting process for data to be supplemented with information obtained from records from hospitals, treatment centers, outpatient centers, clinics, pathology laboratories and physician offices.

INVESTIGATION

641—1.5(135,139A) Investigation of reportable diseases.

1.5(1) A health care provider and a public, private, or hospital clinical laboratory will provide the department, local board, or local department with all information necessary to conduct the investigation, including but not limited to medical records; exposure histories; medical histories; contact information; and test results necessary to the investigation, including positive, pending, and negative test results.

1.5(2) *Issuance of investigatory subpoenas*.

a. The department may upon the written request of a local board of health, the state public health medical director or the state public health epidemiologist or designee, subpoena records, reports, or any other evidence necessary to conduct a disease investigation. The subpoena will be signed by the department following review and approval of the written request for subpoena.

b. Process to challenge a subpoena. Any person who is aggrieved or adversely affected by compliance with the subpoena and who desires to challenge the subpoena shall follow 441—Chapter 7.

ISOLATION AND QUARANTINE

641—1.6(135,139A) Isolation and Quarantine. Isolation and quarantine should be consistent with guidelines provided by the Centers for Disease Control and Prevention.

1.6(1) *General provisions.*

a. Voluntary confinement. Prior to instituting mandatory isolation or quarantine pursuant to this rule, the department or a local board of health may request that an individual or group of individuals voluntarily confine themselves to a private home or other facility.

b. Isolation and quarantine. The department and local boards of health are authorized to impose and enforce isolation and quarantine restrictions. Isolation and quarantine will rarely be imposed by the department or by local boards of health. If a quarantinable disease occurs in Iowa, individuals with a suspected or active quarantinable disease and contacts to the case may be isolated or quarantined as the particular situation requires. Any isolation or quarantine imposed by the department or a local board of health will be established and enforced in accordance with this rule.

1.6(2) *Conditions and principles.* The department and local boards of health will adhere to all of the following conditions and principles when isolating or quarantining individuals or a group of individuals:

a. The isolation or quarantine will be by the least restrictive means necessary to prevent the spread of a communicable or possibly communicable disease to others and may include, but not be limited to, confinement to private homes, other private premises, or public premises.

b. Isolated individuals will be confined separately from quarantined individuals.

c. The health status of isolated or quarantined individuals will be monitored regularly to determine if the individuals require further or continued isolation or quarantine.

d. If a quarantined individual subsequently becomes infected or is reasonably believed to have become infected with a communicable or possibly communicable disease, the individual will be promptly removed to isolation.

e. Isolated or quarantined individuals will be immediately released when the department or local board of health determines that the individuals pose no substantial risk of transmitting a communicable or possibly communicable disease.

f. The needs of isolated or quarantined individuals will be addressed in a systematic and competent fashion including, but not limited to, providing adequate food; clothing; shelter; means of communicating with those in and outside of isolation or quarantine; medication; and competent medical care.

g. The premises used for isolation or quarantine will be maintained in a safe and hygienic manner and will be designed to minimize the likelihood of further transmission of infection or other harm to isolated or

quarantined individuals.

h. To the extent possible, cultural and religious beliefs will be considered in addressing the needs of individuals in isolation or quarantine premises and in establishing and maintaining the premises.

1.6(3

a. A health care provider who attends an individual with a suspected or active quarantinable disease will make all reasonable efforts in accordance with guidance from a local health department or the department to examine or cause all household and other known contacts of the individual to be examined by a health care provider. The health care provider will promptly report to the department the results of such examination. If the individual refuses or is unable to undergo examination, the health care provider will all promptly report such information to the department.

b. When required by the department, all contacts of an individual who has a suspected or active quarantinable disease, including all adult and minor contacts, will submit to a diagnostic test or tests or other monitoring. If any suspicious abnormality is found, steps satisfactory to the department will be taken to refer the individual promptly to a health care provider or appropriate medical facility for further evaluation and, if necessary, treatment. The department or the referring health care provider or facility will notify the receiving health care provider or facility of the suspicious abnormality. When requested by the department, a health care provider will report the results of the examination of a contact to the case or suspected case or incident. If an individual with a suspected or active quarantinable disease fails to comply with a department order to submit to diagnostic testing or monitoring, such individual may be ordered to be isolated or quarantined as determined by the department.

c. Upon order of the department or local board of health, an individual with a suspected or active quarantinable disease will not attend the workplace or school and will not be present at other public places until the individual receives the approval of the department or a local board of health to engage in such activity. Upon order of the department or local board of health, employers, schools and other public places will exclude an individual with a suspected or active quarantinable disease. An individual may also be excluded from other premises or facilities if the department or a local board of health determines the premises or facilities cannot be maintained in a manner adequate to protect others against the spread of the disease.

d. A person diagnosed with or clinically suspected of having infectious tuberculosis shall complete voluntary treatment until, in the opinion of the health care provider or the state public health medical director, the person's tuberculosis is cured or such person is no longer a threat to public health. If such person refuses to complete the course of voluntary treatment, the department or local board of health may issue an order compelling mandatory treatment. Such order shall include the identity of the person subject to the mandatory treatment order, a description of the treatment ordered, the medical basis upon which the treatment is ordered, and a description of the potential medical and legal consequences of violating such order. A person who violates a mandatory treatment order may be subject to the penalties provided in Iowa Code section 135.38 or 137.117 and may be placed under mandatory quarantine or isolation in accordance with the provisions of this chapter.

e. A person diagnosed with extrapulmonary tuberculosis or clinically suspected of having infectious tuberculosis who fails to comply with a health care provider's recommendation for diagnostic testing may be ordered to undergo diagnostic testing by the department or local board of health. Such order shall include the identity of the person subject to mandatory diagnostic testing, a description of the diagnostic testing ordered, the medical basis upon which the diagnostic testing is ordered, and a description of the potential medical and legal consequences of violating such order. A person who violates a mandatory diagnostic testing order may be subject to the penalties provided in Iowa Code section 135.38 or 137.117 and may be placed under mandatory quarantine or isolation in accordance with the provisions of this chapter.

1.6(4) *Premises standards.*

a. If deemed appropriate by the department, isolation or quarantine placards will be posted in accordance with Iowa Code chapter 139A.

b. An individual subject to isolation or quarantine shall obey the rules and orders of the department or the local board of health and shall not go beyond the isolation or quarantine premises unless expressly authorized to do so by the order.

c. The department or a local board of health may authorize physicians, health care workers, or others access to individuals in isolation or quarantine as necessary to meet the needs of isolated or quarantined individuals.

d. No individual, other than an individual authorized by the department or a local board of health, will enter isolation or quarantine premises. If the department has requested the assistance of law enforcement in enforcing the isolation or quarantine, the department will provide law enforcement personnel with a list of individuals authorized to enter the isolation or quarantine premises.

e. Any individual entering an isolation or quarantine premises with or without authorization of the department or a local board of health may be isolated or quarantined pursuant to this rule.

1.6(5) *Isolation and quarantine by local boards of health.*

a. A local board of health may:

(1) Isolate individuals who are presumably or actually infected with a quarantinable disease;

(2) Quarantine individuals who have been exposed to a quarantinable disease;

(3) Establish and maintain places of isolation and quarantine; and

(4) Adopt emergency rules and issue orders as necessary to establish, maintain, and enforce isolation or quarantine.

b. Isolation and quarantine undertaken by a local board of health will be accomplished according to the rules and regulations of the local board of health so long as such rules are not inconsistent with this chapter.

1.6(6) *Isolation and quarantine by the department.*

a. Authority.

(1) The department may:

1. Isolate individuals or groups of individuals who are presumably or actually infected with a quarantinable disease; and

2. Quarantine individuals or groups of individuals who have been exposed to a quarantinable disease, including individuals who are unable or unwilling to undergo examination, testing, vaccination, or treatment, pursuant to Iowa Code chapter 135.144.

(2) The department may:

1. Establish and maintain places of isolation and quarantine; and

2. Adopt emergency rules and issue orders as necessary to establish, maintain, and enforce isolation or quarantine.

(3) Isolation and quarantine undertaken by the department, including isolation and quarantine undertaken by the department in the event of a public health disaster, will be established pursuant to paragraph 1.6(6)*"b"* or *"c."*

b. Temporary isolation and quarantine without notice. The department may temporarily isolate or quarantine an individual or groups of individuals through an oral order, without notice, only if delay in imposing the isolation or quarantine would significantly jeopardize the department's ability to prevent or limit the transmission of a communicable or possibly communicable disease to others. If the department imposes temporary isolation or quarantine of an individual or groups of individuals through an oral order, the department will issue a written order as soon as is reasonably possible and in all cases within 24 hours of issuance of the oral order if continued isolation or quarantine is necessary to prevent or limit the transmission of a communicable or possibly communicable disease.

c. Written order. The department may isolate or quarantine an individual or groups of individuals through a written order issued pursuant to this rule.

(1) The written order will include all of the following:

1. The identity of the individual, individuals, or groups of individuals subject to isolation or quarantine.

2. The premises subject to isolation or quarantine.

3. The date at which isolation or quarantine commences.

4. The suspected communicable disease.

5. A description of the less restrictive alternatives that were attempted and were unsuccessful, or the less restrictive alternatives that were considered and rejected, and the reasons such alternatives were rejected.

6. A statement of compliance with the conditions and principles for isolation and quarantine specified

in subrule 1.9(3).

7. The legal authority under which the order is requested.

8. The medical basis upon which isolation or quarantine is justified.

9. A statement advising the individual, individuals, or groups of individuals of the right to appeal the written order and the rights of individuals and groups of individuals subject to quarantine and isolation.

(2) A copy of the written order will be provided to the individual to be isolated or quarantined within 24 hours of issuance of the order in accordance with any applicable process authorized by the Iowa Rules of Civil Procedure. If the order applies to a group or groups of individuals and it is impractical to provide individual copies, the order may be posted in a conspicuous place in the isolation or quarantine premises.

1.6(7) *Appeal from order imposing isolation or quarantine.* Individuals have the right to appeal an order imposing isolation or quarantine. Appeal procedures are as laid forth in 441—Chapter 7.

8)

a. Jurisdictional issues. The department has primary jurisdiction to isolate or quarantine individuals or groups of individuals if the communicable disease outbreak has affected more than one county or has multicounty, statewide, or interstate public health implications. When imposing isolation or quarantine, the department will coordinate with the local health department as appropriate. If isolation or quarantine is imposed by the department, a local board of health or local health department may not alter, amend, modify, or rescind the isolation or quarantine order.

b. Assistance of local boards of health and local health departments. If isolation or quarantine is imposed by the department, the local boards of health and the local health departments in the affected areas will assist in the implementation of the isolation or quarantine order.

Pursuant to Iowa Code chapter

d. Penalty. Violation of a lawful isolation or quarantine order will be subject to penalties pursuant to Iowa Code chapter 135.

e. Enforcement action. The department may file a civil action in Polk County district court or in the district court for the county in which the individual resides or is located to enforce a department order for isolation or quarantine. Such action will be filed in accordance with the Iowa Rules of Civil Procedure.

7(135,139A) Area quarantine.

7(1)

7(2)

a. Area quarantine will be imposed by the least restrictive means necessary to prevent or contain the spread of a suspected or confirmed quarantinable disease or suspected or known hazardous or toxic agent.

b. Area quarantine will be immediately terminated when the department or a local board of health determines that no substantial risk of exposure to a quarantinable disease or hazardous or toxic agent continues to exist.

c. The geographic boundaries of an area quarantine will be established by risk assessment procedures including medical and scientific analysis of the quarantinable disease or hazardous or toxic agent, the location of the affected area, the risk of spread or contamination, and other relevant information.

7(3)

a. Sites of area quarantine will be prominently identified to restrict ingress to and egress from, to the extent practicable. The department or a local board of health may placard or otherwise identify the site, or may request the assistance of law enforcement in identifying the site.

b. No individual, other than an individual authorized by the department or a local board of health, will enter a building, structure, or other physical location subject to area quarantine. The department or a local board of health may authorize public health officials, environmental specialists, health care providers, or others access to an area quarantine site as necessary to conduct public health investigations, to decontaminate the site, or for other public health purposes. Notwithstanding any provision in this chapter to the contrary, law enforcement, fire service, and emergency medical service providers may enter an area quarantine site to provide emergency response services or to conduct emergency law enforcement investigations or other emergency activities without authorization by the department or a local board of health. If the department has

requested the assistance of law enforcement in enforcing the area quarantine, the department will provide law enforcement personnel with a list of individuals authorized to enter the area quarantine site.

c. An individual authorized to enter an area quarantine site may be required to wear personal protective equipment as appropriate.

d. No individual, other than an individual authorized by the department or a local board of health, will remove any item or object from a building, structure, or other physical location subject to area quarantine.

e. An individual entering an area quarantine site without the department's or local board of public health's authorization may be isolated or quarantined and may be found guilty of a simple misdemeanor.

department

a. Authority.

(1) The department, through the director, the department's medical director, or the director or medical director's designee, may impose area quarantine through oral or written order. Prior to imposing area quarantine, the department will attempt to notify the local board or boards of health in the affected geographic area. If attempts to notify the local boards of health are initially unsuccessful, the department will continue to make regular notification attempts until successful.

(2) A local board of health may impose area quarantine through oral or written order. Prior to imposing area quarantine, a local board of health will attempt to notify the department by contacting the director, medical director, or department duty officer by telephone. If attempts to notify the department are initially unsuccessful, the local board of health will continue to make regular notification attempts until successful.

b. Temporary area quarantine without notice. The department or a local board of health may temporarily impose area quarantine through an oral order, without notice, only if delay in imposing area quarantine would significantly jeopardize the department's or local board's ability to prevent or contain the spread of a suspected or confirmed quarantinable disease or to prevent or contain exposure to a suspected or known hazardous or toxic agent. If the department or local board imposes temporary area quarantine through an oral order, a written order will be issued as soon as is reasonably possible and in all cases within 24 hours of issuance of the oral order if continued area quarantine is necessary.

c. Written order. The department or local board may impose area quarantine through a written order issued pursuant to this rule.

(1) The written order will include all of the following:

1. The building or buildings, structure or structures, or other definable physical location, or portion thereof, subject to area quarantine.

2. The date the area quarantine commences and the date a the area quarantine will be terminated, if known.

3. The suspected or confirmed quarantinable disease or the chemical, biological, radioactive, or other hazardous or toxic agent.

4. A statement of compliance with the conditions and principles for area quarantine specified in subrule 1.13(2).

5. The legal authority under which the order is imposed.

6. The medical or scientific basis upon which area quarantine is justified.

7. A statement advising the owner or owners of the building or buildings, structure or structures, or other definable physical location subject to area quarantine of the right to appeal the written order and the rights of owners of sites subject to area quarantine.

(2) A copy of the written order will be provided to the owner or owners of the building or buildings, structure or structures, or other definable physical location subject to area quarantine within 24 hours of issuance of the order in accordance with any applicable process authorized by the Iowa Rules of Civil Procedure; or, if the order applies to a group of owners and it is impractical to provide individual notice to each owner, the written order will be posted in a conspicuous place at the site of area quarantine.

1.7(5) *Implementation and enforcement of area quarantine.*

a. Jurisdictional issues. The department has primary jurisdiction to impose area quarantine if the quarantinable disease or hazardous or toxic agent has affected more than one county and implicates multicounty or statewide public health concerns. If area quarantine is imposed by the department, a local

board of health or local health department may not alter, amend, modify, or rescind the area quarantine order.

b. Assistance of local boards of health and local health departments. If area quarantine is imposed by the department, the local boards of health and the local health departments in the affected areas will assist in the implementation of the area quarantine.

Pursuant to Iowa Code chapter

d. Emergency response, investigation, and decontamination—authority of other agencies. Emergency response, investigation, and decontamination activities in and around an area quarantine site will be conducted by law enforcement, fire service, emergency medical service providers, or other appropriate federal, state, or local officials in accordance with federal and state law and accepted procedures and protocols for emergency response, investigation, and decontamination. This rule is not to be construed to limit the authority of law enforcement, fire service, emergency medical service providers, or other federal, state, or local officials to conduct emergency response, investigation, or decontamination activities to the extent authorized by federal and state law and accepted procedures and protocols.

e. Penalty. Violation of this section will result in penalty pursuant to Iowa Code chapter 135.

f. Enforcement action. To enforce a department order for quarantine, the department may file a civil action in Polk County District Court or in the district court for the county in which the area quarantine will be enforced. Such action will be filed in accordance with the Iowa Rules of Civil Procedure.

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STATE HYGIENIC LABORATORY

9(135,139A)

APPENDIX A
Iowa Department of Health and Human Services
Table of Reportable Communicable and Infectious Diseases

Report cases of the diseases listed in the following table to the department within the time frame specified in the When to Report column and by the reporting method in the How to Report column.

To report diseases immediately, use the 24/7 disease reporting telephone hotline: 1-800-362- 2736.

IMMEDIATELY report diseases, syndromes, poisonings and conditions of any kind suspected or caused by a biological, chemical, or radiological agent or toxin when there is reasonable suspicion that the disease, syndrome, poisoning or condition may be the result of a deliberate act such as terrorism.

IMMEDIATELY report to the department outbreaks of any kind, diseases that occur in unusual numbers or circumstances, unusual syndromes, or uncommon diseases. Outbreaks may be infectious, environmental or occupational in origin and include food-borne outbreaks or illness secondary to chemical exposure (e.g., pesticides, anhydrous ammonia).

Regulatory Analysis Template

Report diseases by:
Entering into the Iowa Disease Surveillance System (IDSS): For IDSS-related questions, call the Center for Acute Disease Epidemiology (CADE) at 1-800-362-2736.

Fax: (515)281-5698

Mail:
Iowa Department of Health and Human Services
Center for Acute Disease Epidemiology
Lucas State Office Building
321 E. 12th Street
Des Moines, Iowa 50319

Isolates or specimens shall be sent to:
State Hygienic Laboratory at the University of Iowa (SHL) U of I Research Park
2490 Crosspark Road
Coralville, Iowa 52241-4721

For specimen submission questions, call (319)335-4500 or go to http://www.shl.uiowa.edu.

Diseases	When to Report	How to Report
Acquired immune deficiency syndrome (AIDS) and AIDS-defining conditions	7 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Phone (515)242-5141 or (515)281-6918 Mail ∉ Health care providers: use the Pediatric or Adult Confidential Case Report Form ∉ Laboratories: send copy of lab report or the Iowa Confidential Report of Sexually Transmitted Disease & HIV Infection. Mark envelope "Attention 03" **For HIV/AIDS-related questions, call (515)242-5141**
Anthrax	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Botulism (including infant botulism)	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Brucellosis (Brucella)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Campylobacteriosis (Campylobacter)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Chlamydia	3 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Secure electronic data system (as determined by the Department) Fax (515)725-1278 Phone (515)281-3031 Mail ∉ Use the Iowa Confidential Report of Sexually Transmitted Disease

		∉ Mark envelope “Attention 00”
Cholera	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Cryptosporidiosis	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Cyclospora	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Diphtheria	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Escherichia coli shiga toxin-producing and related diseases (includes HUS and TTP)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail Laboratories send isolate or specimen to the SHL
Giardiasis (Giardia)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Gonorrhea	3 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Secure electronic data system (as determined by the Department) Fax (515)725-1278 Phone (515)281-3031 Mail ∉ Use the Iowa Confidential Report of Sexually Transmitted Disease ∉ Mark envelope “Attention 00”
Haemophilus influenzae type B invasive disease	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736 Laboratories send isolate or specimen to the SHL
Hansen’s disease (leprosy)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Hantavirus syndromes	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Hepatitis A	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax
Hepatitis B, C, D, E	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Human immunodeficiency virus (HIV) cases Death of a person with HIV Perinatally exposed newborn and child (newborn and child who was born to an HIV-infected mother)	7 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Phone (515)242-5141 or (515)281-6918 Mail ∉ Health care providers: use the Pediatric or Adult Confidential Case Report Form ∉ Laboratories: send copy of lab report or the Iowa Confidential Report of Sexually Transmitted Disease & HIV Infection. Mark envelope “Attention 03”

		For HIV/AIDS-related questions, call (515)242-5141
Legionellosis (Legionella)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Listeria monocytogenes invasive disease	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS, or fax Laboratories send isolate or specimen to the SHL
Malaria	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Measles (rubeola)	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Meningococcal invasive disease	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736 Laboratories send isolate or specimen to the SHL
Mosquito-borne diseases (includes chikungunya, dengue, eastern equine encephalitis, La Crosse, St. Louis, Venezuelan equine encephalitis, West Nile, and western equine encephalitis)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Mumps	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Pertussis	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Plague	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Poliomyelitis	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Psittacosis	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Q fever	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Rabies, animal	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Rabies, human	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Rubella (including congenital)	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS, or fax
Salmonellosis (Salmonella)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail Laboratories send isolate or specimen to the SHL

Severe acute respiratory syndrome (SARS)	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Shigellosis (Shigella)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail Laboratories send isolate or specimen to the SHL
Smallpox	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Syphilis	3 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Report by one of the following methods: Secure electronic data system (as determined by the Department) Fax (515)725-1278 Phone (515)281-3031 Mail ∉ Use the Iowa Confidential Report of Sexually Transmitted Disease ∉ Mark envelope "Attention 00"
Tetanus	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Tickborne diseases (includes anaplasmosis,babesiosis, ehrlichiosis, Lyme disease, and Rocky Mountain spotted fever)	3 days	Report for Iowa residents. Phone, IDSS, fax or mail
Tuberculosis, pulmonary and laryngeal (infectious)	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone (515)281-7504 or fax to (515)281-4570
Tuberculosis, extrapulmonary	3 days	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone (515)281-7504 or fax to (515)281-4570
Tularemia	3 days	Report for Iowa residents. Phone, IDSS or fax
Typhoid fever	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax
Vancomycin intermediate Staphylococcus aureus (VISA) and vancomycin-resistant Staphylococcus aureus (VRSA)	1 day	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. Phone, IDSS or fax Laboratories send isolate or specimen to the SHL
Viral hemorrhagic fever (VHF) (e.g., Lassa, Marburg, Ebola, and Crimean-Congo)	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736
Yellow fever	**Immediately**	Report for Iowa residents and for residents of other states diagnosed or treated in Iowa. 24/7 disease reporting telephone hotline: 1-800-362-2736

APPENDIX B
Iowa Department of Health and Human Services

Regulatory Analysis Template

Table of Reportable Poisonings and Conditions

Report cases of the poisonings and conditions listed in the following table to the department within the time frame specified in the When to Report column and by the reporting method in the How to Report column.

To report diseases immediately, use the 24/7 disease reporting telephone hotline: 1-800-362-2736.

IMMEDIATELY report diseases, syndromes, poisonings and conditions of any kind suspected or caused by a biological, chemical, or radiological agent or toxin when there is reasonable suspicion that the disease, syndrome, poisoning or condition may be the result of a deliberate act such as terrorism.

IMMEDIATELY report to the department outbreaks of any kind, diseases that occur in unusual numbers or circumstances, unusual syndromes, or uncommon diseases. Outbreaks may be infectious, environmental or occupational in origin and include food-borne outbreaks or illness secondary to chemical exposure (e.g., pesticides, anhydrous ammonia).

Mailing address:
Bureau of Environmental Health Services
Iowa Department of Health and Human Services
321 East 12th Street
Des Moines, Iowa 50319-0075 Telephone:
1-800-972-2026
Fax: (515)281-4529

Poisoning or Condition	Cases to Report	When to Report	How to Report
Arsenic poisoning	Blood arsenic values equal to or greater than 70 µg/L Urine arsenic values equal to or greater than 100 µg/g of creatinine	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Blood lead testing	All analytical results greater than or equal to 20 micrograms per deciliter (µg/dL) in a child under the age of 6 years or a pregnant woman	Daily	By telephone: 1-800-972-2026
	All other analytical values for all blood lead analyses	Weekly	Electronic format specified by the department
Cadmium poisoning	Blood cadmium values equal to or greater than 5 µg/L Urine cadmium values equal to or greater than 3 µg/g of creatinine	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Carbon monoxide (CO) poisoning	Blood carbon monoxide level equal to or greater than 10% carboxyhemoglobin or its equivalent with a breath	Daily	By telephone: 1-800-972-2026

	analyzer test, or a clinical diagnosis of CO poisoning regardless of any test results		
Hypersensitivity pneumonitis	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Mercury poisoning	Blood mercury values equal to or greater than 2.8 µg/dL Urine mercury values equal to or greater than 20 µg/L	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Methemoglobinemia	Blood analyses showing greater than 5% of total hemoglobin present as methemoglobin	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Microcystin toxin poisoning	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Noncommunicable respiratory illness	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Occupationally related asthma, bronchitis or respiratory hypersensitivity reaction	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Pesticide poisoning (including pesticide-related contact dermatitis)	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.
Severe skin disorder	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.

	Toxic hepatitis	All cases	Weekly	Format specified by department. Electronic reporting if available. Alternatives include by mail, telephone, and facsimile.	

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** IAC Chapter 641-2

Iowa Code Section Authorizing Rule 135.19

State or Federal Law(s) Implemented by the Rule NA

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location:https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter defines parameters of a viral hepatitis program. This program is designed to identify people most at risk of exposure to viral hepatitis and to distribute information regarding dangers presented by the disease and to make available hepatitis A and hepatitis B vaccinations and hepatitis C testing.

Rule language defines a list of individuals by category who are at increased risk for viral hepatitis exposure and details the nature of educational information to be provided to such individuals, as well as the form and manner of information distribution. A vaccination and testing program is established offering testing through local health departments, clinics, and community-based organizations to individuals most impacted by the viruses. Agencies offering testing and vaccination services are also to provide education materials, pretest and post test counseling, and referral services.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

NA

    - Classes of persons that will benefit from the proposed rule:

Individuals at increased risk for exposure to viral hepatitis.
Communities in which individuals at increased risk of exposure to viral hepatitis live.

Regulatory Analysis Template

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Estimated figures below are projections based on past program performance as included in the Red Tape Rule Report for this chapter.

Identified Impacts*

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5 Year Total
Costs HHS Implementation	($129,000)	($130,000)	($128,000)	($128,000)	($127,000)	($642,000)
Benefits Improved Public Health & Safety	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	Indeterminate	Indeterminate	Indeterminate	Indeterminate	Indeterminate	Indeterminate

*All monetary figures have been rounded to the nearest thousandth.

    - Qualitative description of impact:

Providing access to vaccination and testing for individuals most at risk of exposure to viral hepatitis prevents further spreading of the virus, thus protecting public health and safety. Testing individuals increases the number of people at increased risk of exposure who are aware of their HCV status. This allows for individuals living with HCV to be linked to treatment earlier preventing costly medical conditions including cirrhosis and hepatocellular carcinoma. In 2022, contracted agencies conducted 1,026 HCV tests and identified 47 people living with HCV. This represented 6.9% of all new diagnoses in Iowa in 2022 (compared to 4.3% in 2021 and 4.1 over the 5-year period).

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs costs for personnel, test kits, vaccine, and processing of laboratory tests at the State Hygienic Laboratory. Testing and vaccination is provided through contracted services. These costs are reflected in the table above as "HHS Implementation."

    - Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a net value of improved public health and safety. Eliminating the viral hepatitis program, or components thereof, would result in a decrease in available education, testing, vaccination, and treatment of the virus. This may result in increased community spread and a negative impact on public health and safety.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

Tests and vaccine are offered to Iowans at no cost on a voluntary basis. Local public health and community-based organizations are reimbursed for their time and effort. This rule chapter defines those at increased risk of exposure to viral hepatitis as outlined by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. HHS has established parameters for education, testing, and vaccination at the level the Department feels necessary to protect public health and safety. A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS implements the viral hepatitis program in accordance to requirements of Iowa Code. The Department has flexibility in setting parameters for educational information to be provided to individuals at risk of exposure, as well as the form and manner of information distribution. The department also has some flexibility in establishing testing and vaccination parameters for local health departments, clinics, and community-based organizations conducting testing under the program.

- Reasons why they were rejected in favor of the proposed rule:

HHS believes the parameters established in this rule chapter for education, testing, and vaccination are at a level necessary to protect public health and safety.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

NA

Text of Proposed Rule:

Regulatory Analysis Template

CHAPTER 2
HEPATITIS PROGRAMS

VIRAL HEPATITIS PROGRAM—VACCINATIONS AND TESTING

641—2.1(135) Definitions. For the purpose of these rules, the following definitions shall apply:

"Contracted agencies" means local health departments, clinics, and community-based organizations that are funded by the department to provide HCV testing and vaccination services.

"HCV" means the hepatitis C virus as defined by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

"HIV" means the same as defined in Iowa Code section 141A.1.

"Viral hepatitis" means inflammation of the liver caused by one of several viruses: hepatitis A, B, C, D, and E.

641—2.2(135) Exposure risks for hepatitis C virus. The following individuals are at increased risk of exposure to HCV as described by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services:

a. People living with HIV;

b. People who have ever injected drugs;

c. People with selected medical conditions, including those who ever received maintenance hemodialysis;

d Recipients of clotting factors made before 1987;

e. Recipients of blood transfusions, blood products, and organ transplants that occurred before 1992;

f. Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV positive-blood; and

g. Infants born to mothers living with HCV.

641—2.3(135) Information for public distribution. The department will make available educational materials to the public on hepatitis C infection, transmission, and where to seek testing services as defined on the department website.

641—2.4(135) Hepatitis vaccination and testing program.

2.4(1) When sufficient state and federal funds are available, the department will maintain a vaccination and testing program. The program shall offer HCV testing and hepatitis A and B vaccinations through local health departments, clinics, and community-based organizations to individuals at an increased risk of exposure to viral hepatitis as described in the Viral Hepatitis Prevention and Testing Services Manual dated December 2023 and available on the department website. Contracted agencies offering testing and vaccination services shall be required to provide integrated HIV, viral hepatitis, and sexually transmitted infection education; pretest and post-test counseling; and referral services.

2.4(2) Contracted agencies shall provide individuals presenting for testing and/or vaccination services with education explaining viral hepatitis and how to reduce the risk of acquiring it.

2.4(3) Contracted agencies shall provide individuals testing positive for viral hepatitis with information about the diagnosis and treatment options and with a referral list of health care providers to aid in seeking treatment, additional follow-up testing, and other hepatitis-related services.

These rules are intended to implement Iowa Code section 135.19.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 641-7

Iowa Code section Section Authorizing Rule 139A.8, 139A.26, 22.7

State or Federal Law(s) Implemented by the Rule NA

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023 at 10 am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter describes immunization requirements for all persons enrolled or attempting to enroll in a licensed child care center or a public or nonpublic elementary or secondary school in Iowa including those who are provided private instruction. Required immunizations listed in the rule are those defined by Iowa Code section or approved by the Council on Health and Human Services.

The rule chapter defines procedure for members of the public to comply with immunization requirements, including how to:

- Request an individual exclusion for medical or religious reasons.
- Provide required education on meningococcal disease to students of institutions of higher education with on campus residence hall or dormitory.
- Provide proof of immunization the school or licensed child care center in which the applicant wishes to enroll.
- Maintain records and complete reporting duties as an admitting official of a licensed child care center or elementary or secondary school.

Regulatory Analysis Template

The department maintains a statewide immunization and health screening registry to allow enrolled users to maintain and access to immunization and health screening histories for purposes of ensuring that patients are fully immunized and screened.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

Parents with children receiving required immunizations or their health insurance provider.
Adults receiving required immunizations or their health insurance provider.

    - Classes of persons that will benefit from the proposed rule:

Licensed child care centers, public or nonpublic elementary or secondary schools, and private education providers serving immunized students.
Communities in which immunized persons reside.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Estimated figures below are projections based on past program performance as included in the Red Tape Rule Report for this chapter.

Identified Impacts*

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5 Year Total
Costs HHS Implementation Required Immunizations	$5,146,000	$5,246,000	$5,346,000	$5,446,000	$5,546,000	$26,130,000
Benefits Improved Public Health and Safety	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	$5,146,000	$5,246,000	$5,346,000	$5,446,000	$5,546,000	$26,130,000

*All monetary figures have been rounded to the nearest thousandth.

    - Qualitative description of impact:

Child care and school immunization requirements play an important role in increasing immunization rates and ensuring environments where children congregate are safe. Vaccines are the best defense against infectious diseases, which may have serious complications such as pneumonia, meningitis and even death. Achieving and maintaining high immunization rates is the best way to protect all children from vaccine-preventable diseases while at the child care and school setting. The CDC estimates that vaccination of children born between 1994 and 2021 will prevent 472 million illnesses, 1,052,000 deaths, and save nearly $2.2 trillion in societal costs. For every $1 spent on each of the 11 vaccines given routinely to children, there is a savings of $10.10 in medical costs by averting costs to treat diseases.

Rules also allow for the creation of an Immunization Registry. Immunization Information Systems (IIS) benefit healthcare providers and the public by storing patient records from all ages and to

keep patients on schedule for recommended immunizations, documenting vaccine contraindications and reactions, validating immunization history, providing vaccine recommendations, producing patient reminder and recall notices, and managing healthcare provider vaccine inventory.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs to support the procedures described in this rule chapter. These costs are reflected in the table above as "HHS Implementation".

    - Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a net value of $26,130,000 and improved public health and safety. Eliminating the immunization tracking and reporting mechanisms required in rule, or significantly decreasing the number and/or types of immunizations required, may significantly lower immunization rates. Lowered immunization rates may lead to increased incidence of vaccine-preventable disease resulting in hospitalizations and deaths. This would also impact the ability of public health agencies and healthcare providers to serve Iowans with or exposed to vaccine-preventable diseases.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

Required immunizations listed in the rule are those defined by Iowa Code section or approved by the Council on Health and Human Services. HHS has established parameters for immunization tracking and reporting at a level the Department feels necessary to protect public health and safety. A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS supports those immunization required in accordance with Iowa Code section, or as approved by the Council on Health and Human Services. This rule chapter clarifies procedure but does not ascribe department duties or implementation elements in addition to those directly defined in Code.

    - Reasons why they were rejected in favor of the proposed rule:

NA

Regulatory Analysis Template

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

NA

Text of Proposed Rule:

Regulatory Analysis Template

CHAPTER 7
IMMUNIZATION AND IMMUNIZATION EDUCATION: PERSONS ATTENDING ELEMENTARY OR SECONDARY SCHOOLS, LICENSED CHILD CARE CENTERS OR INSTITUTIONS OF HIGHER EDUCATION
[Prior to 7/29/87, Health Department[470]]

641—7.1(139A) Definitions.

"Admitting official" means the superintendent of schools or the superintendent's designated representative if a public school; if a nonpublic school or licensed child care center, the governing official of the school or child care center.

"Advanced registered nurse practitioner" or *"ARNP"* means an advanced registered nurse practitioner as defined in 655—Chapter 7.

"Applicant" means any person seeking enrollment in a licensed child care center or elementary or secondary school.

"Certified medical assistant" means a person who is certified to practice as a certified medical assistant following completion of a postsecondary medical assistant program accredited by the Commission on Accreditation of Allied Health Education Programs or the Accrediting Bureau of Health Education Schools and successful completion of the certification examination and who is directed by a supervising physician, physician assistant, or nurse practitioner.

"Competent private instruction" is as defined in Iowa Code section 299A.1.

"Elementary school" means kindergarten if provided, and grades one through eight or grades one through six when grades seven and eight are included in a secondary school.

"Enrolled user" means a user of the registry who has completed an enrollment form that specifies the conditions under which the registry can be accessed and who has been issued an identification code and password by the department.

"Health screening" means a vision screen, dental screen, or refugee health screen.

"Immunization registry" or *"registry*" means the Department of Health and Human Services's database of confidential, population-based, immunization and health screening records.

"Institution of higher education" means a postsecondary school.

"Nurse" means a person licensed to practice as a nurse pursuant to Iowa Code chapter 152.

"On-campus residence hall or dormitory" means campus housing for students that is owned or leased by the institution of higher education and located on a recognized campus site.

"Pharmacist" means a person licensed to practice pharmacy pursuant to Iowa Code chapter 155A.

"Physician" means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to Iowa Code chapter 148.

"Physician assistant" means a person licensed to practice as a physician assistant pursuant to Iowa Code chapter 148C.

"Postsecondary school" means a postsecondary institution under the control of the state board of regents, a community college established under C, or an accredited private institution as defined in Iowa Code section 261.9.

"Postsecondary student" means a person who has officially registered with a postsecondary school, as determined by the school, and who physically attends class on the school's campus. For purposes of these rules, "postsecondary student" does not include a person who is exclusively registered in a correspondence course or continuing education class or who attends class exclusively by means of distance learning or through other means which do not require the person's physical presence on the school's campus.

"Screening provider" means an ophthalmologist, optometrist, physician, free clinic, child care center, local public health department, public or accredited nonpublic school, community-based organization, advanced registered nurse practitioner (ARNP), physician assistant, dentist or dental hygienist.

"Secondary school" means:

1. A junior high school comprising grades 7, 8 and 9, and a senior high school;
2. A combined junior-senior high school comprising grades 7 through 12;

3. A junior high school comprising grades 7 and 8 and a high school comprising grades 9 through12;
4. A high school comprising grades 9 through 12.

"Signature" means an original signature or the authorized use of a stamped signature or electronic signature.

"Student" means an individual who is enrolled in a licensed child care center, elementary school or secondary school.

641—7.2(139A) Persons included. The immunization requirements specified elsewhere in these rules apply to all persons enrolled or attempting to enroll in a licensed child care center or a public or nonpublic elementary or secondary school in Iowa including those who are provided competent private instruction.

641—7.3(139A) Persons excluded. Exclusions to these rules are permitted on an individual basis for medical and religious reasons pursuant to Iowa Code section 139A.8. Applicants approved for medical or religious exemptions shall submit to the admitting official a valid department certificate of immunization exemption.

7.3(1) To be valid, a medical certificate of immunization exemption shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) exempted, and an expiration date (if applicable) and shall bear the signature of a physician, nurse practitioner, or physician assistant. Language included on the medical certificate of immunization exemption referencing 641—7.3(139A) cannot be altered. Any edits or alterations to the medical certificate of immunization exemption referencing 641—7.3(139A) will invalidate the certificate.

a. A medical exemption may apply to a specific vaccine(s) or all required vaccines. If, in the opinion of the physician, nurse practitioner, or physician assistant issuing the medical exemption, the exemption should be terminated or reviewed at a future date, an expiration date shall be recorded on the certificate of immunization exemption; or

b. A medical exemption may apply when the administration of the required vaccine would violate minimum interval spacing and the exemption shall apply only to an applicant who has not received prior doses of the exempted vaccine. An expiration date, not to exceed 60 calendar days, and the name of the vaccine exempted shall be recorded on the medical certificate of exemption.

7.3(2) A religious exemption may be granted to an applicant if immunization conflicts with a genuine and sincere religious belief. To be valid, a religious certificate of immunization exemption for religious reasons shall contain, at a minimum, the applicant's last name, first name, and date of birth and shall bear the signature of the applicant or, if the applicant is a minor, of the applicant's parent or guardian and shall attest that immunization conflicts with a genuine and sincere religious belief and that the belief is in fact religious and not based merely on philosophical, scientific, moral, personal, or medical opposition to immunizations. Language included on the religious certificate of immunization exemption referencing 641—7.3(139A) cannot be altered. Any edits or alterations to the religious certificate of immunization exemption referencing 641—7.3(139A) will invalidate the certificate.

7.3(3) Medical and religious exemptions do not apply in times of emergency or epidemic pursuant to Iowa Code section 139A.8.

641—7.4(139A) Required immunizations.

7.4(1) Applicants enrolled or attempting to enroll shall have received the following vaccines in accordance with the doses and age requirements below:

Institution	Age	Vaccine	Total Doses Required
Licensed Child Care Center	Less than 4 months of age	This is not a recommended administration schedule, but contains the minimum requirements for participation in licensed child care. **Routine vaccination begins at 2 months of age.**	
		Diphtheria/Tetanus/Pertussis	1 dose

	4 months through 5 months of age	Polio[1]	1 dose
		haemophilus influenzae type B	1 dose
		Pneumococcal	1 dose
	6 months through 11 months of age	Diphtheria/Tetanus/Pertussis	2 doses
		Polio[1]	2 doses
		haemophilus influenzae type B	2 doses
		Pneumococcal	2 doses
	12 months through 18 months of age	Diphtheria/Tetanus/Pertussis	3 doses
		Polio[1]	2 doses
		haemophilus influenzae type B	2 doses; or 1 dose received at 15 months of age or older.
		Pneumococcal	3 doses; or 2 doses if both doses were received at 12 months of age or older.
	19 months through 23 months of age	Diphtheria/Tetanus/Pertussis	4 doses
		Polio[1]	3 doses
		haemophilus influenzae type B	3 doses if a dose was received on or after 12 months of age; or 2 doses if the first dose was received on or after 12 months of age; or 1 dose if the dose was received at 15 months of age or older.
		Pneumococcal	4 doses if a dose was received on or after 12 months of age; or 3 doses if 1 or more doses were received on or after 12 months of age; or 2 doses if both doses were received at 12 months of age or older.
		Measles/Rubella	1 dose; or the applicant demonstrates a positive antibody test for measles and rubella from a U.S. laboratory.
		Varicella	1 dose; or the applicant has a reliable history of natural disease.
	24 months of age and older	Diphtheria/Tetanus/Pertussis	4 doses
		Polio[1]	3 doses
		haemophilus influenzae type B	3 doses if a dose was received on or after 12 months of age; or 2 doses if the first dose was received on or after 12 months of age; or

			1 dose if the dose was received at 15 months of age or older. **Hib vaccine is not required for persons 60 months of age or older**.
		Pneumococcal	4 doses if a dose was received on or after 12 months of age; or 3 doses if 1 or more doses were received on or after 12 months of age; or 2 doses if the first dose was received on or after 12 months of age; or 1 dose if the dose was received on or after 24 months of age. Pneumococcal vaccine is not required for persons 60 months of age or older.
		Measles/Rubella	1 dose; or the applicant demonstrates a positive antibody test for measles and rubella from a U.S. laboratory.
		Varicella	1 dose; or the applicant has a reliable history of natural disease.
Elementary or Secondary School (K-12)	4 years of age and older	Diphtheria/Tetanus/ Pertussis [2]	5 doses with at least 1 dose received on or after 4 years of age; or 4 doses if the fourth dose was received on or after 4 years of age; and 1 dose of tetanus/diphtheria/acellular pertussis-containing vaccine (Tdap) received on or after 10 years of age for applicants in grades 7 and above, regardless of the interval since the last tetanus/diphtheria-containing vaccine.
		Polio[1]	4 doses, with at least 1 dose received on or after 4 years of age; or 3 doses if the third dose was received on or after 4 years of age.
		Measles/Rubella	2 doses; or the applicant demonstrates a positive

			antibody test for measles and rubella from a U.S. laboratory.
		Hepatitis B	3 doses
		Varicella	2 doses; or the applicant has a reliable history of natural disease.
		Meningococcal (A, C, W, Y)	1 dose received on or after 10 years of age for applicants in grades 7 through 11; and 2 doses with 1 dose received on or after 16 years of age for applicants in grade 12; or 1 dose for applicants in grade 12 if the dose was received on or after 16 years of age.

[1] Doses of oral polio vaccine (OPV) administered on or after April 1, 2016, are not valid doses and do not count toward the polio vaccine requirement.

[2] Applicants 7 through 18 years of age who received the first dose of diphtheria/tetanus/pertussis-containing vaccine at 12 months of age or older should receive a total of 3 doses, with one dose received on or after 4 years of age.

7.4(2) Vaccine doses administered less than or equal to 4 days before the minimum interval or age shall be counted as valid. Doses administered greater than or equal to 5 days earlier than the minimum interval or age shall not be counted as valid doses and shall be repeated as appropriate.

7.4(3) For vaccine administration, the minimum age and intervals recommended by the advisory committee on immunization practices shall be followed.

641—7.5(139A) Required education. An institution of higher education with an on-campus residence hall or dormitory shall provide vaccination information on meningococcal disease to enrolled students on a student health form pursuant to Iowa Code section 139A.26. For purposes of this rule, student health form(s) means a document(s) prepared by an institution of higher education that contains, at a minimum, information on meningococcal disease, vaccination information and any recommendations issued by the national Centers for Disease Control and Prevention regarding meningococcal disease. The student health form(s) shall also include space for the postsecondary student to indicate whether or not the postsecondary student has received vaccination against meningococcal disease, including, at a minimum, the date of vaccination. The student health form(s) shall also include space for the postsecondary student to indicate whether or not the postsecondary student has received information on meningococcal disease and benefits of vaccine. If a traditional student health form is not utilized by the institution of higher education, any document(s) containing the above information is acceptable.

641—7.6(139A) Proof of immunization.

7.6(1) A valid department certificate of immunization shall be submitted by the applicant or, if the applicant is a minor, by the applicant's parent or guardian to the admitting official of the school or licensed child care center in which the applicant wishes to enroll. To be valid, the certificate shall be the certificate of immunization issued by the department, a computer-generated copy from the immunization registry, or a certificate of immunization which has been approved in writing by the department. The certificate shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) administered, the date(s) given, and the signature of a physician, a physician assistant, a nurse, or a certified medical assistant. A faxed copy, photocopy, or electronic copy of the valid certificate is acceptable. The judgment of the adequacy of the applicant's immunization history should be based on records kept by the person signing the certificate of immunization or on that person's personal knowledge of the applicant's immunization

history, or comparable immunization records from another person or agency, or an international certificate of vaccination, or the applicant's personal health records. If personal health records are used to make the judgment, the records shall include the vaccine(s) administered and the date given. Persons validating the certificate of immunization are not held responsible for the accuracy of the information used to validate the certificate of immunization if the information is from sources other than their own records or personal knowledge.

7.6(2) Persons wishing to enroll who do not have a valid department certificate of immunization available to submit to the admitting official shall be referred to a physician, a physician assistant, a nurse, or a certified medical assistant to obtain a valid certificate.

641—7.7(139A) Provisional enrollment.

7.7(1) Applicants may be granted provisional enrollment pursuant to Iowa Code section 139A.8. A valid department provisional certificate of immunization shall be submitted by the applicant or, if the applicant is a minor, by the applicant's parent or guardian to the admitting official of the school or licensed child care center in which the applicant wishes to enroll. To qualify for provisional enrollment, applicants shall have received at least one dose of each of the required vaccines or be a transfer student from another school system. A transfer student is an applicant seeking enrollment from one United States elementary or secondary school into another. To be valid, the certificate shall be the certificate of immunization issued by the department, a computer-generated copy from the immunization registry, or a certificate of immunization which has been approved in writing by the department. The certificate shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) administered, the date(s) given, the remaining vaccine(s) required, the reason that the applicant qualifies for provisional enrollment, and the signature of a physician, a physician assistant, a nurse, or a certified medical assistant. Persons validating the provisional certificate of immunization are not held responsible for the accuracy of the information used to validate the provisional certificate of immunization if the information is from sources other than their own records or personal knowledge. Persons signing the provisional certificate of immunization shall certify that they have informed the applicant or, if the applicant is a minor, the applicant's parent or guardian of the provisional enrollment requirements.

a. Any applicant seeking provisional enrollment who does not have a valid department provisional certificate of immunization to submit to the admitting official shall be referred to a physician, a physician assistant, a nurse, or a certified medical assistant to obtain a valid certificate.

7.7(2) The amount of time allowed for provisional enrollment shall be as soon as medically feasible but shall not exceed 60 calendar days. The period of provisional enrollment shall begin on the date the provisional certificate is signed. The person signing the provisional certificate shall assign an expiration date to the certificate and shall indicate the remaining immunizations required to qualify for a certificate of immunization.

7.7(3) The applicant or parent or guardian shall ensure that the applicant receive the necessary immunizations during the provisional enrollment period and shall submit a certificate of immunization to the admitting official by the end of the provisional enrollment period.

7.7(4) If at the end of the provisional enrollment period the applicant or parent or guardian has not submitted a certificate of immunization, the admitting official shall immediately exclude the applicant from the benefits, activities, and opportunities of the school or licensed child care center until the applicant or parent or guardian submits a valid certificate of immunization.

7.7(5) If at the end of the provisional enrollment period the applicant has not completed the required immunizations due to minimum interval requirements, a new department provisional certificate of immunization shall be submitted to the admitting official. The admitting official must maintain all issued certificates of provisional immunization with the original provisional certificate until the applicant submits a certificate of immunization.

641—7.8(139A) Records and reporting.

7.8(1) It shall be the duty of the admitting official of a licensed child care center or elementary or secondary school to ensure that the admitting official has a valid department certificate of immunization,

certificate of immunization exemption, or provisional certificate of immunization on file for each student by the first day of attendance.

a. The admitting official shall keep the certificates on file in the school or licensed child care center in which the student is enrolled and assist the student or parent or guardian in the transfer of the certificate to another school or licensed child care center upon the transfer of the student to another school or licensed child care center.

b. Unless otherwise requested by the applicant, or parent or guardian, the admitting official shall retain the department certificate of immunization, or certificate of immunization exemption, or provisional certificate of immunization for three years commencing upon the transfer or graduation of the applicant or the school may choose to provide the permanent immunization record to the student at time of graduation. Included with the immunization record a letter should state that this is an important document that will be needed by the student for college or employment and should be permanently retained.

7.8(2) It shall be the duty of the local boards of health to audit the department certificates of immunization, certificates of immunization exemption, and provisional certificates of immunization in the schools within their jurisdiction to determine compliance with Iowa Code section 139A.8. The local boards of health shall furnish the department within 60 days of the first official day of school a report of the audit. The report shall be submitted for each school within the local board of health's jurisdiction and shall include the enrollment by grade, and the number of department certificates of immunization, certificates of immunization exemption, and provisional certificates of immunization by grade.

7.8(3) The local board of health and the department shall have the right to have access to the department certificates of immunization, certificates of immunization exemption, and the provisional certificates of immunization of children enrolled in elementary and secondary schools and licensed child care centers within the constraints of the privacy rights of parents and students.

7.8(4) The admitting official of an institution of higher education shall provide to the department by December 1 each year aggregate data regarding compliance with Iowa Code section 139A.26. The data shall be forwarded to the department within 30 days. The data shall include, but not be limited to, the total number of incoming postsecondary freshmen students living in a residence hall or dormitory who have:

a. Enrolled in the institution of higher education; and

b. Been provided information on meningococcal disease; and

c. Been immunized with meningococcal vaccine.

641—7.9(139A) Compliance. Applicants not presenting proper evidence of immunization, or exemption, are not entitled to enrollment in a licensed child care center or elementary or secondary school under the provisions of Iowa Code section 139A.8. It shall be the duty of the admitting official to deny enrollment to any applicant who does not submit proper evidence of immunization and to exclude a provisionally enrolled applicant in accordance with this rule chapter.

641—7.10(22) Statewide registry.

7.10(1) *Statewide registry.* The department shall maintain a statewide immunization and health screening registry.

7.10(2) *Purpose and permitted uses of registry.*

a. The registry shall contain immunization and health screening information, including identifying and demographic data, to allow enrolled users to maintain and access a database of immunization and health screening histories for purposes of ensuring patients are fully immunized and screened.

b. The registry may be used to track inventory or utilization of pharmaceutical agents identified by the department to prepare for or respond to an emergency event.

c. Enrolled users shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purpose other than those expressly provided in this rule.

d. The registry shall contain health screening data, including screening results and follow-up information.

7.10(3) *Release of information to the registry.* Enrolled users shall provide immunization and health

screening information, including identifying and demographic data, to the registry. Information provided may include, but is not limited to, the following:

a. Name of patient;
b. Gender of patient;
c. Date of birth;
d. Race;
e. Ethnicity;
f. Birth state and birth country;
g. Address;
h. Parents' names;
i. Mother's maiden name;
j. Type of vaccination administered;
k. Dose or series number of vaccine;
l. Date vaccination was administered;
m. Lot number;
n. Date of health screening;
o. Health screening results;
p. Source of health screening;
q. Health screening follow-up information;
r. Patient comments;
s. Provider name, license, and business address; and
t. Patient history, including previously unreported doses.

7.10(4) *Confidentiality of registry information.* Immunization and health screening information, including identifying and demographic data maintained in the registry, is confidential and may not be disclosed except under the following limited circumstances:

a. The department may release information from the registry to the following:

(1) The person or the parent or legal guardian of the person immunized or screened.

(2) Enrolled users of the registry who have completed a department enrollment form that specifies the conditions under which the registry can be accessed;

(3) Persons or entities requesting immunization or health screening data in an aggregate form that does not identify an individual either directly or indirectly.

(4) Agencies that complete an agreement with the department which specifies conditions for access to registry data and how that data will be used. Agencies shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purposes other than those expressly provided in this rule.

(5) A representative of a state or federal agency, or entity bound by that state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency is subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa. State or federal agencies shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purposes other than those expressly provided in this rule.

(6) The admitting official of a licensed child care center, elementary school, secondary school, or postsecondary school; or medical or health care providers providing continuity of care.

(7) Users from other states or jurisdictions who have signed and completed enrollment in the state's or jurisdiction's immunization registry.

b. Users shall not release data obtained from the registry except to the person or the parent or legal guardian of the person immunized or screened, admitting officials of licensed child care centers and schools, medical or health care providers providing continuity of care, and other enrolled users of the registry.

7.10(5) *Suspend or terminate access.* The department may suspend or terminate an enrolled user's access consistent with department policy if the user violates this chapter, department enrollment forms, or the IRIS Security and Confidentiality Policy. The department will approve, suspend, terminate, and reinstate user

access in accordance with this chapter and department policy.

641—7.11(22) Release of immunization and health screening information.

7.12(1) *Between a physician, physician assistant, nurse, certified medical assistant, pharmacist, or screening provider and the elementary, secondary, or postsecondary school or licensed child care center that the student attends.* A physician, a physician assistant, a nurse, a certified medical assistant, a pharmacist, or a screening provider shall disclose a student's or patient's immunization or health screening information, including the name, date of birth, and demographic information; vaccine(s) administered and the month, day and year of administration; health screening results; and clinic source and location, to an elementary, secondary, or postsecondary school or a licensed child care center upon written or verbal request from the elementary, secondary, or postsecondary school or licensed child care center. Written or verbal permission from a student or parent is not required to release this information to an elementary, secondary, or postsecondary school or licensed child care center that the student attends.

7.11(2) *Among physicians, physician assistants, nurses, certified medical assistants, pharmacists or screening providers.* Immunization or health screening information, including the student's or patient's name, date of birth, and demographic information; vaccine(s) administered and the month, day and year of administration; health screening results; and clinic source and location, shall be provided by a physician, physician assistant, nurse, certified medical assistant, pharmacist, or screening provider to another health care provider without written or verbal permission from the student, parent, guardian or patient.

7.11(3) *Among an elementary school, secondary school, postsecondary school, and licensed child care center that the student attends.* An elementary school, secondary school, postsecondary school, and licensed child care center shall disclose a student's immunization or health screening information, including the student's name, date of birth, and demographic information; vaccine(s) administered and the month, day and year of administration; health screening results; and clinic source and location, to another elementary school, secondary school, postsecondary school, and licensed child care center that the student attends. Written or verbal permission from a student, or if the student is a minor, the student's parent or guardian, is not required to release this information to an elementary school, secondary school, postsecondary school, and licensed child care center that the student attends.

7.11(4) *Among the department and a physician, physician assistant, nurse, certified medical assistant, pharmacist, screening provider, elementary school, secondary school, postsecondary school, and licensed child care center.* A student's or patient's immunization or health screening information, including name, date of birth, grade, and demographic information; vaccine(s) administered and the month, day and year of administration; and health screening results, clinic source, and location, all in a format specified by the department, shall be disclosed upon written or verbal request among the department, physicians, physician assistants, nurses, certified medical assistants, pharmacists, screening providers, elementary schools, secondary schools, postsecondary schools, and licensed child care centers. Written or verbal permission from a student, patient, parent, or guardian is not required to release this information.

7.12(5) *Among the department and physicians, physician assistants, nurses, resettlement agencies, federal, state, and local government agencies, and certified medical assistants conducting refugee health screenings.* Refugee health screenings shall be disclosed only as indicated in this rule. Immunization or health screening information, including the patient's name, date of birth, and demographic information; the vaccine(s) administered and the month, day, and year of administration; health screening results; and clinic source and location, shall be disclosed upon written or verbal request among the department, physicians, physician assistants, nurses, certified medical assistants, resettlement agencies, federal, state, and local government agencies, or screening providers to another health care provider or the department. Written or verbal permission from the parent, guardian or patient is not required to release this information.

These rules are intended to implement Iowa Code sections 139A.8, 139A.26 and 22.7(2).

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 641-11

Iowa Code Section Authorizing Rule 135, 139A, 141A, 915

State or Federal Law(s) Implemented by the Rule 141A.5(2)(c); 135.11(20); 135.11(22); 139A.33; 139A.19

Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter describes HHS procedures and programs related to the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS). This includes reporting of new diagnoses, protocols concerning individuals voluntarily seeking testing, procedures when a health care worker has an occupational exposure, reporting requirements should a positive test be confirmed, and notification and testing requirements when a third party is found to have been exposed.

These rules additionally implement HIV-related training programs and set procedures for eligibility and enrollment in the Ryan White Program. The Ryan White Program is federally designated program that supports eligible low-income Iowans living with HIV/AIDS with medical and support services, and assistance with the cost of medication and health insurance. Under federal legislation, it is the payer of last resort for HIV-related services. The Ryan White Program is not an entitlement program and does not create a right to assistance.

Regulatory Analysis Template

The procedures and programs described in this rule chapter are designed to provide appropriate individual and community-level protections related to an HIV/AIDS diagnosis. They also provide for access to health care services for people diagnosed and living with HIV/AIDS in Iowa.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

Individuals or private insurance companies paying for HIV/AIDS testing.
Employers paying for HIV/AIDS testing for an exposed employee.
The court when ordering testing of a sexual assault victim or convicted or alleged offender.
Employers providing training to employees concerning occupational exposure to blood or other potentially infectious materials.

    - Classes of persons that will benefit from the proposed rule:

Individuals that believe they have been exposed to HIV/AIDS.
Individuals found to have been exposed to HIV/AIDS through a positive confirmed test of a partner.
Pregnant women screened for HIV/AIDS through prenatal care.
Sexual assault victims that may have been exposed to HIV/AIDS.
Individuals diagnosed and living with HIV/AIDS.
Communities in which individuals living with HIV/AIDS or those at high risk of exposure live.
Employees that experience occupational exposure to blood or other potentially infectious materials.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Estimated figures below are projections based on past program performance as included in the Red Tape Rule Report for this chapter.

Identified Impacts*

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5 Year Total
Costs						
HHS Prev. and Surveillance	$1,826,753	$1,826,753	$1,826,753	$1,826,753	$1,826,753	$9,133,765
HIV/AIDS Testing	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
HIV/AIDS Related Training	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
HHS - Ryan White Program	$22,814,089	$22,814,089	$22,814,089	$22,814,089	$22,814,089	$114,070,445
Benefits						
Improved Public Health & Safety	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative

Net Value	Indeterminate	Indeterminate	Indeterminate	Indeterminate	Indeterminate	Indeterminate

*All monetary figures have been rounded to the nearest thousandth.

- Qualitative description of impact:

Providing access to education, testing, and health care services for individuals believed to have been exposed to HIV/AIDS prevents further spread of the virus, thus protecting public health and safety. Training programs where occupational exposure to blood or other potentially infections materials may occur further reduce transmission.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs costs for personnel, test kits, prevention supplies, data systems, and contracting with local public health. These costs are reflected in the table above as "HHS Prevention and Surveillance."

The Ryan White Program provides eligible low-income Iowans living with HIV/AIDS with medical and support services, and assistance with the cost of medication and health insurance. These costs are reflected in the table above as "HHS – Ryan White Program" Federal funds and 340B Drug Pricing Program rebates support the majority of these assistance dollars.

Additional state agencies are impacted by HIV/AIDS training and testing requirements. As these obligations are defined in Iowa Code, and not created in this rule chapter, any associated costs are not included on this analysis.

- Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a net value of improved public health and safety. HIV-related treatment and support is estimated at $20,000 to $50,000 annually for people with HIV. Eliminating the Department's HIV/AIDS programs, or components thereof, would result in a decrease in available education, testing, and treatment around the virus. This may result in increased community spread and a negative impact on public health and safety.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

Early intervention for HIV (diagnosis, treatment, social support) is a cost-effective public health intervention. HHS has established parameters for education, testing, and treatment at the level the Department feels necessary to protect public health and safety. A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS implements HIV/AIDS programs in accordance to requirements of Iowa Code and federal regulations. Early intervention for HIV has been found to be cost effective and reducing costs of more expensive inpatient costs for people with untreated HIV. The Ryan White Program saves the Iowa Medicaid enterprise from costly medical costs for participants with HIV.

    - Reasons why they were rejected in favor of the proposed rule:

NA

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:

Regulatory Analysis Template

CHAPTER 11
HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

641—11.1(139A,141A) Definitions.:

"AIDS" means the same as defined in Iowa Code section 141A.1.

"AIDS-related condition" means the same as defined in Iowa Code section 141A.1.

"Alleged offender" means the same as defined in Iowa Code section 915.40.

"Benefits and drug assistance program" or *"BDAP*" means the Iowa benefits and drug assistance program, a component of the Ryan White Program administered by the bureau of HIV, STI, and hepatitis within the department.

"Blood bank" means a facility for the collection, processing, or storage of human blood or blood derivatives, or from which or by means of which human blood or blood derivatives are distributed or otherwise made available.

"Blood-borne viral hepatitis" means hepatitis B or hepatitis C.

"Care provider" means the same as defined in Iowa Code section 139A.2.

"CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

"Certification of a significant exposure report" means the determination by an authorized infection preventionist, occupational health professional, or other personnel trained in infection control or infectious disease medicine and designated by a facility to review significant exposure reports that the incident described by the exposed care provider meets the definition of a significant exposure as defined in this rule.

"Confirmed positive test" means a reactive result or detectable quantity on any HIV-related test, including an antibody test, an antigen test, a culture, a nucleic acid amplification test, or other test or combination of tests, that is considered to be confirmatory according to prevailing medical technology and algorithms or guidance from CDC. When the confirmed positive test involves more than one test, all test results should be included in any reports to the department.

"Contagious or infectious disease" means hepatitis in any form, meningococcal disease as defined in these rules, AIDS or HIV as defined in section 141A.1, tuberculosis as defined in these rules, and any other disease determined to be life-threatening to a person exposed to the disease based upon a determination by the state epidemiologist or medical director and in accordance with guidelines of the centers for disease control and prevention of the United States department of health and human services..

"Department of corrections" means the Iowa department of corrections.

"Designated representative" means a person who is designated by a department, agency, division, or service organization to act on behalf of the exposed care provider as a liaison with the facility that received the source patient when the exposure occurred in the field or during patient transport.

"Director of a plasma center, blood bank, clinical laboratory, organ procurement organization, or public health laboratory" means the person responsible for direction and operation of the facility, the medical director, or the person designated by the director or medical director to ensure compliance with applicable regulations and requirements.

"Emergency medical services personnel" means "emergency medical care provider" as defined in 641—131.1(147A).

"Exposure" means the same as defined in Iowa Code section 139A.2.

"HBV" means hepatitis B virus.

"Health care facility" means the same as defined in Iowa Code section 139A.2.

"Health care provider" means the same as defined in Iowa Code section 141A.1.

"Health facility" means the same as defined in Iowa Code section 141A.1.

"HIV" means the same as defined in Iowa Code section 141A.1.

"HIV infection" means having acquired the human immunodeficiency virus.

"HIV-related test" means the same as defined in Iowa Code section 141A.1.

"Home health services" means health care services provided by a care provider in a patient's home or

other residence.

"Identifiable third party" means a sexual partner of or a person who shares drug injecting equipment with a person who has been diagnosed with HIV infection.

"Infectious bodily fluids" means bodily fluids capable of transmitting HIV as listed in "Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis," dated September 25, 2013, and updated May 23, 2018, published by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia 30333, on their website. To prevent HIV and blood-borne viral hepatitis disease transmission, this reference indicates that standard precautions should be followed for exposure to the following infectious bodily fluids: blood, amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, vaginal secretions, and saliva contaminated with blood. HIV and blood-borne viral hepatitis disease transmission has not occurred from feces, nasal secretions, sputum, sweat, tears, urine, vomitus, and saliva when it is not contaminated with blood.

"Laboratory" means a clinical or public health laboratory, a plasma center, or a blood bank inside or outside the boundaries of Iowa.

"Meningococcal disease" means acute infectious bacterial meningococcal infection presenting as invasive disease characterized by one or more clinical syndromes including bacteremia, sepsis, or meningitis. "Meningococcal disease" does not include nasopharyngeal colonization by *Neisseria meningitidis*.

"Payer of last resort" means a requirement to coordinate services and seek payment from all other sources before Ryan White funds are used.

"Physician" means a person currently licensed pursuant to Iowa Code chapter 148.

"Physician assistant" means a person currently licensed under Iowa Code chapter 148C.

"Plasma center" means a facility that conducts plasmapheresis.

"Plasmapheresis" means the removal of blood from a human being to obtain plasma with the subsequent reinfusion of the remaining formed elements into the donor, but excludes such a procedure performed for the purpose of improving the health of the donor.

"Public health laboratory" means a laboratory operated by an agency of city, county or state government for the purpose of supporting disease control activities.

"Respite care services" means health care services provided by a care provider in a patient's home or other residence on a short-term, temporary basis as relief to those who are caring for family members.

"Ryan White program" means the Ryan White part B program administered by the bureau of HIV, STI, and hepatitis within the department that provides case management, behavioral health, other supportive services, and assistance with the costs of housing, health insurance, and treatment medications for eligible low-income individuals diagnosed with HIV.

"Sexually transmitted disease or infection" means "sexually transmitted disease or infection" as defined in 641—1.1(139A).

"Significant exposure" means a situation in which there is a risk of contracting disease through exposure to a patient's infectious bodily fluids in a manner capable of transmitting an infectious agent as determined by CDC. Exposure includes contact with blood or other infectious bodily fluids to which standard precautions apply through percutaneous inoculation or contact with an open wound, nonintact skin, or mucous membranes during the performance of normal job duties. Significant exposures include:

1. Transmission of blood, bloody fluids, or other infectious bodily fluids of the source patient onto a mucous membrane (mouth, nose, or eyes) of the care provider.
2. Transmission of blood, bloody fluids, or other infectious bodily fluids of the source patient onto an open wound or lesion with significant breakdown in the skin barrier, including a needle puncture with a needle contaminated with blood, bloody fluids, or other infectious bodily fluids.

"Significant exposure report" means the Report of Exposure to HIV or Other Infectious Disease form provided by the department. This is the only form authorized to be used to document a significant exposure to infectious bodily fluids such that the source patient is deemed to consent to a test to determine if the patient has a contagious or infectious disease, and is deemed to consent to notification of the care provider of the results of the test, pursuant to Iowa Code section 139A.19.

"Tuberculosis" means infectious tuberculosis as defined in 641—1.1(139A).

641—11.2(141A) HIV testing—obtaining consent—voluntary HIV-related tests for adults who are not pregnant.

11.2(1) Prior to conducting a voluntary HIV-related test on an adult, the health care provider requesting the test shall provide information to the subject of the test concerning HIV testing and where to obtain additional information regarding HIV infection and risk reduction.

11.2(2) Patient consent for testing must be obtained as detailed in Iowa Code section 141A.6.

11.2(3) Once an adult has been informed of a confirmed positive HIV-related test, no HIV-specific consent for medical procedures and tests shall be required for subsequent medical procedures and tests involved in the care or treatment of the adult with HIV infection.

641—11.3(139A,141A) HIV testing—obtaining consent—voluntary HIV-related tests for minors who are not pregnant.

11.3(1) Patient consent for testing must be obtained as detailed in Iowa Code section 141A.6. A minor shall have the legal capacity to act and give consent pursuant to Iowa Code section 139A.35.

11.3(2) Prior to conducting a voluntary HIV-related test on a minor, the health care provider requesting the test shall provide information to the subject of the test concerning HIV testing and where to obtain additional information regarding HIV infection and risk reduction.

11.3(3) A minor shall be informed prior to testing of requirements for health facilities to inform the minor's legal guardian of a positive test result pursuant to Iowa Code section 141A.7.

11.3(4) Prior to the test, a minor shall give written consent for performance of the HIV-related test and to the notification of the legal guardian should the test be confirmed as positive.

11.3(5) Once a minor has been informed of a confirmed positive HIV-related test and the legal guardian has been notified, no HIV-specific consent for medical procedures and tests shall be required for subsequent medical procedures and tests involved in the care or treatment of a minor with HIV infection.

641—11.4(141A) HIV testing—obtaining consent—voluntary HIV-related tests for pregnant women.

11.4(1) Health care providers that offer prenatal care to women shall provide HIV testing to all pregnant women as described in Iowa Code section 141A.4. No written or oral consent shall be required.

11.4(2) The testing shall occur as early as possible during each pregnancy.

11.4(3) The health care provider requesting the test shall make information available about HIV prevention, risk reduction, and treatment to all pregnant women pursuant to Iowa Code section 141A.4.

11.4(4) A pregnant woman who is a minor shall be informed prior to testing of requirements for health facilities to inform the minor's legal guardian of a positive test result as described in Iowa Code section 141A.7.

11.4(5) If a pregnant woman declines the test, the decision shall be documented as described in Iowa Code section 141A.4. A health care provider shall encourage women who decline the test early in prenatal care to be tested at a subsequent visit.

11.4(6) Once a pregnant woman has been informed of a confirmed positive HIV-related test and, if the pregnant woman is a minor, the legal guardian has been notified, no HIV-specific consent for medical procedures and tests shall be required for subsequent medical procedures and tests involved in the care or treatment of a pregnant woman with HIV infection.

641—11.5(141A) HIV test results—post-test counseling.

11.5(1) Upon informing the subject of an HIV-related test of a confirmed positive test result, the health care provider who requested the test or other designated personnel shall initiate counseling concerning the emotional and physical health effects of HIV infection as described in Iowa Code section 141A.7.

641—11.6(141A) Reporting of diagnoses and HIV-related tests, events, and conditions to the department.

11.6(1) The following constitute reportable events related to HIV infection:

a. A test result indicating HIV infection, including:

(1) Confirmed positive results on any HIV-related test or combination of tests, including antibody tests, antigen tests, cultures, and nucleic acid amplification tests.

(2) A positive result or report of a detectable quantity on any other HIV detection (non-antibody) tests, and results of all viral loads, including nondetectable levels.

(3) Results of genotypic resistance assays.

b. AIDS and AIDS-related conditions, including all levels of CD4+ T-lymphocyte counts.

c. Birth of an infant to an HIV-infected mother (perinatal exposure) or any (positive, negative, or undetectable) non-antibody detection test (antigen test, viral culture, viral load, or qualitative nucleic acid amplification test) on an infant 18 months of age or younger.

d. Death resulting from an AIDS-related condition, or death of a person with HIV infection.

11.6(2) Reportable events as described in this rule shall be reported to the department pursuant to Iowa Code section 141A.6. The following reporting requirements are in addition to those described in Iowa Code section 141A.6.

a. Within seven days of the receipt of a person's confirmed positive test result indicating HIV infection, the director of a plasma center, organ procurement organization, or public health laboratory that performed the test or that requested the confirmatory test shall make a report to the department.

b. Within seven days of the birth of an infant to mother diagnosed with HIV or a receipt of a laboratory result (positive, negative, or undetectable) of a non-antibody detection test (antigen test, viral culture, viral load, or qualitative nucleic acid amplification test) on an infant 18 months of age or younger, the attending physician shall make a report to the department.

11.6(3) The report shall be made on a form provided by the department that includes those form fields described in Iowa Code section 141A.6 unless approval from the department has been obtained for use of other reporting formats.

11.6(4) All persons who experience a reportable event while receiving services in the state, regardless of state of residence, shall be reported.

Rules 641—11.1(139A,141A) to 641—11.6(141A) are intended to implement Iowa Code sections 139A.35, 141A.4, 141A.6, and 141A.7.

641—11.7(141A) Confidentiality of information. In addition to the entities described in Iowa Code section 141A.9, medical information secured pursuant to Iowa Code section 141A.9 paragraph 1 may be shared between employees and agents of the department and employees and agents of tribes and tribal public health authorities that have a need for the information in the their duties related to HIV prevention, disease surveillance, or care of persons with HIV, only as necessary to administer the program for which the information is collected or to administer a program in the tribe or tribal public health authority. Confidential information transferred to other persons or entities under this rule shall continue to maintain its confidential status as described in Iowa Code section 141A.9.

This rule is intended to implement Iowa Code section 141A.9.

641—11.8(135) HIV and AIDS training programs where occupational exposure to blood or other potentially infectious materials may occur.

11.8(1) *Personnel covered by the rule.*

a. Nonemergency personnel. All supervisory and patient care personnel of any agency listed below:

(1) A licensed hospice,

(2) A homemaker-home health aide provider agency which receives state homemaker-home health aide funds, or

(3) An agency which provides respite care services.

b. Emergency and law enforcement personnel. All personnel from the following agencies:

(1) Emergency medical services

(2) Fire services

(3) Law enforcement

11.8(2) *Topics covered.* Training programs must address the following topics, consistent with standards from the Occupational Safety and Health Administration of the U.S. Department of Labor:

a. Symptoms and modes of transmission of blood-borne diseases, including human immunodeficiency virus and viral hepatitis,

b. Location and handling of personal protective equipment,

c. Information on the hepatitis B vaccine, and

d. Follow-up procedures in the event of an exposure.

11.8(3) *Timing of training.* Training must occur before an initial assignment of tasks where occupational exposure to blood or other potentially infectious materials may take place and at least annually thereafter.

This rule is intended to implement Iowa Code section 135.11.

641—11.9(139A,141A) Partner notification program.

11.9(1) The department will maintain a partner notification program for persons known to have tested positive for sexually transmitted diseases or infections pursuant to the procedures described in Iowa Code section 141A.5 and Iowa Code section 139A.33.

11.9(2) Services provided include, but are not limited to, counseling about the disease or infection, risk reduction techniques, linkage to medical care and treatment, assessment and referral to social and prevention services, and elicitation of exposed partners' names and contact information for referral to testing, as described in the Partner Services Program Manual dated December 2023, adopted and incorporated by this reference. The manual contains the policies and procedures utilized in the implementation of the program. The manual is updated annually. A copy of the manual is available at the department website.

11.9(3) The department may delegate its partner notification duties under this rule for persons who have tested positive for HIV or other sexually transmitted diseases to a local health authority or a physician or other health care provider unless the authority or physician or other health care provider refuses or neglects to conduct the partner notification program in a manner deemed to be effective by the department.

641—11.10(141A) Direct notification of an identifiable third party by a physician, physician assistant or the department.

11.10(1) Direct notification shall be used when a person diagnosed with HIV is having continuing contact with a sexual or needle-sharing partner who is unaware of the person's infection and when both of the following situations exist:

a. A physician or physician assistant for the person diagnosed with HIV is of the good-faith opinion that the nature of the continuing contact through sexual intercourse or the sharing of drug injecting equipment poses an imminent danger of HIV transmission to the third party.

b. When the physician or physician assistant believes in good faith that the person diagnosed with HIV, despite strong encouragement, has not and will not warn the third party and will not participate in the voluntary partner notification program.

11.10(2) The department or a physician or a physician assistant may reveal the identity of a person diagnosed with HIV pursuant to this rule only to the extent necessary to protect a third party from the direct threat of transmission. Notification of a person pursuant to this rule shall be made confidentially. Nothing in this rule shall be interpreted to create a duty to warn third parties of the danger of exposure to HIV through contact with a person diagnosed with HIV.

11.10(3) When the physician or physician assistant is of the good-faith opinion and belief that third-party notification should be performed, notification of a person pursuant to this rule shall be made:

a. Directly by the physician or physician assistant, or

b. By the department at the request of the physician or physician assistant.

11.10(4) Notification by the physician or physician assistant. Prior to notification of a third party by the physician or physician assistant of a person diagnosed with HIV, the physician or physician assistant shall make reasonable efforts to inform, in writing, the person diagnosed with HIV. The written information shall state that, due to the nature of the person's continuing contact through sexual intercourse or the sharing of

drug injecting equipment with the third party and the physician's or physician assistant's belief that the person diagnosed with HIV, despite strong encouragement, has not and will not warn the third party and will not participate in the voluntary partner notification program, the physician or physician assistant is forced to take action to provide notification to the third party. The physician or physician assistant, when reasonably possible, shall provide the following information to the person diagnosed with HIV:

a. The nature of the disclosure and the reason for the disclosure.

b. The anticipated date of disclosure.

c. The name of the party or parties to whom disclosure is to be made.

NOTE: Reasonable efforts to inform, in writing, the person diagnosed with HIV shall be deemed satisfied when the physician or physician assistant delivers the written notice in person or directs a written notice to the diagnosed person's last-known address by restricted certified mail, return receipt requested, at least five days prior to the anticipated date of disclosure to the third party.

11.10(5) When performed by the diagnosed person's physician or physician assistant, notification of the third party and any disclosure concerning the purpose of that notification shall be made in person. However, initial contact with the third party may be made by telephone, mail, or other electronic means to arrange the meeting with the physician or physician assistant at the earliest opportunity to discuss an important health matter. The nature of the health matter to be discussed shall not be revealed in the telephone call, letter, or other electronic message.

11.10(6) Notification by the department.

a. The physician or physician assistant attending the person diagnosed with HIV shall provide by telephone to the department any relevant information provided by the person diagnosed with HIV regarding any party with whom the person diagnosed with HIV has had sexual relations or has shared drug injecting equipment. The information may include the third party's name, address, telephone number, and any other locating information known to the physician or physician assistant. The department shall use the information in accordance with procedures established for the voluntary partner notification program.

b. Notification of the third party and any disclosure concerning the purpose of that notification shall be made in person. However, initial contact with the third party may be made by telephone, mail, or other electronic means to arrange the meeting with the department representative. The nature of the matter to be discussed shall not be revealed in the telephone call, letter, or other electronic message.

11.10(7) Confidentiality. The physician or physician assistant of the person diagnosed with HIV and the department shall protect the confidentiality of the third party and the person diagnosed with HIV. The identity of the person diagnosed with HIV shall remain confidential unless it is necessary to reveal it to the third party so that the third party may avoid exposure to HIV. If the identity of the person diagnosed with HIV is revealed, the third party shall be presented with a statement in writing at the time of disclosure which includes the following or substantially similar language: "Confidential information revealing the identity of a person diagnosed with HIV has been disclosed to you. The confidentiality of this information is protected by state law. State law prohibits you from making any further disclosure of the information without the specific written consent of the person to whom it pertains. Any breach of the required confidential treatment of this information subjects you to legal action and civil liability for monetary damages. A general authorization for the release of medical or other information is not sufficient for this purpose."

11.10(8) Immunity. A health care provider attending a person diagnosed with HIV has no duty to disclose to or to warn third parties of the dangers of exposure to HIV through contact with the person diagnosed with HIV and is immune from any liability, civil or criminal, for failure to disclose to or warn third parties of the condition of the person diagnosed with HIV.

Rules 641—11.9(139A,141A) to 641—11.10(141A) are intended to implement Iowa Code sections 139A.33 and 141A.5.

641—11.11(139A,141A) Care provider notification upon exposure to contagious or infectious diseases - Exposures in non-clinical settings.

11.11(1) If a care provider sustains a significant exposure from a patient while rendering health care or other services, other than home-health or respite care services, outside of a health care facility or hospital, the

care provider shall file a significant exposure report as soon as reasonably possible following the exposure. When the exposure occurred outside a clinical setting, a care provider who has sustained a significant exposure should file this report with the infection control, occupational health, or other designated office of the facility to which the patient was transported.

11.11(2) The source patient to whom the care provider was exposed is deemed to consent to a test to determine if the patient has a contagious or infectious disease and is deemed to consent to notification of the care provider or the designated representative of the results of the test, upon submission of a significant exposure report and certification of the significant exposure by an authorized infection preventionist, occupational health professional, or other professional trained in infectious disease control. No further consent from the source patient is required. However, the source patient shall be notified that an exposure has occurred and shall be told which specific tests are being performed to determine the presence of contagious or infectious diseases. If the source patient is a minor, the minor shall be informed prior to an HIV-related test that, upon positive confirmation of an HIV-related test result, the minor's legal guardian shall be informed of the positive result, pursuant to Iowa Code section 141A.7(3).

11.11(3) Hospitals, clinics, or other health care facilities, institutions administered by the department of corrections, and jails shall have written policies and procedures pursuant to Iowa Code section 139A.19. In addition to those policies and procedures required by Iowa Code section 139A.19, hospitals, clinics, or other health care facilities, institutions administered by the department of corrections, and jails shall have written policies and procedures for reviewing and certifying significant exposure report forms, testing a source patient, and notifying a care provider who sustained a significant exposure while rendering health care services or other services to the source patient when the source patient is delivered to the facility and the exposure occurred prior to the delivery.

11.11(4) The hospital, clinic, or other health care facility to whom the source patient is delivered shall conduct the test. If the source patient is delivered to an institution administered by the department of corrections, the test shall be conducted by the staff physician of the institution. If the source patient is delivered to a jail, the test shall be conducted by the attending physician of the jail or the county medical examiner. If the source patient was deemed to consent upon certification of a significant exposure report, the sample and test results shall only be identified by a number.

11.11(5) If a test result is positive, the hospital, clinic, or other health care facility, or other person performing the test shall notify the source patient and make any required reports to the department pursuant to Iowa Code sections 139A.3 and 141A.6. The report to the department shall include the name of the source patient.

11.11(6) If a source patient is diagnosed or confirmed as having a contagious or infectious disease, the hospital, clinic, or other health care facility, or other person performing the test shall notify the care provider or the designated representative of the care provider who shall then notify the care provider. If the source patient is a minor and is diagnosed with HIV infection, the hospital, clinic, or other health facility, or other person performing the test shall notify the legal guardian of the minor.

11.11(7) The notification shall advise the care provider of possible exposure to a particular contagious or infectious disease and recommend that the provider seek medical attention. The notification shall be provided as soon as reasonably possible following determination that the source patient has a contagious or infectious disease. The notification shall not include the name of the source patient unless the patient consents. If the care provider who sustained a significant exposure determines the identity of a source patient who has been diagnosed or confirmed as having a contagious or infectious disease, the identity of the source patient shall be confidential information and shall not be disclosed by the care provider to any other person unless a specific written release is obtained from the source patient.

11.11(8) This rule does not preclude a hospital, clinic, other health care facility, or a health care provider from providing notification to a care provider under circumstances in which the hospital's, clinic's, other health care facility's, or health care provider's policy provides for notification of the hospital's, clinic's, other health care facility's, or health care provider's own employees of exposure to a contagious or infectious disease that is not life-threatening if the notice does not reveal a source patient's name, unless the patient consents.

11.11(9) The infection control, occupational health, or other designated office of the facility shall maintain a record of all significant exposure reports it receives and shall retain each report for a period of five years.

11.11(10) The significant exposure report form is a confidential record pursuant to Iowa Code section 141A.9.

641—11.12(139A,141A) Care provider notification upon exposure to contagious or infectious diseases - Exposures in clinical settings.

11.12(1) If a care provider sustains a significant exposure from a patient while rendering health care services or other services within a hospital, clinic, or other health care facility, or while delivering home-health or respite care services, the care provider shall file a report as soon as reasonably possible following the exposure. A care provider who has sustained a significant exposure should file the report with the infection control, occupational health, or other office designated by the facility in which the exposure occurred, or by the facility which has oversight for the delivery of home-health or respite care services.

a. If a general consent form was signed and in effect at the time of the significant exposure and the source patient is an adult, a significant exposure report form shall not be required to document the significant exposure. The health care facility or hospital may use an employee incident report or other similar form for this purpose. The source patient to whom the care provider was exposed is deemed to consent to a test to determine if the patient has a contagious or infectious disease and is deemed to consent to notification of the care provider or the designated representative of the results of the test, upon submission and review of an employee incident report and certification of the significant exposure by an authorized infection preventionist, occupational health professional, or other professional trained in infectious disease control. No further consent from the source patient is required. However, a source patient shall be notified that an exposure has occurred and shall be told which specific tests are being performed. Prior to conducting an HIV-related test, the health care facility or hospital shall provide information to the source patient concerning testing and a means of obtaining additional information regarding HIV infection and risk reduction pursuant to Iowa Code section 141A.6.

b. If no consent form was signed or in effect at the time of the exposure, or if the source patient is a minor, the source patient is deemed to consent to a test to determine if the patient has a contagious or infectious disease and is deemed to consent to notification of the care provider or the designated representative of the results of the test upon submission of a significant exposure report form and certification of the significant exposure by an authorized infection preventionist, occupational health professional, or other professional trained in infectious disease control. Source patients shall be notified that an exposure has occurred and shall be told which specific tests are being performed to determine the presence of contagious or infectious diseases. If the source patient is a minor, the minor shall be informed prior to an HIV-related test that, upon positive confirmation of an HIV-related test result, the minor's legal guardian shall be informed of the positive result, pursuant to Iowa Code section 141A.7(3).

11.12(2) Hospitals, clinics, or other health care facilities, institutions administered by the department of corrections, and jails shall have written policies and procedures for reviewing and certifying significant exposure report forms or other employee incident report forms, testing a source patient, and notifying a care provider who sustained a significant exposure while rendering health care services or other services to a patient during the admission, care, or treatment of the patient at the facility, or while delivering home-health or respite care services.

11.12(3) The hospital, clinic, or other health care facility where exposure occurred or which has oversight for the delivery of home-health or respite care services shall conduct the test. If a general consent form was signed and in effect and the source patient is an adult, the sample and test results shall be identified by name. If the source patient was deemed to consent to a test and to notification of the care provider upon certification of a significant exposure report pursuant to these rules because no general consent was signed and in effect at the time of the exposure or because the source patient is a minor, the sample and test results shall be identified only by a number.

11.12(4) If a test result is positive, the hospital, clinic, or other health care facility or other person performing the test shall notify the source patient and make any required reports to the department pursuant

to Iowa Code sections sections 139A.3 and 141A.6. The reports to the department shall include the name of the source patient.

11.12(5) If a source patient is diagnosed or confirmed as having a contagious or infectious disease, the hospital, clinic, or other health care facility or other person performing the test shall notify the care provider or the designated representative of the care provider who shall then notify the care provider. If the source patient is a minor and is diagnosed with HIV infection, the hospital, clinic, or other health care facility or other person performing the test shall notify the legal guardian of the minor.

11.12(6) The notification shall advise the care provider of possible exposure to a particular contagious or infectious disease and recommend that the provider seek medical attention. The notification shall be provided as soon as reasonably possible following determination that the source patient has a contagious or infectious disease.

11.12(7) The infection control, occupational health, or other designated office of the facility shall maintain a record of all significant exposure reports it receives and shall retain each report for a period of five years.

11.12(8) The significant exposure report form is a confidential record pursuant to Iowa Code section 141A.9.

Rules 641—11.11(139A,141A) to 641—11.12(139A,141A) are intended to implement Iowa Code section 139A.19.

641—11.13(915) Testing, reporting, and counseling of convicted of alleged sexual assault assailants.

11.13(1) Prior to ordering an HIV-related test on a convicted or alleged offender pursuant to Iowa Code sections 915.40 through 915.43, the physician or practitioner shall provide information to the subject of the test concerning testing and where to obtain additional information on HIV transmission and risk reduction, pursuant to Iowa Code section 141A.6. The department may be contacted for brochures that may assist in meeting the requirements of Iowa Code section 141A.6.

11.13(2) At any time that the subject of an HIV-related test is informed of confirmed positive test results, the physician or other practitioner who ordered the test shall initiate counseling concerning the emotional and physical health effects of HIV infection, as required under Iowa Code section 141A.7, and shall make any required reports to the department pursuant to Iowa Code section 141A.6.

a. The physician or other practitioner shall encourage a person diagnosed with HIV to participate in the voluntary partner notification program pursuant to rule 641—11.9(139A, 141A).

b. The physician or other practitioner may provide to the department any relevant information provided by the person diagnosed with HIV regarding any party with whom the person has had sexual relations or has shared drug injecting equipment.

Rule 641—11.13(915) is intended to implement Iowa Code section 135.11(22).

641—11.14(141A) The Ryan White program.

11.14(1) General purpose and incorporation. The Ryan White program is a state-administered program that provides support services and assistance with the costs of health insurance and treatment medications for eligible low-income individuals diagnosed with HIV when adequate state and federal funding is available for administration of the program.

a. The program is authorized under Part B of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87). This legislation requires that the Ryan White program, including the benefits and drug assistance program, be the payer of last resort for HIV-related services. The Ryan White program is not an entitlement program and does not create a right to assistance. In the event that funding is exhausted or terminated or there are changes in state or federal guidelines, programs, or regulations that impact funding available to the program, the department reserves the right to close enrollment, cease to provide specific services, or alter eligibility criteria until such time that funding is again sufficient.

b. The Ryan White program will be administered in accordance with the Ryan White Program Manual dated December 2023, adopted and incorporated by this reference. The manual contains the policies and procedures utilized in the implementation of the program. The manual is updated annually. A copy of the manual is available at the department website.

c. The benefits and drug assistance program will be administered in accordance with the Benefits and Drug Assistance Program Manual dated December 2023, adopted and incorporated by this reference. The manual contains the policies and procedures utilized in the implementation of the program. The manual is updated annually. A copy of the manual is available at the department website.

11.14(2) Collaboration with Iowa Medicaid. To ensure that the Ryan White program is the payer of last resort and to maximize the efficiency and effectiveness of HIV-related prevention and care services, Iowa Medicaid shall grant the department access to client information for persons enrolled in Medicaid.

11.14(3) Confidentiality. Applications, assessments, and all other client-level information received or maintained by the department in connection with the Ryan White program shall be considered confidential information in accordance with Iowa Code section 141A.9.

Rule 641—11.14(141A) is intended to implement Iowa Code section 141A.3.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 641-24

Iowa Code Section Authorizing Rule 135.11

State or Federal Law(s) Implemented by the Rule 135.11, 455E.11

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter sets forth department procedure in administering the Grants to Counties program for the purpose of testing private water wells, reconstructing private water wells, and the proper plugging of abandoned private water wells within the jurisdiction of each county board of health.

Grant program parameters are defined in Iowa Code 455E.11. HHS administers these grants in coordination with the Iowa Department of Natural Resources.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

No direct costs to the public have been identified.

    - Classes of persons that will benefit from the proposed rule:

County boards of health receiving grant funds.

Communities and individuals that live in a county that receives grant funds. HHS incurs personnel costs for team members to administer the grants to counties program. These costs are reflected in the table above as "HHS Implementation".

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Figures below are actuals incurred in the fiscal years shown.

Identified Impacts*

	SFY2018	SFY2019	SFY2020	SFY2021	SFY2022	5 Year Total
Costs HHS Implementation Grants to Counties	($81,000) ($2.6M)	($84,000) ($3M)	($87,000) ($3M)	($90,000) ($4M)	($93,000) ($4M)	($435,000) ($16.6M)
Benefits Increased Public Trust Improved Public Health and Safety	Intangible Qualitative	Intangible Qualitative	Intangible Qualitative	Intangible Qualitative	Intangible Qualitative	Intangible Qualitative
Net Value	$2,681,000	$3,084,000	$3,087,000	$4,090,000	$4,093,000	$17,035,000

*All monetary figures have been rounded to the nearest thousandth.

Sound grant administration ensures that grantees are using grant funds efficiently and appropriately, leading to public trust in government programming and improved public health and safety driven by the goals of the grants to counties program**.**

- Qualitative description of impact:

Sound grant administration ensures that grantees are using grant funds efficiently and appropriately, leading to public trust in government programming and improved public health and safety driven by the goals of the grants to counties program**.**

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for team members to administer the grants to counties program. These costs are reflected in the table above as "HHS Implementation".

- Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows increased public trust, and improved public health and safety. Eliminating grant administration measures as defined in this rule chapter would weaken

oversight of grant dollars, which could result in a diminished quality of work completed by grantees under the Grants to Counties program. A grantee using funds fraudulently or in contradiction to the requirements of Iowa Code may diminish public trust in the Grants to Counties program and the department, and eliminate gains to public health and safety that might have been realized under the program.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS administers the Grants to Counties program in accordance to requirements of Iowa Code. This rule chapter does not ascribe department duties or implementation elements in addition to those directly defined in Code.

    - Reasons why they were rejected in favor of the proposed rule:

N/A

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:

Regulatory Analysis Template

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

614—24.1(455E,135) Grant procedures.

24.1(1) The department has adopted policies to administer the awarding of grants for the grants to counties program. Grants will be awarded pursuant to Iowa Code section 455E.11.

24.1(2) The department will:

a. Determine program objectives;

b. Set eligible and ineligible grant costs for which the department will reimburse county programs;

c. Define performance requirements for grant recipients that set minimum standards to be met by all county programs;

d. Develop a grant application and a grant application submission procedure;

e. Terminate a grant found to be obtained by fraud or misrepresentation regardless of whether grant moneys have already been given to the grantee;

f. Allow for an applicant to appeal the denial of a properly submitted grant application. Appeals shall be governed by 441—Chapter 7.

These rules are intended to implement Iowa Code sections 455E.11 and 135.11(26).

Regulatory Analysis Template

PubliTEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 641-153

Iowa Code Section Authorizing Rule 142D

State or Federal Law(s) Implemented by the Rule Smokefree Air Act, 142D

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name
Joe Campos

Address
Joe.campos@idph.iowa.gov

Email and/or phone number
515-304-0963

Purpose and summary of proposed rule:

This rule chapter defines procedure in implementing Iowa's Smokefree Air Act. This includes the duty of employers, owners, or other persons having control of an area where smoking is prohibited to inform employees and persons accessing the site of that prohibition through proper signage. The rules also describe procedure for receiving complaints and implementing enforcement actions against persons who fail to comply with provisions of the Act. Enforcement action may be taken against a person who smokes in an area where smoking is prohibited or a person who owns, operates, manages or otherwise has custody or control of a place where smoking is prohibited and fails to properly prohibit smoking.

This rule chapter describes procedure to support the requirements for signage, complaints, and enforcement detailed in Iowa Code. This chapter does not create additional, substantive requirements to be complied with.

Regulatory Analysis Template

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

Employers, owners, operators, managers, and persons having custody or control of an area declared nonsmoking.
Persons who smoke in an area where smoking is prohibited.

    - Classes of persons that will benefit from the proposed rule:

Persons who inhabit or otherwise use an area declared nonsmoking.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Estimated figures below are projections based on past program performance as included in the Red Tape Rule Report for this chapter.

Identified Impacts*

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5 Year Total
Costs HHS Implementation Signage in Nonsmoking Areas	($) Unknown	($) Unknown	($) Unknown	($) Unknown	($) Unknown	($) Unknown
Benefits Citations & Civil Penalties Improved Public Health & Safety	Unknown Qualitative	Unknown Qualitative	Unknown Qualitative	Unknown Qualitative	Unknown Qualitative	Unknown Qualitative
Net Value						

*All monetary figures have been rounded to the nearest thousandth.

    - Qualitative description of impact:

Enforcing the Smokefree Air Act through proper signage in designated nonsmoking areas and enforcement actions against those in noncompliance ensures the law is being implemented as intended to prevent secondhand smoke exposure, thus protecting public health and safety.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for team members to oversee the procedures described in this rule chapter. These costs are reflected in the table above as “HHS Implementation”.

    - Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above indicates improved public health and safety. Enforcement costs are also defrayed through citations and civil penalties pursuant to Iowa Code. Eliminating the signage and complaint/enforcement procedures detailed in this rule chapter could result in confusion among property owners and the public in how to comply with the law. This may lead to increased noncompliance that could drive an increase in citations and civil penalties, and a negative impact on public health and safety.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

HHS has established signage requirements and complaint procedures at the level the Department feels necessary to protect public health and safety. Citation and civil penalty enforcement is implemented as defined in Iowa Code. A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS implements the Smokefree Air Act in accordance to requirements of Iowa Code.

    - Reasons why they were rejected in favor of the proposed rule:

N/A

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Regulatory Analysis Template

Text of Proposed Rule:

Regulatory Analysis Template

CHAPTER 153
SMOKEFREE AIR

641—153.1(142D) Definitions. For the purposes of this chapter, definitions found in Iowa Code section 142D.2 and the following definitions apply:

"Ashtray" means any receptacle, including a can, bottle, bowl, tray, or other vessel that is used for extinguishing or disposing of any lighted cigar, cigarette, pipe, or other tobacco product in any manner or form including ash, cigarette butts or filters, or cigar stubs. However, "ashtray" shall not include any receptacle located outdoors and on the perimeter of any public place, the perimeter of the grounds of any public building, the perimeter of school grounds, or the perimeter of any other outdoor space subject to the prohibition in Iowa Code chapter 142D.

"Entrance" means any doorway to an enclosed area used by the public or employees for ingress to any public place or place of employment, but does not include any doorway designated for use as an exit in an emergency only. "Entrance" also includes the commonly understood points of entry to an outdoor area, subject to the prohibitions of this chapter, such as a driveway, sidewalk, pathway, access road, gate, or dedicated point of entry, but not including a street, road, highway, or sidewalk in the public right-of-way.

"Grounds of any public building" means an outdoor area of a public building that is used in connection with the building, including but not limited to a sidewalk or driveway immediately adjacent to the building, but not including a sidewalk in the public right-of-way; a sitting or standing area immediately adjacent to the building; a patio; a deck; a curtilage or courtyard; a swimming or wading pool; a beach; or any other outdoor area as designated by the person having custody or control of the public building. A person having custody or control of a public building may exclude from the designated grounds of any public building the following: a parking lot, the course of play at a golf course, a hiking trail, locations of an individual campsite or campfire, or a lake, river, or other body of water. Nothing in this definition prohibits any owner, operator, manager, or other person having custody or control of an area that is exempt from the prohibitions of Iowa Code chapter 142D from declaring the entire area or property a nonsmoking place.

"Public building" means an enclosed area owned, leased, or operated by or under the control of the state government or its political subdivisions.

641—153.2(142D) Duties of employers, owners, operators, managers, and persons having custody or control of a public place, place of employment, area declared nonsmoking pursuant to Iowa Code chapter 142D or outdoor areas where smoking is prohibited.

153.2(1) The employer, owner, operator, manager, or person having custody or control of a place where smoking is prohibited under Iowa Code chapter 142D, shall:

a. Not permit smoking in a public place, place of employment, outdoor area where smoking is prohibited, or an area declared nonsmoking pursuant to Iowa Code chapter 142D.

b. Inform all current employees and all prospective employees upon application for employment of the prohibitions of Iowa Code chapter 142D.

c. Not retaliate against any employee, applicant for employment, or customer that exercises any rights, registers a complaint, or attempts to prosecute a violation pursuant to Iowa Code chapter 142D.

d. Post signs in and at every entrance to the public place, place of employment, area declared nonsmoking, and outdoor area where smoking is prohibited that inform persons that they are entering a no smoking facility or area.

(1) The signs shall be clear and conspicuous in or at the entrance where posted.

(2) The signs shall be at least 24 square inches in size (for example, 4 inches by 6 inches) and shall be in legible font type.

(3) The signs shall contain the words "No Smoking" or the international "no smoking" symbol; the telephone number for reporting complaints, 1.888.944.2247; and the department website, https://hhs.iowa.gov/smokefreeair.

e. Place no smoking signs in every vehicle that constitutes a public place, place of employment, or area declared nonsmoking pursuant to Iowa Code section 142D.5.

(1) Such signs shall be clear and conspicuous from the exterior of the vehicle.

(2) The signs shall be at least 9 square inches (for example, 3 inches by 3 inches) and shall be in legible font type.

(3) The signs shall contain the words "No Smoking" or the international "no smoking" symbol; the telephone number for reporting complaints, 1.888.944.2247; and the department's website, https://hhs.iowa.gov/smokefreeair.

(4) Nothing in this rule requires the placement of a sign in any vehicle that the director of the department of administrative services or the director of transportation orders to receive a regular registration plate pursuant to Iowa Code section 321.19.

f. Remove all ashtrays from areas where smoking is prohibited.

153.2(2) The owner or operator of a building or facility that contains more than one public place, place of employment, or area declared nonsmoking pursuant to Iowa Code chapter 142D which is controlled by other employers, owners, or operators shall comply with the provisions of these rules for the area of the building or facility under the owner's or operator's control.

153.2(3) An employer, owner, or operator of a public place, place of employment or area declared nonsmoking pursuant to Iowa Code chapter 142D that is within a public place that is owned or operated by another person shall comply with the provisions of these rules for the area under the control of the employer, owner, or operator within that public place.

153.2(4) An employer, owner, operator, manager, or person having custody or control of a place where smoking is prohibited under Iowa Code chapter 142D shall inform any individual smoking in a place where smoking is prohibited that the individual is violating the smokefree air Act and shall request that the individual stop smoking immediately.

a. If the individual refuses to stop smoking, the employer, owner, operator, manager, or person having custody or control of the place where smoking is prohibited may discontinue service to that individual.

b. If the individual refuses to stop smoking, the employer, owner, operator, manager, or person having custody or control of the place where smoking is prohibited may request that the individual leave the area where smoking is prohibited.

c. If the individual refuses to leave the area where smoking is prohibited, the employer, owner, operator, manager, or person having custody or control of the place where smoking is prohibited may notify the state or local law enforcement agency with jurisdiction over the area where smoking is prohibited.

641—153.3(142D) Leases. Any lease entered into by the state or its political subdivisions shall require that all areas where smoking is prohibited pursuant to Iowa Code chapter 142D comply with the provisions of these rules and Iowa Code chapter 142D.

641—153.4(142D) Complaints and enforcement.

153.4(1) *Duties of department.* The department will maintain a system for receiving and investigating complaints against persons who own, operate, manage, or otherwise have custody or control of a place where smoking is prohibited and who fail to comply with the provisions of Iowa Code chapter 142D.

a. The department may designate one or more public agencies through a 28E agreement or other written contract to assist with enforcement.

b. The department may refer complaints regarding a violation to the law enforcement authorities of the state or of the political subdivision of the state in which the alleged violation occurred.

153.4(2) *Enforcement against a person who smokes in an area where smoking is prohibited.* Pursuant to Iowa Code chapter 142D the department designates the law enforcement authorities of the state and of each political subdivision of the state to assist with enforcement. A peace officer may issue a citation in lieu of arrest pursuant to Iowa Code chapter 805 against a person who smokes in an area where smoking is prohibited pursuant to Iowa Code chapter 142D, and such person shall pay a civil penalty pursuant to Iowa Code section 805.8C(3) for each violation.

153.4(3) *Enforcement against a person who owns, operates, manages, or otherwise has control of a place where smoking is prohibited.* Pursuant to Iowa Code chapter 142D the department designates the law enforcement authorities of the state and of each political subdivision of the state to assist with enforcement.

The department or its designee may initiate a civil action against an owner, operator, manager, or person who otherwise has custody or control of a place where smoking is prohibited pursuant to Iowa Code chapter 142D, and such person shall pay the applicable civil penalty pursuant to Iowa Code chapter 142D.

153.4(4) *Manner of filing a complaint.* Any person may register a complaint with the department by calling the toll-free number, 1-888-944-2247, or registering a complaint on the department's website, https://hhs.iowa.gov/smokefreeair.

153.4(5) *Contents of the complaint.* A complaint filed with the department shall include:

a. The name or location of the public place, place of employment, area declared a nonsmoking place pursuant to Iowa Code chapter 142D, or outdoor area where smoking is prohibited which is the subject of the complaint;

b. A description of the occurrence that prompted the complaint; and

c. Any other information relevant to the occurrence.

153.4(6) *Review of complaint by department.* Upon receipt of a complaint, the department or its designee may contact the individual making the complaint to confirm the details of the complaint and obtain any additional information.

153.4(7) *Information from inspections.* Information received by the department of one or more violations of Iowa Code chapter 142D as a result of an inspection of a public place by the state or political subdivision of the state shall be considered a credible complaint under this rule.

153.4(8) *Notice of potential violation.* If the department determines that a complaint against a public place, place of employment, area declared nonsmoking pursuant to Iowa Code chapter 142D, or outdoor areas where smoking is prohibited is credible, the department shall:

a. For the first complaint.

(1) Issue a written notice of potential violation to the owner, operator or person having custody or control including the details of the complaint.

(2) The notice shall include educational materials about how to comply with Iowa Code chapter 142D, and information on whom to contact for further information and assistance for compliance.

b. For the second and subsequent complaints within one year.

(1) Issue a subsequent notice of potential violation to the owner, operator, or person having custody or control.

(2) In addition, the department may authorize one or more public agencies to conduct a compliance check of the location.

(3) In addition, the department may pursue any remedy authorized by Iowa Code chapter 142D, including the enforcement of civil penalties.

641—153.5(142D) Limitation of rules. Nothing in these rules is intended to limit any other state administrative rule or federal regulation that prohibits smoking.

These rules are intended to implement Iowa Code chapter 142D.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** IAC 641-154

Iowa Code Section Authorizing Rule IAC 124E

State or Federal Law(s) Implemented by the Rule NA

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name
Joe Campos

Address
Joe.campos@idph.iowa.gov

Email and/or phone number
515-304-0963

Purpose and summary of proposed rule:

This rule chapter implements a medical cannabidiol program for the in-state manufacture and dispensing of medical cannabis products for patients with qualifying debilitating medical conditions. Registration cards to purchase at a dispensary in Iowa are issued to patients who are at least eighteen years of age, permanent residents of Iowa, and for whom a health care practitioner determines suffer from a medical condition that qualifies for use of medical cannabidiol. Registration cards may also be issued to the primary caregivers of such patients.

The rule chapter defines licensing requirements for medical cannabidiol manufacturers and dispensaries, fees for application and licensure, safety protocols, marketing and advertising restrictions, and limits on manufacturing and dispensing. Manufacturers may only manufacture products in the forms recommended by the Medical Cannabidiol Board and approved by the Board of Medicine. The General Assembly maintains sole authority to revise the definition of medical cannabidiol.

HHS maintains a secure sales and inventory tracking system available to dispensaries 24 hours a day, seven days a week for the purpose of verifying that a person is lawfully in possession of

a registration card and for tracking the date of the sale and quantity purchased. This system tracks products and inventory from creation by a manufacturer, transfers for testing and delivery, dispensing at a dispensary, and chain of custody; or "seed-to-sale."

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
   - Classes of persons that will bear the costs of the proposed rule:

The cost for these updates is included within application fees for medical cannabis patients and caregivers and license fees for our licensees. Fees will not go up due to these changes

   - Classes of persons that will benefit from the proposed rule:

Medical cannabis patients and caregivers.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
   - Quantitative description of impact:

Figures below are actuals incurred in the fiscal years shown.

Identified Impacts*

	SFY2019	SFY2020	SFY2021	SFY2022	SFY2023	5 Year Total
Costs						
HHS Implementation	$627,000	$898,000	$813,000	$809,000	$909,000	$4.056M
Benefits						
Registration Card Fees	$157,000	$305,000	$446,000	$827,000	$1,330,000	$3.065M
License & Application Fees	$675,000	$400,000	$333,000	$220,000	$125,000	$1.753M
Improved Outcomes for Patients	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Improved Public Health & Safety	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	+ $205,000	- $193,000	- $34,000	+ 238,000	+ 546,000	+ $762,000

*All monetary figures have been rounded to the nearest thousandth.

The physical security requirements, manufacturer and dispensary data requirements, testing protocols, and other safeguards defined in this rule chapter ensure medical cannabidiol facilities operate in a manner protective of public health and safety.

   - Qualitative description of impact:

HHS has not conducted an observational study on patient outcomes. HHS focuses on customer service metrics, and strategies for improving the registration experience and processing time, which averages <1 day from submission to approval. Patient outcomes can also improve by reducing the cost of participation, by reducing compliance and regulatory costs, and annual license fees to the industry.

3. Costs to the state
   - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for team members to support the regulation of the medical cannabidiol program. Additional expenses are incurred, mainly IT and software, to also support the regulation of the program and registration of patients and caregivers. These costs are reflected in the table above as "HHS Implementation".

The Iowa Department of Public Safety (DPS) incurs costs to conduct background investigations to support licensure of manufacturers and dispensaries, and are paid by the industry to conduct necessary background checks. There are unknown costs to law enforcement for education and training on medical cannabis. These costs are unknown and not reflected in the table above.

- Anticipated effect on state revenues:

The Medical Cannabidiol Act is a fee-based program, receives no appropriation, and does not impose a specific cost on the public. The program is funded by license application and annual fees from manufacturers and dispensaries, and patient and caregiver application fees.

Licensed facilities pay an annual fee to the department to cover costs associated with regulation, inspection, and other expenses necessary for the administration of the program, which have been reduced each year. License Application and Annual Fee revenues are reflected in the table above. Patients issued registration cards are charged a fee of $100 or $25 per patient card, and primary caregivers are charged $25. Registration cards expire one year from the date of issuance. This revenue is reflected in the table above as "Registration Card Fees".

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above reflects a net value of +$762,000 for FY19-FY23 and indicates improved outcomes for patients with qualifying medical conditions, and the industry that serves them. By investing in scalable IT solutions early on, the program has been able to limit traditional expenses as volume and revenue have increased.

Eliminating this rule chapter would remove the department's regulatory structure for the medical cannabidiol manufacturing and dispensing program, remove the procedural clarification of administrative rule to support the program, and introduce general and widespread regulatory uncertainty. This would create confusion among licensed entities, and possibly the misapplication of state law. This could result in adverse health impacts for patients by eliminating their safe and legal access to products for the treatment of their qualifying condition.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

No less costly methods were identified.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

Regulatory Analysis Template

HHS believes the regulatory approach defined in this rule chapter is at the level necessary to ensure public health and safety. Should adjustments be made, less restrictive alternatives might include:

- Adjust sampling protocols to sample less frequently and/or sample for fewer contaminants;
- Inspect facilities less often than annually or on an ad hoc basis;
- Reduce the number or type of required safety elements such as physical property security systems and chain of custody;
- Reduce the manufacturing and dispensary data required to be transmitted to HHS; or
- Reduce restrictions related to marketing and other advertising of medical cannabidiol.

- Reasons why they were rejected in favor of the proposed rule:

HHS implements the medical cannabidiol program in accordance with requirements of Iowa Code; overall, HHS implements the program as prescribed and has limited latitude in determining regulatory requirements. The Department maintains flexibility and authority for:

- Setting sampling protocols and testing procedures for the testing of medical cannabidiol produced;
- Determining the frequency of inspection of licensed facilities;
- Determining the method, type, and frequency of certain operational data;
- Setting specific criteria for the implementation of safety requirements; and
- Setting reasonable restrictions related to marketing, signage, display, packaging, and advertising of medical cannabidiol.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

NA

Text of Proposed Rule:

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.

"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.

"*Advertisement*" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of medical cannabidiol;

"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 review by authorized personnel 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 specifically identified quantity of dried flower and other cannabis plant matter that is uniform in strain or cultivar, harvested at the same time, and cultivated using the same pesticides and other crop inputs.

"Biosecurity" means a set of preventative measures designed to reduce the risk of transmission of:

a. Infectious diseases in crops;

b. Quarantined pests;

c. Invasive alien species;

d. Living modified organisms.

"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.

"CBD" means cannabidiol, Chemical Abstracts Service number 13956-29-1. *"CBDA"* means cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

"Certificate of analysis" means the report prepared for the requester about the analytical testing performed and the results obtained by a laboratory.

"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.

"*Combusted*" means the addition of a flame to medical cannabidiol or raw flower cannabis for the purposes of burning for inhalation, or smoking cannabis.

"*Consumable hemp product*" means a hemp product that includes a substance that is metabolized or is otherwise subject to a biotransformative process when introduced into the human body.

a. A consumable hemp product may be introduced into the human body by ingestion or absorption by any device including but not limited to an electronic device.

b. A consumable hemp product may exist in a solid or liquid state.

c. A hemp product is deemed to be a consumable hemp product if it is any of the following:

(1) Designed by the processor, including the manufacturer, to be introduced into the human body.

(2) Advertised as an item to be introduced into the human body.

(3) Distributed, exported, or imported for sale or distribution to be introduced into the human body.

(4) "Consumable hemp product" includes but is not limited to any of the following:

a. A noncombustible form of hemp that may be digested, such as food; internally absorbed, such as chew or snuff; or absorbed through the skin, such as a topical application.

b. Hemp processed or otherwise manufactured, marketed, sold, or distributed as food, a food additive, a dietary supplement, or a drug.

(5) "Consumable hemp product" does not include a hemp product if the intended use of the hemp product is introduced into the human body by any method of inhalation, as prohibited under section 204.14A.

"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.

"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.

"Debilitating medical condition" means the same as the definition at Iowa Code section 124E.2.

"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 chapter124E and these rules.

"Disqualifying felony offense" means the same as the definition at Iowa Code section 124E.2.

"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.

"Health care Practitioner" means the same as the definition at Iowa Code section 124E.2.

"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.

"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.

"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.

"Laboratory" means the same as the definition at Iowa Code section 124E.2.

"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.

"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 hawki, as administered by the Iowa Medicaid enterprise of the department.

"Medical cannabidiol" means the same as the definition at Iowa Code section 124E.2.

"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.

"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.

"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 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.

"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 the same as the definition at Iowa Code section 124E.2.

"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 be sold by a manufacturer or a dispensary.

"Production" or *"produce"* means:

a. Cultivating or harvesting plant material;

b. Processing or manufacturing; or

c. Packaging of medical cannabidiol.

"Stability Study" or "studies" means the process of determining the shelf-life or expiration date of a medical cannabidiol product. 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 641— Chapter 154.

"Proficiency test" means an evaluation of a laboratory's performance against preestablished criteria by means of interlaboratory comparisons of test measurements.

"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.

"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.

"Relative percent difference" or *"RPD"* means a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation: RPD = absolute value (primary sample measurement - duplicate sample measurement) / ([primary sample measurement + duplicate sample measurement] / 2) × 100.

"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.

"Security alarm system" means the same as the definition at 661—277.2.

"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.

"Standard operating procedure" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

"Synthetic" or *"semisynthetic cannabinoid"* means a cannabinoid extracted from a cannabis plant, a cannabis flower, a hemp plant, or hemp plant parts with a chemical makeup that is changed after extraction to create a different cannabinoid or other chemical compound by applying a catalyst other than heat or light. Synthetic or semi synthetic derived cannabinoid includes but is not limited to any tetrahydrocannabinol created from cannabidiol.

"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.

"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.

"Total tetrahydrocannabinol" means 87.7 percent of the amount of tetrahydrocannabinolic acid plus the amount of tetrahydrocannabinol.

"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.

"Trade name" means the name which manufacturers give to a product or range of products.

"Validation" means the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled.

"*Vaporization*" means the heating of a medical cannabidiol concentrate or extract to a specific temperature using a device. For the purposes of these rules, vaporization does not include raw or dried cannabis flower.

"*Valid photo identification*" means any of the following for a patient or primary caregiver: (1) valid Iowa driver's license; (2) valid Iowa nonoperator's identification card; (3) An alternative form of valid photo identification. An individual who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. An individual 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. An individual who applies for an exemption is subject to verification of the primary caregiver's identity through a process established by the department to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

"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.

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 follow all provisions of Iowa Code section 124E.3, this chapter and requests from the department for more information.

a. The written documentation required by Iowa Code section 124E.3(1)*"a"* shall be submitted on the application form at the department's website.

b. Explanatory information pursuant to Iowa Code section 124E.3(1)*"*b," is located at the department's website.

154.2(2) A health care practitioner may make a written request to the department to rescind a written certification the practitioner previously provided, based on reasons deemed appropriate by the health care practitioner.

154.2(3) Health care practitioner prohibitions. A health care practitioner shall not:

a. 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 manufacturer or dispensary for the purposes of:

(1) Certifying a patient's condition, other than accepting a fee for a patient consultation to determine if the patient should be issued a certification under Iowa Code chapter 124E.

(2) Certifying an individual as a primary caregiver, 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.

b. Advertise the certification of patients as one of the health care practitioner's services.

c. 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.

d. Be designated to act as a primary caregiver for a patient for whom the health care practitioner has certified a qualifying debilitating medical condition.

e. Receive or provide medical cannabidiol product samples.

641—154.3(124E) Medical cannabidiol registration card—application and issuance to patient.

154.3(1) The department may issue a registration card to a patient who meets the criteria listed at Iowa Code section 124E.4(1). The application form is available on the department's website. The department shall not approve an application that does not include the information requested on the application form.

154.3(2) Upon the completion, verification, and approval of the patient's application and the receipt of the required fee, the department shall issue a registration card to the patient.

154.3(3) A registration card issued to a patient 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 valid photo identification. If the patient's information has changed since the issuance of the patient's valid photo identification, the patient shall first update the patient's valid identification to reflect the patient's current information.

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. A statement that the registration card is not valid for identification purposes.

154.3(4) Every patient 18 years of age or older must obtain a valid registration card to use medical cannabidiol in Iowa.

154.3(5) An authorization to use medical cannabidiol or cannabis for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E and is not a valid registration card for purposes of purchasing medical cannabidiol at dispensaries in Iowa.

641—154.4(124E) Medical cannabidiol registration card —Reciprocity. A registration card's reciprocity with other states is established in Iowa Code section 124E.18.

154.4(1) A patient with a valid registration card from another state or jurisdiction maintains the affirmative defense for possession of medical cannabidiol provided the cannabis product in their possession may be manufactured and sold at a licensed dispensary in Iowa.

154.4(2) A patient with a valid registration card under the laws of another state or jurisdiction, has no affirmative defense for possession of medical cannabidiol, if the cannabis product in their possession may not be manufactured and sold at a licensed dispensary in Iowa. Prohibited forms of medical cannabidiol include:

a. Raw cannabis flower that may be combusted or smoked;

b. Edible products with a "total THC" concentration > 0.3% that is not a consumable hemp product.

641—154.5(124E) Medical cannabidiol registration card—application and issuance to primary caregiver.

154.5(1) For a patient in a primary caregiver's care, the department may issue a registration card to a primary caregiver who meets the criteria listed at Iowa Code section 124E.4(3). The application form is available on the department's website. The department shall not approve an application that does not include the information requested on the application form.

154.5(2) Upon the completion, verification, and approval of the primary caregiver's application, the department shall issue a registration card to the primary caregiver.

154.5(3) A registration card issued to a primary caregiver 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 valid photo identification. If the primary caregiver's information has changed since issuance of the primary caregiver's valid photo identification, the primary caregiver shall first update the primary caregiver's valid photo identification to reflect the primary caregiver's current information.

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 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 registration number.

d. A statement that the registration card is not valid for identification purposes.

e. A statement distinguishing the registration cardholder as a primary caregiver.

154.5(4) An authorization to use, or to act as a primary caregiver for a patient authorized to use medical cannabidiol or cannabis for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E and is not a valid registration card for purposes of purchasing medical cannabidiol at dispensaries in Iowa..

641—154.6(124E) Denial and cancellation. The department may deny an application for a registration card, or may cancel a registration card, for any of the following reasons:

a. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.

b. The department is unable to verify the identity of the applicant from the photo identification or other documentation presented during application.

c. The department has reasonable belief, or proof, that the patient is engaged in diversion of medical cannabidiol.

d. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.

e. 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 registration card. The department shall notify a primary caregiver in writing when the registration card of the primary caregiver's patient has been canceled.

f. A primary caregiver requests in writing that the department cancel the primary caregiver's registration card. The department shall notify a patient in writing when the registration card of the patient's primary caregiver has been canceled.

g. The department becomes aware of the death of a patient or primary caregiver.

h. A health care practitioner requests in writing that the department rescind the written certification the practitioner provided to a patient or caregiver.

i. A patient requests in writing that the department cancel the patient's primary caregiver's registration card.

641—154.7(124E) Appeal.

154.7(1) *Written notice of denial or cancellation.* If the department denies an application for or cancels a registration card, the department shall inform the applicant or cardholder of the denial or cancellation, state the reasons for the denial or cancellation in writing, and state the effective date of the denial or cancellation. If the department cancels a card upon request from a patient or primary caregiver, or the department becomes aware of the death of a patient or primary caregiver, the cancellation is effective immediately upon issuance of the written notice of cancellation. If the department cancels a card upon any other ground listed, the cancellation shall become effective 30 days following issuance of the written notice of cancellation.

154.7(2) *Effect of written notice of cancellation on use and possession of medical cannabidiol.* A cardholder is authorized to purchase, possess, and use medical cannabidiol up to and including the effective date of the cancellation. For purposes of the affirmative defenses in Iowa Code section 124E.12, a patient or primary caregiver shall be deemed to be in possession of a valid registration card up to and including the effective date of the cancellation.

154.7(3) *Request for appeal.* A request for appeal concerning the denial or cancellation of a registration card shall be submitted pursuant to the provisions of 441—7. In the event of a timely appeal, cancellation of the card shall be deemed to be suspended pending the outcome of the contested case proceeding. If the cancellation is

affirmed following the contested case proceeding, the card cancellation shall become effective 30 days following issuance of the department's final agency action.

641—154.8(124E) Duplicate card.

154.8(1) *Lost, stolen, or destroyed card.* To replace a registration card that is lost, stolen, or destroyed, a cardholder shall present to the department the cardholder's valid photo identification that was provided at the time of application.

154.8(2) *Change in card information and voluntary replacement.*

a. To replace a registration card that is damaged, the cardholder shall surrender the card to be replaced to the department and present the cardholder's valid photo identification that was provided at the time of application.

b. A patient or primary caregiver to whom a registration card is issued shall notify the department of a change in information listed on the card, within ten calendar days of the change. To replace a registration card to change the patient or primary caregiver's information, the cardholder shall surrender the card to be replaced to the department and present the patient or primary caregiver's updated valid photo identification.

c. To replace a registration card held by a primary caregiver to change, add, or remove a patient's 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—154.5(124E). A registration card issued pursuant to this paragraph shall not be considered a duplicate card.

154.8(3) *Expiration date.* A duplicate registration card shall have the same expiration date as the registration card being replaced, changed, or amended.

641—154.9(124E) Renewal. A registration card shall be valid for one year from the date of issuance, unless canceled. Renewal of a registration card will follow the application and issuance rules of this chapter.

641—154.10(124E) Confidentiality. The department will follow the confidentiality provisions in Iowa Code section 124E.11(1)

154.10(1) Personally identifiable information of patients and primary caregivers will be maintained as confidential and is not accessible to the public. The department will release aggregate and statistical information regarding the 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 only pursuant to Iowa Code section 124E.11(1)(b) and to a patient, primary caregiver, or health care practitioner, upon written authorization of the patient or primary caregiver.

641—154.11(124E) Fees. All fees are nonrefundable. Application fees are established in Iowa Code section 124E.4.

641—154.12(124E) Consumption of medical cannabidiol. Medical cannabidiol should be consumed privately, and patients are subject to all applicable laws regarding public impairment and operating a vehicle, including but not limited to Iowa Code section 123.46 and Iowa Code chapter 321J. Medical cannabidiol products shall not be consumed on the property of a medical cannabidiol dispensary or manufacturer.

641—154.13(124E) Allowable forms of medical cannabidiol.

154.13(1) *Modification of allowable forms.* Allowable forms of medical cannabidiol may be modified by approval of a recommendation by the medical cannabidiol board, subsequent approval of the board of medicine, and adoption of the recommendations by the department.

154.13(2) *Allowable forms.*

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 shall not produce medical cannabidiol in any form that may be smoked.

c. A manufacturer shall not produce edible medical cannabidiol products.

MANUFACTURER AND DISPENSARY LICENSING

641—154.14(124E) Notice to law enforcement. The department shall notify local law enforcement agencies and the department of public safety of the locations of manufactures and 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.

641—154.15 (124E) Manufacturer and dispensary licensure.

154.15(1) To be eligible for licensure, an applicant manufacturer or dispensary shall complete a background investigation pursuant to Iowa Code section 124E.19. Applicants must provide information on forms and in a manner required by the department of public safety.

154.15(2) The license shall be renewed annually unless a manufacturer or 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.

154.15(3) A license to manufacture or dispense medical cannabidiol issued by the department is not assignable or transferable.

641—154.16(124E) Collection of fees in competitive licensing 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.

154.16(1) *Fees to the department for manufacturers and dispensaries*. Fees for manufacturing applicants are established by Iowa Code section 124E.6(4). Fees for dispensary applicants are esablished by Iowa Code section 124E.8(4).

a. Licensed manufacturers and dispensaries shall pay an annual fee to the department to cover costs associated with regulating and inspecting, 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, payable to the department no later than December 1. Annual fees assessed by the department shall not exceed $100,000 for a manufacturing license and shall not exceed $50,000 for a dispensary license.

154.16(2) *Fees to the department of public safety.*

a. An applicant manufacturer or dispensary shall reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure. The department of public safety retains the right to bill a licensee for additional background investigations, as needed.

b. Each manufacturer or dispensary awarded a license shall, at the time of notice of award to license, 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 or dispensary.

c. A licensed manufacturer or 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 manufacturer or dispensary. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the manufacturer or 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 manufacturer or 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.

154.16(3) *Criminal background checks.*

a. A manufacturer or the 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 record check.

b. An employee of a manufacture or 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 manufacture or 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.

641—154.17(124E) Licensure Renewal

154.17(1) A licensed manufacturer or dispensary shall apply to renew its license with the department at least six months before the license expires. The application shall be submitted on a form on the department's website.

154.17(2) The department shall notify a manufacturer or dispensary of the decision to approve or deny the manufacturer or dispensary's license by August 1 of the year in which the renewal application is submitted.

641—154.18(124E) Suspension or Revocation of a manufacturing or dispensary license.

154.18(1) The department may suspend or revoke a manufacturer or 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 manufacturer or dispensary's business owner or investors to have a satisfactory result in a background investigation or national criminal history background check as determined by the department.

154.18(2) The department shall notify the manufacturer or dispensary of the proposed action pursuant to Iowa Code section 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.

154.18(3) A request for appeal concerning the suspension or revocation of a license shall be submitted pursuant to the provisions of 441—7.

641—154.19(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.

641—154.20(124E) Closure of operations.

154.20(1) A manufacturer or dispensary shall notify the department at least six months before the closure of the manufacturing facility.

154.20(2) If a manufacturer or dispensary ceases operation, the manufacturer or dispensary shall work with the department to verify the remaining inventory of the manufacturer or dispensary and ensure that any plant material, plant material waste, and/or medical cannabidiol products are destroyed at a waste facility or returned to a manufacturer.

641—154.21(124E) Manufacturer and dispensary security requirements.

154.21(1) *Restricted access.* A manufacturer or dispensary shall limit entrance to all restricted areas by completing all of the following:

a. Mark restricted access areas with signs that state: "Do Not Enter – Restricted Access Areas Access Limited to Authorized Personnel Only".

b. Use a controlled access system that:

(1) Limits access to authorized individuals;

(2) Maintains a log of individuals with approved access, including dates of approvals and revocations;

(3) Tracks times of personnel entry to and exit from the facility;

(4) Stores data for retrieval for a minimum of one year; and

(5) Limits access to authorized individuals in the event of a power failure.

c. If the controlled access system cannot electronically record visitors, visitors to restricted access areas sign manifests with name, date, and times of entry and exit. These manifests shall be kept and stored for a minimum of one year.

d. Visitors wear badges that are visible at all times and identify them as visitors.

e. If requested by the department, submit stored controlled access system data to the department within five business days.

154.21(2) *Perimeter intrusion detection system.*

a. Computer-controlled video surveillance system. A manufacturer or dispensary shall operate and maintain 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, if applicable;

(2) All areas that might contain plant material and/or medical cannabidiol;

(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 manufacturer or dispensary or its parking areas;

(2) Produce a clear, color still photograph live or from a recording;

(3) Have 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. Video recording equipment shall:

(1) Export still images in an industry standard image format, such as .jpg, .bmp, or .gif.;

(2) Archive exported video in a format that ensures authentication and guarantees that the recorded image has not been altered; and,

(3) Save exported video shall be saved in an industry standard file format that can be played on a standard computer operating system.

d. Location: 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 manufacturer or 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; and

(3) Maintained free of alteration or corruption.

f. Required signage. A manufacturer or dispensary shall post a sign in capital letters in a conspicuous location at every entrance to the manufacturing facility or dispensary that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

154.21(3) *Security alarm system requirements*

a. A manufacturer or dispensary shall use a professionally monitored security alarm system that provides intrusion and fire detection of all the following: Dispensary entrances and exits;

(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. A manufacturer or dispensary's security alarm system and all devices shall continue to operate during a power outage.

c. A manufacturer or dispensary shall provide documentation of the annual inspection and device testing, by a qualified alarm vendor, to the department upon request.

154.21(4) *Personnel identification system.* A manufacturer or dispensary shall use a personnel identification system that controls and monitors individual employee access to restricted access areas .

a. 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 or dispensary '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 or dispensary shall immediately:

(1) Revoke the employee's access to the manufacturing facility or dispensary; and

(2) Destroy the employee's identification card, if possible.

641—154.22 (124E) Advertising and marketing.

154.22(1) *Permitted marketing and advertising activities.* A manufacturer or dispensary must include medical cannabidiol pricing and hours of operation on its website and may do the following:

a. Display the manufacturer or 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.

b. Display signs on the manufacturing facility or dispensary; and

c. Maintain a business website that contains the following information:

(1) The manufacturer or dispensary's name and contact information;

(2) The medical cannabidiol forms and quantities manufactured or available in Iowa; and

(3) Other information as approved by the department.

154.22(2) *Prohibited conduct, statements and illustration.*

a. An advertisement for medical cannabidiol shall not contain:

(1) Colloquial references to cannabis;

(2) Names of cannabis plant strains or varieties;

(3) Any statement that is false or misleading;

(4) Any statement that disparages a competitor's products;

(5) Any statement, design, or representation, picture or illustration that is obscene or indecent;

(6) Any statement, design, representation, picture or illustration that reasonably appeals to or targets children;

1. Appealing to children means:

- when taken literally or as a plan language reading, there is a resemblance to food or product used by children;
- contains child-appealing visuals/graphics, such as intense colors, bubble letters, or other interesting fonts or lettering;
- unconventional or interesting product names;
- unconventional or unexpected flavor, color, or shape of the product;
- games or activities present on the package; or
- presence of branded characters, spokespersons, licensed characters, cartoons, or celebrities

(7) Any statement, design, representation, picture or illustration that encourages or represents the use of medical cannabidiol for a condition other than a qualifying debilitating medical condition;

(8) Any statement, design, representation, picture or illustration that encourages or represents the recreational use of medical cannabidiol or marijuana, tobacco or nicotine products, or alcohol;

(9) Any statement, design, representation, picture or illustration related to the safety or efficacy of medical cannabidiol, unless supported by substantial evidence, substantial clinical data, and/or direct patient testimonials;

(10) Any statement, design, representation, picture or illustration portraying anyone reasonably appearing to be under the age of 18, objects suggestive of the presence of anyone under the age of eighteen, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of eighteen, except that an advertisement may address medical cannabidiol products as they relate to minor patients;

(11) Any offer of a prize, award or inducement to a qualifying patient, primary caregiver, or healthcare practitioner related to the purchase of medical cannabidiol or a certification for the use of medical cannabidiol, except that non-product specific price discounts are allowed;

(12) Any statement or assertion that medical cannabidiol products are safe because they are regulated under this chapter or have been tested by an approved laboratory;

(13) Any reference to a prohibited form of medical cannabidiol;

(14) Any statement which claims that medical cannabidiol products are endorsed or supported by any government agency; or

(15) Any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the department, the state of Iowa or any person or entity associated with the state of Iowa.

b. A manufacturer or dispensary shall not engage in any of the following activities:

(1) Host, promote, refer, or otherwise advertise a third party patient certification service;

(2) Engage in any advertising, marketing, or branded educational activities within 1,000 feet of a school;

(3) Host, promote, sponsor, or otherwise participate in a cannabis consumption lounge or other such encouragement of public consumption of cannabis or medical cannabidiol; or

(4) Advertise, or make reference to, non-approved forms of medical cannabidiol in any of its advertisements, including, but not limited to:

1. Referring to an approved form of medical cannabidiol as a prohibited form of medical cannabidiol.
2. Advertising non-approved forms of medical cannabidiol. Consumable hemp products regulated under Iowa Code Chapters 204 and 641—Chapter 156 are exempt from this provision.

154.22(3) *Review of advertisements by the department*. Any advertisement for medical cannabidiol shall be submitted to the department, on a form or in a format prescribed by the department, at the same time as, or prior to, the dissemination of the advertisement.

a. The department may:

1. Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the department determines that the advertisement would be false or misleading without such a disclosure; or

2. Require changes that are necessary to protect the public health, safety and welfare or

3. Require statements for inclusion in the advertisement to address the specific efficacy of medical cannabidiol as it relates to specific disease states or approved debilitating medical conditions, disease symptoms, and population groups.

b.The Department reserves the right to require that a licensee amend or remove a public advertisement.

641—154.23(124E) 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 and medical cannabidiol;
b. Transport of plant 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.

641—154.24(124E) Financial Transactions.

154.24(1) A manufacturer or dispensary shall maintain records that reflect all financial transactions and the financial condition of the business.

154.24(2) 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; and

d. Records of all financial transactions, including contracts and agreements for services performed or services received.

641—154.25(124E) Inspection by department or independent consultant. A manufacturer or dispensary 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.

154.25(1) *Types of inspections.* Inspections may include:

a. Aspects of the business operations;

b. The manufacturing facility or the physical location of a dispensary, including any storage 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. Health and sanitary inspection

g. Other inspections as determined by the department.

154.25(2) *Compliance required.* A manufacturer or 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 manufacturer or 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 manufacturer or dispensary cannot reconcile the physical inventory with the inventory recorded in the secure sales and inventory tracking system, the manufacturer or 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.

(3) 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 or dispensary license.

(4) At the department's request and in a timely manner, a manufacturer or dispensary shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

Regulatory Analysis Template

MANUFACTURING

641—154.26(124E) Manufacturer operations.

154.25(1) *Operating documents.* 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 means.

a. 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 disposal methods for all waste materials;
5. Employee training methods for the specific phases of production. A manufacturer may make operating documents for these procedures available on site only;
6. 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;
7. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;
8. Sampling strategy and quality testing for labeling purposes. A manufacturer may make operating documents for these procedures available on site only;
9. Medical cannabidiol packaging and labeling procedures;
10. Procedures for recall of medical cannabidiol;
11. 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;
12. A business continuity plan. A manufacturer may make this operating document available on site only;
13. Records relating to all transport activities; and
14. 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.

154.26(2) *Prohibited activities.* In addition to following all provisions of Iowa Code section 124E.7, a manufacturer shall not:

a. Produce or manufacture medical cannabidiol in any location except in those areas approved by the department;

b. Sell, deliver, transport, or distribute medical cannabidiol from any location except its manufacturing facility or a dispensary facility;

c. Produce or manufacture medical cannabidiol in Iowa for sales or distribution outside of Iowa;

d. Sell or distribute medical cannabidiol to any person or business other than a dispensary or manufacturer licensed by the department under Iowa Code chapter 124E;

e. 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;

f. Transport or deliver medical cannabidiol to any location except as allowed in subrule 154.22(1);

g. Introduce synthetic or semi synthetic cannabinoids derived from hemp into medical cannabidiol products .

h. Produce synthetic or semi synthetic cannabinoids within the licensed manufacturing facility .

641—154.27 (124E) Record-keeping requirements.

154.27(1) *Manufacturer 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.

154.27(2) *Manufacturer operations and inventory reporting other records*.

a. A manufacturer or dispensary 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) Transportation manifests and incident reports; and

(4) Records of all samples sent to a testing laboratory and the quality assurance test results.

b. A manufacturer or dispensary shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

154.27(3) *Manufacturer entry into the secure sales and tracking system*.

a. A manufacturer or dispensary shall use the secure sales and inventory tracking system to maintain the following:

(1) Batch and Harvest records;

(2) Crop input and additive records;

(3) Extraction and production records;

(4) Transportation records;

(5) Inventory records;

(6) Solvent and processing chemical records; and

(7) Other records as determined by the department.

b. Unless otherwise provided in these rules, a manufacturer shall adhere to the following schedule for entering data into the secure sales and inventory tracking system.

(1) A manufacturer shall enter data in real time for data related to:

1. Transport of medical cannabidiol, plant material, and laboratory samples;
2. Sales of medical cannabidiol to dispensaries;
3. The creation of process lots containing a unique identifier; and
4. The creation of package lots containing a unique identifier

c. A manufacturer shall enter inventory reports on key inventory events into the secure sales and inventory tracking system within five business days in which the event occurred. These inventory reports include, but are not limited to:

(1) Batch reports;

(2) Crop input and additive reports;
(3) Harvest reports;
(4) Extraction reports;
(5) Solvent and processing chemical reports;
(6) Package lot reports;
(7) Certificates of Analysis from a laboratory;
(8) Other records as determined by the department.

d. State of Iowa Manufacturer API guide. The department shall maintain a document describing the IT requirements and acceptance criteria for reporting information to the secure sales and inventory tracking system. The department shall provide manufacturers 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 include:

(1) The schedule and means of data reporting;
(2) Integration requirements for third party vendors; and
(3) Be available on the department's website (hhs.iowa.gov).

641 – 154.28(124E) Recall of medical cannabidiol products. Medical cannabidiol products may be recalled in the following ways:

154.28(1) Voluntarily by a licensed manufacturer.

154.27(2) By the department. If the department determines, based on an evaluation, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may require a manufacturer to recall such violative medical cannabidiol products from dispensaries. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be conducted by an ad hoc committee of scientists appointed by the department and shall consider, but need not be limited to, each of the following factors:

a. Whether any disease or injuries have already occurred from the product.

b. Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

c. A holistic assessment of the hazard and its present and future potential consequences.

641—154.29(124E) Quality assurance and control.

154.29(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 stability studies, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and product expiration dates.

154.29(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.

154.29(3) *Sampling and testing*. A manufacturer shall:

a. Work with the department and laboratory personnel to develop acceptance criteria for contaminants, including, but not limited to: cannabinoid content, metals, microbiological impurities, solvents, 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. sampling methods results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol are homogenous and representative of the process or package lot.

c. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, and any other relevant quality control criteria when remixing and retesting are not warranted;

d. Develop and follow a written procedure for responding to results failing to meet established standards, 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 when remixing and retesting are not warranted; and

(3) Instructions for determining the source of contamination;

e. Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.29(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 departmental guidance pursuant to subrule 154.47(1);

(2) Storage conditions for samples retained for testing; and

(3) Reliable and specific test methods.

(4) Stability studies shall include:

(5) Medical cannabidiol testing at appropriate intervals; and

(6) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.

b. If product-expiration-date studies have not been completed a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information.

c. If a manufacturer determines a product expiration date beyond one year, a manufacturer shall submit justification to the department, and receive approval, prior to labeling a product with an expiration date beyond one year.

154.29(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 one year from the date of manufacture.

c. After one year from the date of manufacture, reserve samples shall be destroyed.

154.29(6) *Retesting*. If the department deems that public health may be at risk, the department may require the manufacturer to retest any sample of medical cannabidiol.

154.29(7) *Disposal of substandard product*. A manufacturer shall dispose of all medical cannabidiol when samples fail to meet established standards, and other relevant quality control criteria.

154.29(8) *Recall procedures*. Each manufacturer shall establish a procedure for recalling product from the market 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 necessary;

b. Manufacturer's personnel who are responsible for overseeing the recall ; and

c. How to notify affected parties of a recall.

641—154.29(124E) Packaging and labeling.

154.30(1) *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.

154.30(2) *Medical cannabidiol packaging*.

a. Requirements of medical cannabidiol package containers. 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—154.30(2)"c";

(2) Designed to maximize the shelf life of the contained medical cannabidiol;

(3) Tamper-evident; and

(4) Child-resistant.

b. Medical Cannabidiol Package prohibitions. The packaging for medical cannabidiol shall not:

1. Bear a reasonable resemblance to commonly available nonmedical commercial products;

2. Depict images other than the manufacturer's business name or logo on the packaging;

3. Reasonably appeal to children. See also 641 — 154.22(2);

4. Reasonably appeal to recreational or adult use; or

5. Depict images other than the manufacturer's business name or logo on the packaging.

c. Requirements of medical cannabidiol packaging. A manufacturer shall ensure that all medical cannabidiol packaging includes the following information:

(1) The name of the manufacturer, and trade name if applicable;

(2) A label claim concentration for cannabinoid content including:

1. Tetrahydrocannabinol,
2. Tetrahydrocannabinolic acid; concentrations of tetrahydrocannabinolic acid may be omitted if the manufacturer uses decarboxylation or other means to substantially remove the acids from the product prior to testing;
3. Cannabidiol; and
4. Cannabidiolic acid; concentrations of cannabinolic acid may be omitted if the manufacturer uses decarboxylation or other means to substantially remove the acids from the product prior to testing;

(3) The number of servings per package;

(4) The directions for use of the product, including recommended and maximum amount by age and weight, if applicable;

(5) All ingredients of the product shown with common or usual names, including but not limited to, any additives, terpenes or artificial flavors, diluents and carriers, and preservatives, listed in descending order by predominance of weight. Any third-party hemp-derived cannabinoids into medical cannabidiol products shall be specifically indicated on the ingredients list, separately from medical cannabidiol produced within the manufacturer's facility;

(6) Instructions for storage, including light and temperature requirements, if any; and

(7) The universal warning symbol provided by the department.

d. The following information shall be included with medical cannabidiol packaging, or contained within a package insert:

(1) 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.";

(2) 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;"

(3) A package may contain multiple labels if the information required by this rule is not obstructed.

154.30(3) *Medical cannabidiol labeling.*

a. After receiving a passing certification of analysis for a package lot from a laboratory, and prior to distribution to dispensaries, a manufacturer shall affix a label to each individual package of medical cannabidiol containing that contains following information:

(1) A unique lot number;

(2) The date of manufacture;

(3) Product expiration date;

1. This date shall be one year from the date of manufacture unless a manufacturer has conducted stability studies, and received approval from the department for an extended expiration date.

b. Cannabinoid content for:

(1) tetrahydrocannabinol,

(2) tetrahydrocannabinolic acid, concentrations of tetrahydrocannabinolic 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) cannabidiol; and

(4) cannabidiolic acid.

641—154.31(124E) Transportation of medical cannabidiol and plant material.

154.31(1) *Transport of medical cannabidiol or plant material.* A manufacturer is authorized to transport medical cannabidiol or plant material to and from:

a. Dispensaries;

b. A laboratory for testing;

c. A waste facility for disposal;

d. A manufacturer licensed by the department under Iowa Code chapter 124E;

e. Other sites only with departmental approval.

154.31(2) *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 unique ID of each individual process lot or package lot 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

(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, manufacturer, or waste facility, as applicable, of the expected arrival time and transmit a copy of the manifest to the dispensary, laboratory, manufacturer, 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, manufacturer, or waste facility.

d. An authorized employee at the dispensary, laboratory, manufacturer, 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, manufacturer, 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.

154.31(3) *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 non-emergency 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. An employee in a transport motor vehicle shall have telephone access with the manufacturer's personnel.

641—154.32(124E) Disposal of medical cannabidiol and plant material.

154.32(1) *Return of medical cannabidiol from dispensaries and laboratory.* A manufacturer may collect at no charge medical cannabidiol waste from dispensaries. A manufacturer who chooses to collect medical cannabidiol waste may use it for research and development or retained samples, but the manufacturer shall not introduce medical cannabidiol returned from laboratory into lots of products intended for sale. Notwithstanding this provision, a manufacturer shall:

a. Dispose of medical cannabidiol waste; and

b. Maintain a written record of disposal.

154.32(2) *Medical cannabidiol and plant material waste.* A manufacturer shall store, secure, manage, and record 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 and plant material waste at an approved facility.

b. Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable.

c. 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 applications regulations.

641—154.33(124E) Production requirements.

154.33(1) *Cultivation and processing.*

a. All phases of production shall take place in designated, restricted access areas in accordance with rule 641—154.21(124E).

b. The production process shall be designed to limit contamination.

c. Each production area shall allow for access, observation, and inventory of each plant group.

154.33(2) *Crop inputs and plant batches.*

a. The manufacturer shall use the 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; and

(5) A copy of or electronic link to the safety data sheet for the crop input applied.

b. At the time of harvesting, 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.

c. Each batch or part of a batch of cannabis plants that contributes to a lot of medical cannabidiol shall be recorded in the secure sales and inventory tracking system or other manifest system.

154.33(3) *Production of medical cannabidiol.*

a. A manufacturer shall obtain approval from the department for use of any hydrocarbon-based extraction process.

b. Medical cannabidiol shall be prepared, handled, and stored in compliance with the sanitation requirements in this rule.

c. A manufacturer shall produce shelf-stable, nonperishable forms of medical cannabidiol.

d. A manufacturer shall ensure that the cannabinoid content of the medical cannabidiol it produces is homogenous.

e. Each lot of medical cannabidiol shall be assigned a unique lot number and recorded in the secure sales and inventory tracking system or other manifest system.

154.33(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. Employees have accessible toilet facilities that are sanitary and in good repair; and

m. Plant material and medical cannabidiol that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

154.33(5) *Storage.*

a. A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing, ensuring that:

(1) Plant material and medical cannabidiol are returned to a secure location immediately after completion; and

(2) The tanks, vessels, bins, or bulk containers containing plant material or medical cannabidiol are locked inside a secure area.

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, at all times, a manufacturer shall store all plant material and 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.

154.33(6) *Scales.* All scales used to weigh usable plant material for purposes of these rules shall be certified in accordance with ISO/IEC 17025 dated 2017, which is incorporated herein by reference.

641 – 154.33 (124E) Supply and inventory.

154.34(1) *Reliable and ongoing supply.* A manufacturer shall provide a reliable and ongoing supply of medical cannabidiol to medical cannabidiol dispensaries.

154.34(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.

154.34(3) *Inventory tracking required.* A manufacturer shall use the secure sales and inventory tracking system to track medical cannabidiol production from seed or plant cutting through distribution of medical cannabidiol to a dispensary.

154.34(4) *Reconciliation.* No less often than every two calendar weeks, a manufacturer shall reconcile its physical inventory with the inventory recorded in the 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

b. Discrepancies between the physical inventory of the manufacturer and the inventory recorded in the secure sales and inventory system shall be handled as follows:

(1) A manufacturer shall report suspected diversion of medical cannabidiol to the department-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

DISPENSING

641—154.35(124E) Duties of the department.

154.35(1) *Inspection of dispensaries.* The department or its agents shall conduct regular inspections of dispensaries and their facilities.

154.35(2) *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.

c. Total tetrahydrocannabinol purchased in the last 90 days by a patient and the patient's primary caregiver.

154.35(3) *Recall of medical cannabidiol products.* If the department determines, based on an evaluation of the health hazard presented, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may require a dispensary to recall such violative medical cannabidiol products from the dispensary facility and from patients. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be conducted by an ad hoc committee of scientists appointed by the director of the department and shall consider, but need not be limited to, each of the following factors:

a. Whether any disease or injuries have already occurred from the product.

b. Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

c. A holistic assessment of the hazard and its present and future potential consequences.

154.35(4) *Permissible disclosure*. The department may disclose patient-specific dispensing data to the certifying provider upon written request by the patient, caregiver, or certifying provider.

641—154.36(124E) Dispensary operations.

154.36(1) *Operating documents.* A dispensary shall maintain operating documents that accurately reflect the dispensary's standard operating procedures. Unless otherwise noted, a dispensary shall make the operating documents available to the department upon request, through secure means.

a. The operating documents of a dispensary shall include all of the following:

(1) 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. Procedures to ensure the dispensary does not dispense more than a patient's certified limit of total tetrahydrocannabinol to a patient and the patient's primary caregiver(s) in a 90-day period;
7. Medical cannabidiol labeling procedures;
8. Procedures for recall of medical cannabidiol;
9. Plans for responding to a security breach at the dispensary facility;
10. A business continuity plan; and
11. 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 of the dispensary facility containing medical cannabidiol.

154.36(2) *Prohibited activities.* In addition to following all provisions of Iowa Code section 124E.7, a dispensary shall not:

a. Dispense medical cannabidiol in any location except in those areas approved by the department;

b. Sell, receive, transport, or distribute medical cannabidiol from any location except its dispensary;

c. Sell, receive, or distribute medical cannabidiol from any entity other than a manufacturer licensed by the department;

d. Sell or distribute medical cannabidiol to any person other than an approved patient or primary caregiver;

(1) Transport or deliver medical cannabidiol to any location, unless approved by the department;

(2) Sell medical cannabidiol that is not packaged and labeled in accordance with rules

(3) Repackage medical cannabidiol or remove the manufacturer's label;

641—154.37 (124E) Record-keeping requirements.

154.37(1) *Dispensary sales*. Within one business day of sale, a dispensary shall record complete and accurate electronic sales transaction records in the 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 and time 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.

641—154.38(124E) Storage.

154.38(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.
154.38(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.

641—154.39(124E) Dispensing.

154.39(1) *Access to all forms of product.* A dispensary shall provide access to all medical cannabidiol forms produced by each licensed manufacturer.
154.39(2) *Dispensing to a patient or primary caregiver.*
a. Prior to dispensing any medical cannabidiol to a patient, a dispensary shall do all of the following:
(1) Verify the patient or primary caregiver's identity using acceptable photo identification and is over 18 years of age. Acceptable photo identification includes:
1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. A U.S. passport,
4. A U.S. military ID or veteran ID,
5. A tribal ID card/document;
(2) Verify that the patient and primary caregiver, if applicable, is registered and listed in the secure sales and inventory tracking system and has a valid medical registration card;
(3) Check the secure sales and inventory tracking system for the patient's total tetrahydrocannabinol 90-day purchase limit and the amount of total tetrahydrocannabinol that the patient and the patient's primary caregiver(s) have purchased on behalf of the patient in the past 90 days to ensure that the amount of total tetrahydrocannabinol sold by the dispensary to the patient does not exceed the patient's purchase limit;
(4) Assign a tracking number to any medical cannabidiol that is to be dispensed to the patient or primary

caregiver;

(5) Issue a label that contains the following information, which may be printed on a secondary label or package insert:

1. The medical cannabidiol tracking number;
2. The patient registration number;
3. The date and time the medical cannabidiol is dispensed;
4. The name and address of the dispensary; and,
5. 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.

641—154.40(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.

641—154.41(124E) Disposal of medical cannabidiol.

154.41(1) *Identification of excess, expired, or damaged medical cannabidiol.* Dispensaries shall identify unused, excess, expired, or damaged medical cannabidiol.

154.41(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 may 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 medical cannabidiol returned from a patient or primary caregiver being returned to the manufacturer:

(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;

(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

154.41(3) Unused, excess, expired, damaged, or returned medical cannabidiol shall be stored as described in subrule 154.38(2).

154.41(4) *Return of medical cannabidiol to a manufacturer.* A dispensary shall record information on all medical cannabidiol collected by the manufacturer in the secure sales and inventory tracking system. Information shall include:

a. The date the medical cannabidiol was collected by the manufacturer;

b. The quantity of medical cannabidiol collected; and

c. The type and lot number of medical cannabidiol collected.

641—154.42(124E) Inventory.

154.42(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.

154.42(2) *Real-time inventory required.* A dispensary shall use the 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.

154.42(3) *Reconciliation.* At least once a calendar week, a dispensary shall reconcile all medical cannabidiol with the inventory recorded in the 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.

154.43 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.

MEDICAL CANNABIDIOL BOARD

641—154.44(124E) Purpose and duties of board The purpose of the board is to administer the provisions of Iowa Code section 124E.5.

641—154.45(124E) Organization of board and proceedings.

154.45(1) *Membership.* The board shall be composed of members as set forth in 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.

154.45(2) *Vacancies.* Vacancies shall be filled in the same manner in which the original appointments were made for the balance of the unexpired term.

154.45(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.

154.45(4) *Board meetings.*

a. Board meetings shall be conducted in accordance with the open meetings requirements of Iowa Code chapter 21.

b. The department's Bureau of Cannabis Regulation shall schedule the time, date and location of meetings.

c. A majority of the members shall constitute a quorum for conducting business of the board.

d. An affirmative vote of a majority of the board members present at a meeting is required for a motion to pass.

154.45(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.

154.45(6) *Subcommittees.* The board may designate one or more subcommittees to perform such duties as may be deemed necessary.

641—154.46(124E) Petitions for the addition or removal of medical conditions, medical treatments or debilitating diseases. Pursuant to Iowa Code section 124E.5(3)(a) the board shall accept and review petitions to modify the list of debilitating medical conditions for the medical use of cannabidiol. The petition shall be in accordance with 441–Chapter 4, except that the caption should read Petition for Addition or Removal.

154.46(1) *Inquiries.* Inquiries concerning the status of a petition may be made to the Bureau of Cannabis Regulation at the Department's address.

154.46(2) *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.

154.46(3) *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.

154.46(4) *Board response.* The board shall notify the petitioner, in writing of the decision within six months after the filing, unless the petitioner agrees to a time extension. If the petition is granted, the board will recommend addition or removal of the medical condition, medical treatment or debilitating disease to the board of medicine. If the petition is denied the board will provide the rationale for the denial. Notification occurs when the board mails the writing to the petitioner.

154.46(5) *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.

LABORATORY TESTING

641—154.47(124E) Requirements of the department.

154.47(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 (hhs.iowa.gov).

154.47(2) *Review and approval of manufacturer sampling protocols.* The department shall have two weeks to review and approve or request revisions to a manufacturer's sampling protocols.

154.47(3) *Review and approval of manufacturer stability-testing procedures.* The department shall have two weeks to review and approve or request revisions to a manufacturer's stability-testing procedures.

154.47(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.

154.47(5) *Review of laboratory applications.* The department shall establish a process to review applications from prospective medical cannabidiol testing laboratories. Prospective laboratories shall apply on a form created by the department. The department will determine whether the laboratory meets the criteria for an independent medical cannabidiol testing facility as set forth in the definition of "laboratory" in Iowa Code section section 124E.2 in addition to determining whether the laboratory meets laboratory requirements pursuant to these rules.

154.47(7) *Regulation of independent laboratories.* The department shall determine on an annual basis whether any approved independent laboratory continues to meet the application criteria of this rule. The department shall establish a process for the annual review of approved independent laboratories. An independent laboratory 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.

641—154.48(124E) Requirements of a laboratory.

154.48(1) *Minimum testing requirements.* A laboratory shall establish and implement test methods, corresponding standard operating procedures for the analyses of cannabinoids, residual solvents and processing chemicals, pesticides, microbiological impurities, and metals and other analyses as requested by the department.

154.48(2) *Level of quantitation.* A laboratory shall be able to demonstrate that its level of quantitation (LOQ) is below any action level established by the department.

154.48(3) *Inventory tracking.* A laboratory shall record the following:

a. The receipt of medical cannabidiol from a manufacturer for testing.

b. The return of medical cannabidiol or waste to a manufacturer.

154.48(4) *Hazardous waste disposal.* A laboratory shall do the following when dealing with hazardous waste:

a. Discard hazardous waste, including hazardous waste containing medical cannabis goods, in accordance with federal and state hazardous waste laws.

b. Document the waste disposal procedures followed for each sample.

641—154.49(124E) Requirements of a manufacturer.

154.49(1) *Assuming costs.*

a. A manufacturer shall assume the costs for all laboratory testing pertaining to verification studies on new products, the cost of standard testing protocols as outlined in a Laboratory Acceptance and Criteria Document and other tests as requested by the department. A manufacturer shall provide any necessary reference materials to the laboratory at no cost.

154.49(2) *Obtaining approval for sampling protocols.* A manufacturer shall obtain approval from the department for the manufacturer's sampling protocols prior to submitting samples for laboratory testing related to content and contamination.

154.49(3) *Obtaining approval for stability-testing procedures.* A manufacturer shall obtain approval from the department for the manufacturer's stability-testing procedures prior to submitting samples for laboratory testing related to stability testing and product-expiration-date studies.

641—154.50(124E) Content testing.

154.50(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 and CBD potency testing according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.47(1).

c. 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 154.50(1)*"b."*

d. The laboratory may test for and provide test results for additional cannabinoid analytes if asked to do so by a requester.

154.50(2) *Contaminants testing*

a. For each unique lot of medical cannabidiol, unless otherwise referenced in the laboratory testing requirements and acceptance criteria document described in subrule 154.47(1), a laboratory shall conduct contaminants testing, for the following analytes:

(1) Residual solvents and processing chemicals

(2) Pesticides

(3) Microbiological impurities

(4) Heavy metals

b. The laboratory may test and provide test results for additional contaminants if asked to do so by a requestor.

c. The department shall provide a list of contaminants for which primary samples are to be tested with corresponding action levels on the department's website (hhs.iowa.gov).

d. For each contaminant for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of contaminant is at or below the action level approved by the department.

e. For each contaminant for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of contaminants is above the action level approved by the department.

f. If a laboratory is using GC-mass spectrometry instrumentation to analyze primary samples for contaminants and the laboratory determines that a primary sample contains contaminants or 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 contaminants analytes.

g. The laboratory may test for and provide test results for additional contaminants or processing chemicals if asked to do so by a requester.

h. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each contaminant 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 contaminant 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 154.50(2)*"c"* and 154.50(2)*"d."*

(3) The names and amounts of any additional contaminants identified by the laboratory.

i. If the primary sample fails testing for residual solvents and processing chemicals, the lot fails laboratory testing.

j. When a laboratory identifies additional contaminants in a primary sample, the laboratory shall:

(1) Notify the department of the additional contaminants and the amounts detected, if applicable.

(2) Refrain from issuing a final certificate of analysis until given approval to do so by the department.

641—154.51(124E) Reporting requirements.

154.51(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 and the department

154.51(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 until given approval to do so by the department.

154.51(3) *Additional reporting requirements.*

a. In addition to the requirements described in rule 641—154.50(124E), the certificate of analysis shall contain, at a minimum, the following information:

d. All requirements of ISO/IEC 17025 dated 2017;

e. Date of primary sample collection;

f. Date the primary sample was received by the laboratory;

g. Date of each analysis;

h. The LOQ and action level for each analyte, as applicable;

i. Whether the primary sample and lot passed or failed laboratory testing; and

j. A signature by the laboratory quality officer or delegate and the date the certificate of analysis was validated as being accurate by the laboratory quality officer or delegate.

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 ≥ 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.

641—154.52(124E) Record-keeping requirements.

154.52(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.

154.52(2) *Review of data package.* After the laboratory has compiled a data package, an individual at the laboratory who was not previously involved in the creation of the data package 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.

154.52(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.

154.52(4) *Other records*. A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the testing of medical cannabidiol.

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 cannabidiol:

(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.

641—154.53(124E) Quality control. The laboratory shall have quality control protocols that include the following elements:

154.53(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.

154.53(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 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 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 (hhs.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 154.47(1). The acceptance criterion between the primary sample and the duplicate sample is less than or equal to 20 percent relative percent difference.

154.53(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.

154.53(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.

154.53(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.

154.53(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.

641—154.54(124E) Security requirements.

154.54(1) *Security policy requirement.* A laboratory shall maintain a security policy to prevent the loss, theft, or diversion of medical cannabidiol samples. The security policy shall apply to all staff and visitors at a laboratory facility.

154.54(2) *Restricted access.* A laboratory shall limit entrance to all restricted areas by completing all of the following:

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 to and exit from the laboratory;

(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. A laboratory shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

154.54(3) *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.

a. 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 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.

154.54(4) *Video monitoring and surveillance.* 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.

a. 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) Produce a clear, color still photograph live or from a recording;

(3) Have 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.

b. Video recording specifications. Video recording equipment shall:

(1) Export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Archive in a format that ensures authentication and guarantees that the recorded image has not been altered; and

(3) Save 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.

c. Additional requirements. A laboratory shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

d. 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

Retained longer, as needed, if a laboratory is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

154.54(5) *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.

154.54(6) *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.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 641-177

Iowa Code Section Authorizing Rule 1996 Iowa Acts, chapter 1212, Iowa Code 135.166

State or Federal Law(s) Implemented by the Rule 135

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10:00am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule provides that hospitals must submit data to a selected contractor of Iowa HHS. The contractor serves as an intermediary of Iowa HHS and completes data collection, maintenance, and dissemination to Iowa HHS and on Iowa HHS' behalf. Allows Iowa HHS to charge fees for administrative costs related to providing data. Requires data be kept confidential in compliance with state and federal law.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

Individuals do not bear any cost of this rule.

    - Classes of persons that will benefit from the proposed rule:

All Iowans, as this is a complete dataset representative of all incidents requiring inpatient or outpatient care.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

There is no quantitative impact associated with this chapter.

    - Qualitative description of impact:

Availability of data allows for evaluations and analyses of acute and chronic conditions to improve public health, improve the quality of health services in Iowa, and design public health programs and interventions. Also allows for data availability to provide aggregate and statistical data to partners and the public.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

No costs to the state are identified. Minimal personnel time is allocated to maintaining this dataset and all work fits into other duties as assigned.

    - Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

Nominal costs are absorbed into other duties as assigned, and less information would be available to quantify health-related needs of Iowans if this rule didn't exist.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

HHS is collecting health data in accordance with the requirements of Iowa Code. A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS implements health data collection in accordance with the requirements of Iowa Code and Iowa Acts.

    - Reasons why they were rejected in favor of the proposed rule:

Identified alternatives have not been seriously considered as any alternatives are anticipated to require additional HHS resources for implementation.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

N/A

Text of Proposed Rule:

Regulatory Analysis Template

CHAPTER 177
HEALTH DATA

641—177.1(76GA,ch1212) Definitions. For purposes of this chapter, the following definitions shall apply:

"Confidential record" in these rules means a record which is not available as a matter of right for examination and copying by members of the public under applicable provisions of law. Confidential records include records or information contained in records that the agency is prohibited by law from making available for examination by members of the public, and records or information contained in records that are specified as confidential by Iowa Code section 22.7, or other provision of law, but that may be disclosed upon order of a court, the lawful custodian of the record, or by another person duly authorized to release the record. Mere inclusion in a record of information declared confidential by an applicable provision of law does not necessarily make that entire record a confidential record. Included in the definition are those data collected by the department, pursuant to 1996 Iowa Acts, chapter 1212, for preparation and dissemination as compilations.

"Record" in these rules means the whole or a part of a "public record" as defined in Iowa Code section 22.1, that is owned by or in the physical possession of this agency.

641—177.2(76GA,ch1212) Description of data to be submitted.

177.2(1) The department shall collect information from other state agencies for the purpose of public dissemination of health data.

177.2(2) Hospitals shall submit data to the contractor selected through the request for proposal process which shall serve as an intermediary for the department. The information shall include inpatient, outpatient and ambulatory information.

177.2(3) The contractor selected through the request for proposal process shall collect, maintain, and disseminate hospital inpatient, outpatient, and ambulatory information pursuant to a memorandum of understanding with the department. The contractor selected through the request for proposal process shall submit data to the department pursuant to the memorandum of understanding.

641—177.3(76GA,ch1212) Fees. An hourly fee may be charged for fulfilling a data request. The hourly fee shall not exceed the estimated hourly wage of the department employee fulfilling the data request.

641—177.4(76GA,ch1212) Patient confidentiality. The department shall protect patient confidentiality. Confidential records or parts of such records collected as a part of this process shall be kept confidential. All health data shall be collected, maintained, and disseminated only in accordance with Iowa and federal law.

These rules are intended to implement 1996 Iowa Acts, chapter 1212, section 5, and Iowa Code section 135.166.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 641-194

Iowa Code Section Authorizing Rule 272D

State or Federal Law(s) Implemented by the Rule N/A

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter sets forth HHS procedure in denying the issuance, renewal, suspension or revocation of a professional license for nonpayment of state debt. This process commences upon receipt of a certificate of noncompliance from the centralized collection unit of the Department of Revenue.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

Applicants or licensees found to be noncompliant by the Department of Revenue.

    - Classes of persons that will benefit from the proposed rule:

Members of the public served by professionals licensed by HHS.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Regulatory Analysis Template

Estimated figures below are projections based on past program performance as included in the Red Tape Rule Report for this chapter.

Identified Impacts*

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5 Year Total
Costs HHS Implementation	($350)	($350)	($350)	($350)	($350)	($1750)
Benefits Increased Public Safety & Trust	Intangible	Intangible	Intangible	Intangible	Intangible	Intangible
Net Value	($350)	($350)	($350)	($350)	($350)	($1750)

*All monetary figures have been rounded to the nearest thousandth.

- Qualitative description of impact:

Denying professional licensure for nonpayment of state debt ensures licensees of the Department engage in professional conduct at a level suitable to their profession, leading to increased public safety and trust in HHS licensure programs.

3. Costs to the state
   - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for team members to manage this process. These costs are reflected in the table above as "HHS Implementation".

   - Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a net value of $1750 and an increase in public safety and trust. Eliminating the denial of licensure for nonpayment of state debt may result in the licensure of some individuals that do not engage in professional conduct of the level to which the state desires. Diminished professional conduct of licensees may lead to a decrease in public safety and a lack of trust in licensees regulated by the Department.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
   - Description of any alternative methods that were seriously considered by the agency:

HHS implements this process in accordance to the procedure set forth in Iowa Code. This rule chapter describes HHS timelines and communication methods for completing the procedure

but does not ascribe additional department duties or implementation elements in addition to those directly defined in Code.

- Reasons why they were rejected in favor of the proposed rule:

NA

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

NA

Text of Proposed Rule:

Regulatory Analysis Template

CHAPTER 194
NONPAYMENT OF STATE DEBT

641—194.1(272D) Definitions. For the purpose of this chapter, the following definitions shall apply.

"Applicant" means an individual who is seeking the issuance of a license.

"Centralized collection unit" means the centralized collection unit of the Iowa department of revenue.

"Certificate of noncompliance" means the same as defined in Iowa Code section 272D.1.

"Denial notice" means a licensing authority notification denying an application for the issuance or renewal of a license as required by Iowa Code section 272D.

"License" means the same as defined in Iowa Code section 272D.1.

"Licensing authority" means a board, commission, or any other entity of the department which has authority within this state to suspend or revoke a license or deny the renewal or issuance of a license authorizing a person to engage in a business, occupation, or profession.

"Revocation or suspension notice" means a licensing authority notification suspending a license for an indefinite or specified period of time or a notification revoking a license as required by Iowa Code chapter 272D.

"Withdrawal certificate" means the same as defined in Iowa Code section 272D.1

641—194.2(272D) Denial of issuance or renewal of a license or suspension or revocation of a license. The licensing authority shall deny the issuance or renewal of a license or suspend or revoke a license upon the receipt of a certificate of noncompliance from the centralized collection unit per the procedure set forth in Iowa Code chapter 272D. This rule shall apply in addition to the procedures set forth in Iowa Code chapter 272D.

194.2(1) *Service of denial, suspension or revocation notice.* Notice will be served upon the applicant or licensee by certified mail, return receipt requested; by personal service; or through authorized counsel.

194.2(2) *Licensees and applicants responsible to inform licensing authority.* Licensees and applicants shall keep the licensing authority informed of all court actions and all centralized collection unit actions taken under or in connection with Iowa Code chapter 272D. Licensees and applicants shall also provide the licensing authority copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code chapter 272D, all court orders entered in such actions, and any withdrawals of certificates issued by the centralized collection unit.

194.2(3) *Reinstatement following license denial, suspension or revocation.* All licensing authority fees required for application, license renewal, or license reinstatement must be paid by applicants or licensees before a license will be issued, renewed, or reinstated after the licensing authority has denied the issuance or renewal of a license or suspended or revoked a license pursuant to Iowa Code chapter 272D.

194.2(4) *Effect of filing in district court.* In the event an applicant or a licensee files a timely district court action following service of a denial notice by a licensing authority or service of a revocation or suspension notice, the licensing authority will continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the licensing authority to proceed. For purposes of determining the effective date of the denial of the issuance or renewal of a license or of the suspension or revocation of a license, the licensing authority will count the number of days before the action was filed and the number of days after the action was disposed of by the court.

194.2(5) *Final notification.* The licensing authority will notify the applicant or licensee in writing through regular first-class mail, or by such other means as the licensing authority determines appropriate in the circumstances and will similarly notify the applicant or licensee if the license is issued or renewed following the licensing authority's receipt of a withdrawal certificate.

641—194.3(272D) Sharing of information. The department may share applicant or licensee information with the centralized collection unit pursuant to Iowa Code chapter 272D.

These rules are intended to implement Iowa Code chapter 272D.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** Chapter 641-196

Iowa Code Section Authorizing Rule 272C

State or Federal Law(s) Implemented by the Rule Iowa Code 147D.1 – EMS Personnel Licensure Interstate Compact

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

This rule chapter sets forth HHS procedure to expedite the application for a professional license for those persons married to an active-duty member of the military forces of the United States or for those persons who are a veteran, and to provide reciprocity in licensure for such persons who are currently licensed in another state. The chapter also provides for the application of military education, training, and service as credit toward any experience or educational requirement of licensure.

This chapter applies only to the Department's emergency medical services licensure program; this is the only licensing program covered by the requirements of Iowa Code 272C to remain under the auspices of HHS upon implementation of the government reorganization. Procedures detailed additionally support the EMS Personnel Licensure Interstate Compact described in Iowa Code 147D.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

None identified.

    - Classes of persons that will benefit from the proposed rule:

Veterans applying for licensure.

Military Service applicants and Spouses of active-duty members of the military applying for licensure. Members of the public served by professionals licensed by HHS.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

Estimated figures below are projections based on past program performance as included in the Red Tape Rule Report for this chapter.

Identified Impacts*

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5 Year Total
Costs HHS Implementation	($166)	($166)	($166)	($166)	($166)	($830)
Benefits Increased Veteran and Public Safety Support	Intangible	Intangible	Intangible	Intangible	Intangible	Intangible
Net Value						

*All monetary figures have been rounded to the nearest thousandth.

- Qualitative description of impact:

Expedited licensure of qualified current and former military members and their spouses increases public access to emergency medical services personnel, thus enhancing the state's ability to protect public health and safety.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs personnel costs for team members to manage this process. These costs are reflected in the table above as "HHS Implementation". The costs to staff time will be less than typical for a non-veteran/active-duty spouse due to the expedited nature of the licensure. The calculation is 1 hour of staff time saved multiplied by a predicted 5 veteran or active-duty spouses or veteran applicants each year. The EMS training programs will justify the military credit received by military service applicants, therefore no cost to the department will be incurred.

- Anticipated effect on state revenues:

No impact identified.

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

The cost benefit analysis above shows a net value of approximately $166 in savings per year and an increase in public health and safety. Eliminating expedited licensure for current and former members of the military and their spouses or eliminating privilege to practice in licensure across states for such individuals, may result in fewer persons applying for licensure. This could

result in a decrease in emergency medical services personnel available to protect public health and safety.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

A less costly method has not been identified to achieve the purpose of this rule.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

HHS implements this process in accordance with the procedure set forth in Iowa Code. This rule chapter describes HHS timelines and communication methods for completing the procedure but does not ascribe additional department duties or implementation elements in addition to those directly defined in Code.

- Reasons why they were rejected in favor of the proposed rule:

NA

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

NA

Text of Proposed Rule:

Regulatory Analysis Template

CHAPTER 196
EMERGENCY MEDICAL SERVICES - MILITARY SERVICE, VETERAN RECIPROCITY, AND SPOUSES OF ACTIVE DUTY SERVICE MEMBERS

641—196.1(272C) Definitions.

"License" means the same as defined in Iowa Code section 272D.1.

"Licensing authority" means the same as defined in Iowa Code section 272D.1.

"Military service" means honorably serving on federal active duty, state active duty, or national guard duty, as defined in Iowa Code 29A.1; in the military services of other states, as provided in 10 U.S.C. Section 101(c (2021) ; or in the organized reserves of the United States, as provided in 10 U.S.C. Section 10101(2006) .

"Military service applicant" means an individual requesting credit toward licensure for military education, training, or service obtained or completed in military service.

"Spouse" means a spouse of an active duty member of the military forces of the United States.

"Veteran" means the same as defined in Iowa Code section 35.1.

641—196.2(272C,147D) Military education, training, and service credit. A military service applicant may apply for credit for verified military education, training, or service toward any experience or educational requirement for licensure by submitting a military service application form to the licensing authority. No fee is required with submission of an application for military service credit.

196.2(1) The licensing authority shall grant credit requested in the application pursuant to the EMS Personnel Licensure Interstate Compact described in Iowa Code section 147D.1.

196.2(2) The licensing authority shall inform the military service applicant in writing of the credit, if any, given toward an experience or educational qualification for licensure or explain why no credit was granted. The applicant may request reconsideration upon submission of additional documentation or information.

196.2(3) A military service applicant who is aggrieved by the licensing authority's decision may appeal pursuant to the provisions of 441—Chapter 7, except that no fees or costs shall be assessed against the military service applicant in connection with a contested case conducted pursuant to this subrule.

196.2(4) The licensing authority shall grant or deny the credit requested in the military service application prior to ruling on the application for licensure. The applicant shall not be required to submit any fees in connection with the licensure application unless the licensing authority grants the credit requested in the military service application. If the licensing authority does not grant the credit requested in the military service application, the applicant may withdraw the licensure application or request that the licensure application be placed in pending status for up to one year or as mutually agreed. The withdrawal of a licensure application shall not preclude subsequent applications supported by additional documentation or information.

641—196.3(272C,147D) Veteran and active duty military spouse privilege to practice.

196.3(1) A veteran or spouse with an unrestricted license in another EMS Personnel Licensure jurisdiction may practice in Iowa pursuant to the EMS Personnel Licensure Interstate Compact described in Iowa Code section 147D.1.

These rules are intended to implement Iowa Code sections 272C.4 and 147D.1.

Regulatory Analysis Template

TEXT BOXES WILL EXPAND AS YOU TYPE

Agency Name Health & Human Services (HHS) **Rule #** IAC 441-1, 441-3, 441-4, 441-5, 441-7, 441-9, 441-16

Iowa Code Section Authorizing Rule I217.6

State or Federal Law(s) Implemented by the Rule 17A

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: November 28, 2023, 10am

Location: https://meet.google.com/nkg-jzin-yvp

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

Joe.campos@idph.iowa.gov

Email and/or phone number

515-304-0963

Purpose and summary of proposed rule:

Regulatory Analysis Template

Each legacy department merged into HHS as part of the government reorganization and maintained their own set of uniform rules. HHS proposes to keep one set of uniform rules for the combined department.
Existing uniform rule chapters:

- 17-2, 11, 13, 17, 18, 19
- 421-1, 2, 3, 4, 5, 6, 7
- 441-1, 3, 4, 5, 7, 9, 16
- 489-5
- 641-170, 171, 172, 173, 174, 175, 178
- 817-1, 2, 3, 5, 6

These rule chapters comprise the HHS uniform rules on agency procedure. HHS seeks to repeal all uniform rules that exist for a department or program merged into the Department as part of the government reorganization and to re-promulgate one set of uniform rules for HHS under agency number 441.

Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

None identified

    - Classes of persons that will benefit from the proposed rule:

All Iowans benefit from uniform rules on agency procedure being applied consistently across HHS.

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred
    - Quantitative description of impact:

N/A

    - Qualitative description of impact:

This rulemaking eliminates uniform rules of agency practice and procedure that are redundant or duplicative of existing rules adopted by the Iowa Department of Health and Human Services [441] to reduce confusion and establish a single set of uniform rules for the newly reorganized department.

3. Costs to the state
    - Implementation and enforcement costs borne by the agency or any other agency:

These administrative procedures are a part of HHS standard business operations and absorbed in the general cost of administering the work of the Department.

    - Anticipated effect on state revenues:

N/A

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

By incorporating the uniform rules on agency procedure as Department procedure HHS ensures members of the public can interact with the Department in a manner that is consistent, efficient, and effective.

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

No less costly or intrusive methods exist.

6. Alternative methods considered by the agency
    - Description of any alternative methods that were seriously considered by the agency:

N/A

    - Reasons why they were rejected in favor of the proposed rule:

HHS is implementing the uniform rules on agency procedure prescribed on the Legislative Services Agency website.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

This rule is not expected to have any impact on small businesses.

Text of Proposed Rule:

Regulatory Analysis Template

CHAPTER 1
DEPARTMENT ORGANIZATION AND GENERAL DEFINITIONS

441—1.1(217) History and mission. The Iowa department of health and human services was established in 2022 pursuant to 2022 Iowa Acts, HF 2578 and fully codified pursuant to 2023 Iowa Acts, Senate File 514. The authority delegated to the department had previously been delegated to the departments of human services, public health, aging, human rights, the Iowa Commission on Volunteer Service, the Child Advocacy Board and the department of inspections and appeals. In 2023, the general assembly combined these agencies and programs to create the department of health and human services. The department's mission is published on the department's website.

441—1.2(217) Definitions. For the purposes of 441 Iowa Administrative Code, unless otherwise defined:

1.2(1) "*Council*" means the health and human services council.

1.2(2) "*Department*" means the department of health and human services.

1.2(3) "*Director*" means the director of health and human services.

1.2(4) "*Electronic signature*" means a confidential personalized digital key, code, or number that is used for secure electronic data transmission and that identifies and authenticates the signatory.

441—1.3(217) Department structure.

1.3(1) *General.* The department's organizational structure consists of the council, the director and such divisions as the director may from time to time create.

1.3(2) *Director.* The department director is appointed pursuant to the requirements in Iowa Code section 217.5.

1.3(3) *Delegation of Director Authority.* The director may designate employee(s) to administer the department in the director's absence. The director may also delegate the director's authority to administer the department to other employees as determined necessary for efficient and effective department operations. Delegations of the director's authority will be documented by the department.

1.3(4) *Divisions.* The director may from time to time reorganize the department into administrative divisions to most efficiently and effectively carry out the department's responsibilities. Reorganization may include creating new division, eliminating existing divisions, or combining divisions as the director deems necessary.

441—1.4(217) Information. The general public may obtain information about the department by contacting the department at its offices located at 321 E. 12th Street, Des Moines, Iowa 50319, telephone (515)281-5452, or through the department's website.

441-1.5(217) Health and Human Services Council. The council is established in Iowa Code section 217.2 and its duties are in Iowa Code section 217.3. Meetings of the council and any ad hoc committee it may establish are conducted in accordance with the provisions of Iowa Code chapter 21.

441-1.6(217) State Council on Developmental Disabilities. The state developmental disabilities council and its duties are established in 42 U.S.C.A §15025.

1.5(1) *Designated state agency.* The department serves as the designated state agency.

1.5(2) *Membership.* The council consists of up to 26 members appointed by the governor. Members serve three-year terms. Appointments are staggered so at least one-third of the members are appointed each year. The nonattendance provisions of Iowa Code section 69.15 apply to the council's members.

1.5(3) *Meetings.* Meetings of the council are conducted in accordance with the provisions of Iowa Code chapter 21.

1.5(4) *Council information.* The general public may obtain information about the council at its offices located at 700 2nd Avenue, Suite 101, Des Moines, Iowa, 50309, telephone (800) 452-1936, or the website iowaddcouncil.org.

CHAPTER 3
DEPARTMENT PROCEDURE FOR RULE MAKING

The department adopts the agency procedure for rule making segment of the Uniform Administrative Rules which is printed in the first volume of the Iowa Administrative Code and can be found at www.legis.iowa.gov/DOCS/Rules/Current/UniformRules.pdf, with the following amendments.

441—3.3(17A) Public rule-making docket.

3.3(2) *Anticipated rule making.* In lieu of the words "(commission, board, council, director)" insert "director".

441—3.4(17A) Notice of proposed rule making.

3.4(3) *Notices mailed.* In lieu of the words "(specify time period)" insert "one calendar year".

441—3.5(17A) Public participation.

3.5(1) *Written comments.* In lieu of the words "(identify office and address) or" insert "Compliance Division, Iowa Department of Health and Human Services, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319".

3.5(5) *Accessibility.* In lieu of the words "(designate office and telephone number)" insert "Compliance Division of the Department, (515)281-7689".

441—3.6(17A) Regulatory flexibility analysis.

3.6(3) *Mailing list.* In lieu of the words "(designate office)" insert "Compliance Division, Iowa Department of Health and Human Services, Lucas State Office Building, Des Moines, Iowa 50319".

441—3.11(17A) Concise statement of reasons.

3.11(1) *General.* In lieu of the words "(specify the office and address)" insert "Compliance Division, Iowa Department of Health and Human Services, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319".

441—4.13(17A) Agency rule-making record.

3.13(2) *Contents.* Amend paragraph *"c"* by inserting "director" in lieu of "(agency head)".

CHAPTER 4
PETITIONS FOR RULE MAKING

The department adopts the petitions for rule making segment of the Uniform Administrative Rules which is printed in the first volume of the Iowa Administrative Code and can be found at www.legis.iowa.gov/DOCS/Rules/Current/UniformRules.pdf, with the following amendments.

441—4.1(17A) Petition for rule making. In lieu of the words" designate office" insert "Compliance Division, Iowa Department of Health and Human Services, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319" and in lieu of the words "AGENCY NAME," the heading on the Petition should read "THE DEPARTMENT OF HEALTH AND HUMAN SERVICES".

441—4.3(17A) Inquiries. Inquiries concerning the status of a petition may be made to the Compliance Division at the department's address or at compliancerules@idph.iowa.gov.

CHAPTER 5
DECLARATORY ORDERS

The department adopts the declaratory orders segment of the Uniform Administrative Rules which is printed in the first volume of the Iowa Administrative Code and can be found at www.legis.iowa.gov/DOCS/Rules/Current/UniformRules.pdf with the following amendments. Every instance that lists "designate agency" shall be read as the department of health and human services.

441—5.1(17A) Petition for declaratory order. In lieu of the words "designate office" insert "Compliance Division, at the department's address".

441—5.2(17A) Notice of petition. The department shall have 15 days after receipt to give notice.

441—5.3(17A) Intervention.

5.3(1) *Nondiscretionary intervention.* 15 days shall be the time frame for a person to file for an intervention.

5.3(3) *Filing and form of petition for intervention.* In lieu of the words "designate office" insert "Compliance Division, at the department's address".

441—5.5(17A) Inquiries. Inquiries concerning the status of a declaratory order proceeding may be made to the Compliance Division at the department's address or at compliancerules@idph.iowa.gov.

441—5.6(17A) Service and filing of petitions and other papers.

5.6(2) *Filing – when required.* In lieu of the words "specific office and address" insert "Compliance Division, at the department's address or compliancerules@idph.iowa.gov" and in lieu of "agency name" insert "department".

5.6(3) *Method of service, time of filing, and proof of mailing.* Method of service, time of filing, and proof of mailing shall be as provided by X.12(17A) of the contested cases segment of the uniform rules on agency procedure published on the Iowa general assembly's website at www.legis.iowa.gov/DOCS/Rules/Current/UniformRules.pdf.

441—5.8(17A) Action on petition.

5.8(1) *Time frames for action.* Within 30 days after receipt of a petition for a declaratory order, the department shall take action on the petition as required by Iowa Code section 17A.9(5).

5.8(2) *Date of issuance of order.* The date of issuance of an order or of a refusal to issue an order is the date of mailing of the order or refusal or date of delivery if service is by other means unless another date is specified in the order.

CHAPTER 7
APPEALS AND HEARINGS
Preamble

The provisions of this chapter shall apply to contested case proceedings conducted by or on behalf of the department pursuant to Iowa Code chapter 17A. The definitions in rule 441—7.1(17A) apply to the rules in both Division I and Division II.

441—7.1(17A) Definitions.

"Adverse benefit determination" means any adverse action taken as to any individual's benefits pursuant to an assistance program administered by the department or on the department's behalf, excluding determinations related to requests for exceptions to policy.

"Appeals section" means the section of the department charged with administering the department's appeals.

"Appellant" means a person, including an authorized representative acting on the person's behalf, seeking to appeal some action pursuant to this chapter.

"Assistance program" means a program administered by the department or on the department's behalf through which qualifying individuals receive benefits or services. Assistance programs include, but are not necessarily limited to, the Supplemental Nutrition Assistance Program (SNAP), Medicaid, the family investment program, refugee cash assistance, child care assistance, emergency assistance, the family planning program, the family self-sufficiency grant, PROMISE JOBS, state supplementary assistance, the healthy and well kids in Iowa (hawki) program, foster care, adoption, and aftercare services.

"Authorized representative" means a person lawfully designated by an individual to act on the individual's behalf or who has legal authority to act on behalf of the individual.

"Contested case" refers to an evidentiary hearing mandated by state or federal constitutional or statutory authority whereupon a presiding officer makes a determination pertaining to the relative rights and obligations of parties to an appeal under this chapter.

"*DIAL*" means the department of inspections, appeals and licensing.

"Enrollee" means any applicant to or recipient of benefits or services pursuant to an assistance program.

"Good cause," for purposes of this rule, shall have the same meaning as "good cause" for setting aside a default judgment under Iowa Rule of Civil Procedure 1.977.

"In-person hearing" means an appeal hearing where the administrative law judge and appellant are physically present in the same location but witnesses are not required to be physically present.

"Intentional program violation" means deliberately making a false or misleading statement; or misrepresenting, concealing, or withholding facts; or committing any act that is a violation of the Supplemental Nutrition Assistance Program (SNAP), SNAP regulations, or any state law relating to the use, presentation, transfer, acquisition, receipt, possession, or trafficking of SNAP benefits or an electronic benefit transfer (EBT) card. An intentional program violation is determined through a SNAP administrative disqualification hearing, a court conviction, or when an individual signs and returns Form 470-5530, Waiver of Right to an Administrative Disqualification Hearing, which may result in a period of ineligibility for the program, a claim for overpayment of benefits, or both.

"Issuance" means the date of mailing of a decision or order or date of delivery if service is by other means unless another date is specified in the order. *"Managed care organization*" or *"MCO*" has the meaning assigned to it in rule 441—73.1(249A) and includes prepaid ambulatory health plans.

"Medicaid" means Iowa's medical assistance program administered under Iowa Code chapter 249A.

"Party-in-interest" refers to the party, including enrollees, whose rights or obligations are the subject of a contested case hearing under this chapter. Parties-in-interest may or may not be the appellant.

"Presiding officer" means an administrative law judge from DIAL or the director of the department or the members of a multimember board or commission.

"Self-represented" means representing oneself without an attorney.

441—7.2(17A) Governing law and regulations. In the absence of an applicable rule in this chapter, the DIAL rules found at 481—Chapter 10 govern department appeals. Notwithstanding the foregoing and the rules contained in this chapter, to the extent that federal or state law (including regulations and rules) related to a specific program is more specific than or contradicts these rules or the applicable DIAL rules, the program-specific federal or state law shall control.

DIVISION I
GENERAL APPEALS PROCESS

441—7.3(17A) When a contested case hearing will be granted.

7.3(1) *Requirements.* A person shall be granted a contested case hearing if the party-in-interest fulfills all of the following requirements:

a. The party-in-interest is entitled to a contested case hearing;

b. The party-in-interest has an ongoing, specific and personal interest in the outcome of the contested case hearing; and

c. The party-in-interest meets all of the other requirements contained in these rules.

7.3(2) *Refusal to process an application.* Unless otherwise provided by law, when an appellant seeks a contested case hearing after the department refuses to process an application for benefits or services, a hearing shall be granted.

7.3(3) *When a hearing is not granted.* A hearing shall not be granted when one of the following issues is appealed:

a. Patient treatment interventions outlined in the patient handbook of the civil commitment unit for sexual offenders.

b. Children have been removed from or placed in a specific foster care setting or preadoptive placement.

c. A final decision from a previous hearing with a presiding officer has been implemented.

7.3(4) *Contractual rights not subject to contested case hearing.* Unless otherwise provided by law, when an appellant seeks a contested case hearing of an issue predicated upon or governed by the terms of a contract between appellant and another party, including the department, a contested case hearing shall not be provided.

7.3(5) *Change in law.* A contested case hearing shall not be granted when the sole issue raised is a federal or state law requiring an automatic change adversely affecting some or all beneficiaries to an assistance program.

7.3(6) *Competitive procurement bid appeals.* Competitive procurement bid appeals shall be adjudicated pursuant to Division II of this chapter.

441—7.4(17A) Initiating an appeal.

7.4(1) *Exhaustion of remedies.* An appellant shall only be granted a contested case hearing if the appellant has exhausted all other appeal remedies available to the party-in-interest. An appellant should refer to program-specific provisions for the appropriate procedures applicable to specific programs.

7.4(2) *Medicaid managed care enrollees exhaustion of remedies.*

a. A Medicaid managed care enrollee shall be granted a contested case hearing only if the enrollee has either received a decision from a managed care organization in the time and manner required by rule 441—73.12(249A) or has been deemed to have exhausted the managed care organization appeals under paragraph 7.4(2)*"b."*

b. If a Medicaid enrollee's managed care organization fails to provide a decision in the time and manner required by rule 441—73.12(249A), the enrollee shall be deemed to have exhausted the managed care organization's appeals process and may initiate a contested case hearing.

7.4(3) *Time to appeal.* For a contested case hearing to be granted, the following appeal timelines must be met:

a. Supplemental Nutrition Assistance Program (SNAP), Medicaid eligibility, healthy and well kids in Iowa (hawki), fee-for-service Medicaid coverage, family planning program and autism support program. On or before the ninetieth day following the date of notice of an adverse benefit determination.

b. Managed care organization medical services coverage. On or before the one hundred twentieth day following the date of exhaustion, actual or deemed, of the managed care organization appeal process outlined in rule 441—73.12(249A).

c. Tax offsets. Except for counties appealing an offset under 441—Chapter 14, for appeals of state or federal tax offsets, on or before the fifteenth day following the date of notice of the action. For counties appealing a debtor offset under 441—Chapter 14, on or before the thirtieth day following the date of notice of the offset.

d. Iowa individual disaster assistance program. On or before the ninetieth day following the date of the department's reconsideration decision, pursuant to 441—subrule 58.7(1).

e. Iowa disaster case management program. On or before the ninetieth day following the date of the department's reconsideration decision, pursuant to 441—subrule 58.7(1).

f. Dependent adult abuse. Within six months of the date of notice of the action as provided in Iowa Code section 235B.10.

g. Child abuse. For appeals regarding child abuse, the person alleged responsible for the abuse must appeal on or before the ninetieth day following the date of notice of the action as provided in Iowa Code section 235A.19. A subject of a child abuse report, other than the alleged person responsible for the abuse, may file a motion to intervene in the appeal on or before the tenth day following the date of notice of the right to intervene.

h. Assistance program overpayments. For appeals pertaining to the family investment program, refugee cash assistance, PROMISE JOBS, child care assistance, medical assistance, healthy and well kids in Iowa (hawki), family planning program or Supplemental Nutrition Assistance Program (SNAP) overpayments, the party-in-interest's right to appeal the existence, computation and amount of the overissuance or overpayment begins when the department sends the first notice informing the party-in-interest of the overissuance or overpayment.

i. All other appeals. For all other appeals, and unless federal or state law provides otherwise elsewhere, the appellant must appeal on or before the thirtieth day following the date of notice of the action being appealed. If such an appeal is made more than 30 days, but less than 90 days, of the date of notice, the director or director's designee may, at the director's or designee's sole discretion, allow a contested case hearing if the delay was for good cause, substantiated by the appellant.

7.4(4) *Written and oral notification.* The department shall advise each applicant and recipient of the right to appeal any adverse decision affecting the person's status.

a. Written notification of the following shall be given at the time of application and at the time of any agency action affecting the claim for assistance.

(1) The right to request a hearing.

(2) The procedure for requesting a hearing.

(3) The right to be represented by others at the hearing unless otherwise specified by statute or federal regulation.

b. Written notification shall be given on the application form and all notices of decision.

441—7.5(17A) How to request an appeal.

7.5(1) *Ways to request a hearing.* An appellant may request a contested case hearing:

a. Via the department's website,

b. By telephone, except as specified in subrule 7.5(4),

c. By mail,

d. In person, except as specified in subrule 7.5(4), or

e. Through other commonly available electronic means (such as email or facsimile).

7.5(2) *Hearing request.* The request for a contested case hearing must be sufficiently detailed so that the department can reasonably understand the action being appealed. The department may request additional information to determine the scope of the appeal. The department may deny if there is not sufficient information to determine the action being appealed.

7.5(3) *Filing date.* The date of filing for appeal requests sent by regular mail shall be the date postmarked on the envelope sent to the department or, when a postmarked envelope is not available, on the date the appeal is stamped received by the agency. The date of filing for appeal requests sent electronically shall be determined by the date on which the electronic submission was completed.

7.5(4) *Appeals that must be filed in writing.* Appeal requests pertaining to foster care, adoption, state supplementary assistance, the autism support program, the Iowa individual disaster assistance program, the Iowa disaster case management program, sex offender risk assessment, record check evaluation, child care registered or nonregistered homes, child abuse, dependent adult abuse or child support must be made in writing.

7.5(5) *Department's responsibilities.* Unless the appeal is voluntarily withdrawn, the department shall:

a. Within one working day of receipt of an appeal request, forward the request for appeal and envelope (if any) and a copy of the notice to the appeals section.

b. Within ten days of the receipt of the appeal, forward a summary and supporting documentation of the worker's or agent's factual basis for the proposed action to the appeals section.

c. Copies of all materials sent to the appeals section or the presiding officer to be considered in reaching a decision on the appeal are to be provided to the appellant at the same time as the materials are sent to the appeals section or the presiding officer.

441—7.6(17A) Prehearing procedures.

7.6(1) *Acknowledgment of appeal.* When the appeals section receives a request for appeal, it shall send acknowledgment of the receipt of the appeal to the parties to the appeal. For appeals regarding child abuse, all subjects other than the person alleged responsible (party-in-interest) will be notified of the opportunity to file a motion to intervene as provided in Iowa Code section 235A.19.

7.6(2) *Acceptance or denial of appeal.* The appeals section will determine with reasonable promptness whether the party-in-interest is entitled to a contested case hearing. If a request is accepted, the appeals section will certify the appeal to DIAL and designate the issues on appeal. If a request for a contested case hearing is denied, the appeals section will provide written notice of and the reasons for the denial. On or before the thirtieth day following the denial, the individual requesting the appeal may provide additional information related to the individual's asserted right to a contested case hearing and request reconsideration of the denial.

7.6(3) *Designation of issues for appeal.*

a. Initial designation. After determining that the party-in-interest is entitled to a contested case hearing, the appeals section will designate the issues to be decided at the contested case hearing. The issues designated shall be certified to DIAL and be identified in the notice of hearing issued pursuant to subrule 7.6(5).

b. Additional designation of issues. If any party believes additional issues should be designated, the party shall identify the additional issues within the following timelines. The presiding officer shall determine whether all issues have properly been preserved.

(1) Child abuse and dependent adult abuse registry appeals. For child abuse and dependent adult abuse registry appeals, the party shall identify additional issues at least 30 days before the date of hearing.

(2) Appeals set on or before the tenth day following the notice of hearing. If the hearing is on or before the tenth day following the date of the notice of hearing, the party shall identify any additional issues at the hearing.

(3) All other appeals. For all other appeals not identified in this paragraph, the party shall identify the additional issues on or before the tenth day following the date of the notice of hearing.

7.6(4) *Group hearings regarding medical assistance.* The appeals section may respond to a series of related, individual requests for hearings regarding medical assistance by consolidating individual hearings into a single group hearing where the sole issue is based on state or federal law or policy. An appellant scheduled for a group hearing may withdraw and request an individual hearing.

7.6(5) *Notice of hearing.*

a. Issuance of hearing notice. Except as provided in paragraph 7.6(5)*"b,"* DIAL shall send notice to the parties of the appeal at least ten calendar days in advance of the hearing setting forth the date, time, method, and place of the hearing; that evidence may be presented orally or documented to establish pertinent facts; that the parties may bring and question witnesses and refute testimony; and that the parties may be represented by others, including an attorney, at the parties' own cost and as subject to state and federal law. Notice shall be mailed by first-class mail, postage prepaid, and addressed to the appellant at the appellant's last-known address.

b. Intentional program violation hearing notices. DIAL shall send notices of hearing regarding alleged intentional program violations at least 30 days in advance of the hearing date. The notices under this paragraph shall otherwise comply with the requirements of paragraph 7.6(5)*"a."*

7.6(6) *Appellant's right to department's case file.* Prior to and during the contested case hearing, the department must provide enrollees or their authorized representative with the opportunity to examine the content of the appellant's case file, if any, and all documents and records to be used by the department at the hearing.

7.6(7) *Informal conference.* The purpose of an informal conference is to provide information as to the reasons for the intended adverse action, to answer questions, to explain the basis for the adverse action or position, and to provide an opportunity for the appellant to examine the contents of the case record.

a. When requested by the appellant, an informal conference with a representative of the department or one of its contracted partners, including a managed care organization, shall be held as soon as possible after the appeal has been filed. An appellant's representative shall be allowed to attend and participate in the informal conference, unless precluded by federal rule or state statute.

b. An informal conference need not be requested for the appellant to examine the contents of the case record.

441—7.7(17A) Timelines for contested case hearings.

7.7(1) *Medical assistance.* In cases involving the determination of medical assistance, the contested case hearing shall be held within a time frame such that the final administrative action is timely pursuant to 42 CFR 431.244(f) as amended to December 8, 2021.

7.7(2) *Community spouse resource allowance.* In cases involving the determination of the community spouse resource allowance, the hearing shall be held within 30 days of the date of the appeal request.

7.7(3) *Sex offender risk assessment.* In cases involving an appeal of a sex offender risk assessment, the hearing or administrative review shall be held within 30 days of the date of the appeal request.

441—7.8(17A) Contested case hearing procedures.

7.8(1) *Method.* Contested case hearings may be conducted via telephone or videoconference. Upon request of a party to the appeal or order of the presiding officer, the contested case hearing shall be conducted in person.

7.8(2) *Evidence.*

a. The parties to a contested case hearing may:

(1) Bring witnesses,

(2) Submit competent evidence to establish all pertinent facts and circumstances,

(3) Present arguments without undue interference,

(4) Question or refute any testimony or evidence, including through cross-examination, and

(5) Respond to evidence and arguments on all issues.

b. Evidence shall be received or excluded as provided in Iowa Code section 17A.14.

7.8(3) *Right to counsel.* Parties to an appeal shall be permitted to be represented by counsel at the parties' own expense.

7.8(4) *Self-represented appellants.* The presiding officer shall, at the officer's discretion, provide reasonable assistance to self-represented appellants. The presiding officer must, however, ensure that such assistance does not impact the independence and fairness of the contested case hearing process.

7.8(5) *Closed to public.* Contested case hearings are closed to the public, and unless otherwise provided by state or federal law, only the parties, their representatives, permissible intervenors, and witnesses may be present for a contested case hearing in the absence of mutual agreement of the parties.

7.8(6) *Administration of appeals.* Except as otherwise provided in this chapter or other applicable federal or state law, discretion in the conduct and administration of appeals is vested in the contested case hearing presiding officer.

7.8(7) *Contested cases with no factual dispute.* If the parties in a contested case agree that there is no dispute of material fact, the parties may present all admissible evidence either by stipulation, or as otherwise agreed, in lieu of an evidentiary hearing. If an agreement is reached, the parties shall jointly submit a schedule for submission of the record, briefs and oral arguments to the presiding officer for approval. If the parties cannot agree, any party may file and serve a motion for summary judgment pursuant to the rules governing such motions.

441—7.9(17A) Miscellaneous rules governing contested case hearings.

7.9(1) *Ex parte communication.* Ex parte communications between the presiding officer and person or party in connection with any issue of fact or law in the contested case proceeding is prohibited except as permitted by Iowa Code section 17A.17. All of the provisions of Iowa Code section 17A.17apply.

7.9(2) *Default.* If a party fails to appear at a scheduled hearing or prehearing conference without good cause as determined by the presiding officer, the party's appeals may be denied and dismissed or may be heard and ruled upon, consistent with Iowa Code section 17A.12(3). Defaulting parties may file a timely motion to vacate, which shall be granted if the presiding officer determines good cause has been shown.

7.9(3) *Withdrawal.* An appellant may submit a withdrawal of a fair hearing request at any time prior to hearing through any of the methods identified in subrule 7.5(1), except for programs listed in subrule 7.5(4). For programs listed in subrule 7.5(4), a written request may be submitted via the department's website, by mail, in person, or through other commonly available electronic means (such as email or facsimile). Unless otherwise provided, a withdrawal shall be with prejudice.

7.9(4) *Medical assessment.* For Medicaid enrollees engaged in an appeal involving medical issues, the department may request, at the department's own expense, that the appellant submit to an appropriate medical assessment. The presiding officer shall order such assessment upon sufficient showing of necessity.

7.9(5) *Standard of review.* In child abuse appeals, the criteria and level of deference by which the presiding officer shall render a decision is based on a preponderance of evidence.

7.9(6) *Interpreters.* The department shall provide translation and interpretation services to appellants if requested In all cases when an appellant is illiterate or semiliterate, the presiding officer shall advise the appellant of the appellant's rights to the satisfaction of the appellant's understanding.

7.9(7) *Persons living with disabilities.* Persons living with disabilities shall be provided assistance through the use of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

441—7.10(17A) Proposed decision.

7.10(1) *Contents.* The presiding officer shall issue a written proposed decision to all parties clearly identifying the issues on appeal, holding, findings of fact, conclusions of law, and order. The findings of fact shall cite and be based exclusively on the record as defined by Iowa Code section 17A.12(6). The conclusions of law shall be limited to the contested issues of fact, policy or law and shall identify the specific provisions of law that support the ultimate conclusion.

7.10(2) *Access to record.* After receiving the proposed decision, appellants shall be given reasonable access to the record at a convenient place and time.

441—7.11(17A) Director's review.

7.11(1) *Time.* Parties, including the department, may appeal the proposed decision to the director.

a. A request for director's review shall be in writing and postmarked or received within 14 calendar days of the date on which the proposed decision was issued, except as provided for under paragraph 7.11(1)*"b."* A request for director's review may be accompanied by a brief written summary of the arguments in favor of director's review.

b. A managed care organization appealing a proposed decision reversing an adverse benefit determination shall request director's review within 72 hours from the date it received notice of the proposed decision.

7.11(2) *Grant or denial of review.* The department has full discretion to grant or deny a request for review. In addition, the director may initiate review of a proposed decision on the director's own motion at any time on or before the thirtieth day following the issuance of the proposed decision.

When the department grants a request for director's review, the appeals section shall notify the parties and enclose a copy of the request. All other parties shall have 14 calendar days from the date of notification to submit further written arguments or objections for consideration upon review.

7.11(3) *Cross-appeal.* When a party requests director's review in accordance with subrule 7.11(1), the remaining parties shall have 14 calendar days from that date to submit cross-requests for director's review. The party originally seeking director's review shall have 14 calendar days from the date of the cross-request for director's review to submit further written arguments or objections for consideration upon review.

7.11(4) *Limited record.* Director's review shall be limited to the issues and record before the contested case hearing presiding officer.

7.11(5) *Oral arguments.* Upon specific request, the director may, at the director's discretion, permit parties to present oral arguments with the parties' requests for director's review.

441—7.12(17A) Final decisions.

7.12(1) *No appeal or denial of director review.* If there is no timely appeal from or review of the proposed decision, the presiding officer's proposed decision becomes the final decision of the agency.

7.12(2) *Timelines.*

a. The department or director will issue a final decision within the timelines prescribed by federal or state law. For all appeals for which there is no federal or state timeliness standard, the department or director will issue a final decision on or before the ninetieth day from the date the department receives an appeal request.

b. Except as otherwise provided by state or federal law, the time frames for a final decision provided under this rule may be tolled when:

(1) The appellant requests a delay;

(2) The appellant fails to take a required action; or

(3) There is an administrative or other emergency beyond the department's control.

c. DIAL shall document in the record the reasons for any delay and the requesting party.

7.12(3) *Written notice of final decision.* The parties to the appeal shall be provided written notice of the department's final decision. The department shall also notify the appellant of the appellant's right to seek judicial review, where applicable.

441—7.13(17A) Expedited review.

7.13(1) *Expedited review criteria.* Appellants to a medical assistance appeal may, at any time, file with the department a request for expedited review of the appeal. Expedited review shall be granted when the department determines, or a provider acting on behalf or in support of an appellant indicates, that taking the time for a standard resolution could seriously jeopardize the party-in-interest's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

7.13(2) *Managed care expedited proceedings.*

a. If the appellant is granted an expedited review pursuant to subrule 73.12(2), all subsequent proceedings shall also be expedited without an additional request if the appeal request indicates that the managed care organization appeal was expedited and provides the basis for expedited relief.

b. When review is expedited pursuant to paragraph 7.13(2)*"a,"* the presiding officer shall issue a proposed decision as expeditiously as the enrollee's health condition requires, but no later than three working days after the department receives from the managed care organization the case file and information for any appeal of a denial of a service that, as indicated by the managed care organization:

(1) Meets the criteria for expedited resolution but was not resolved within the time frame for expedited resolution; or

(2) Was resolved within the time frame for expedited resolution but reached a decision wholly or partially adverse to the enrollee.

7.13(3) *Medicaid eligibility, nursing facility transfers or discharges, or preadmission and annual resident review expedited proceedings.* For expedited appeals related to Medicaid eligibility, nursing facility transfers or discharges, or preadmission and annual resident review requirements, the presiding officer shall issue a proposed decision as expeditiously as possible, but no later than seven working days after the department receives a request for expedited fair hearing.

7.13(4) *Medicaid-covered benefits or services expedited proceedings.* For expedited appeals related to Medicaid-covered benefits or services, the presiding officer shall issue a proposed decision as expeditiously as possible, but no later than provided in paragraph 7.13(2)*"b."*

7.13(5) *Final decision for expedited proceeding.* The department shall issue its final decision in accordance with this rule, except as provided by subrule 7.12(2).

7.13(6) *Notification if expedited relief is granted or denied.* The department shall notify the appellant as expeditiously as possible whether the request for expedited relief is granted or denied. Such notice must be provided orally or through electronic means to the extent consistent with federal and state law. If oral notice is provided, the department shall follow up with written notice, which may be through electronic means to the extent consistent with federal and state law.

441—7.14(17A) Effect.

7.14(1) If the contested case hearing presiding officer's proposed decision is favorable to an enrollee in a Medicaid appeal, the department must promptly make corrective payments retroactive to the date an incorrect action was taken, and, if appropriate, provide for admission or readmission of an individual to a facility. If the presiding officer reverses a decision of a managed care organization to deny, limit, or delay services that were not furnished while the appeal was pending, the managed care organization must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date the managed care organization receives notice reversing the determination.

7.14(2) Unless there is contravening federal or state law, all final decisions shall be put into effect within seven days of the issuance of the final decision.

441—7.15(17A) Calculating time. In computing any time period specified in this chapter, the period:

1. Excludes the day of the event that triggers the period;
2. Includes every day of the time period (including Saturdays, Sundays, and holidays on which the department is closed); and
3. Includes the last day of the period, but if the last day is a Saturday, Sunday, or legal holiday, the period continues to run until the end of the next day that is not a Saturday, Sunday, or legal holiday.

441—7.16(17A) Authorized representatives.

7.16(1) *Regulations.* The provisions of this rule only apply to the extent the standards expressed in this rule are not in conflict with other state or federal law.

7.16(2) *Designation of authority.* Legally recognized delegations of authority, such as guardianships, applicable designations of power of attorney, or similar designations, shall be sufficient for a delegate to serve as authorized representative under this chapter. A person who is not designated a legally recognized delegation of authority but who otherwise seeks to act as an authorized representative for an individual in an appeal under this chapter shall provide a written, signed designation of authority to the department with the request for appeal. The designation must provide the scope of the representation, applicable waivers for the release of confidential information, and any temporal or other limitations on the scope of representation. An authorized representative of a party-in-interest only represents the party-in-interest and has no independent right to appeal by virtue of the authorized representative's representation.

7.16(3) *Written designation.* For persons other than attorneys seeking to act as authorized representative of a party-in-interest in a Medicaid managed care appeal, the authorized representative's written designation of authority pursuant to subrule 7.16(2) shall be Form 470-5526, Authorized Representative for Managed Care Appeals. This form is required for all managed care appeals, including those handled through the expedited appeals process. Failure to provide the form or legal documentation may result in denial of the appeal request.

7.16(4) *Appearance by attorney.* Legal counsel appearing on behalf of any person in a proceeding under this chapter shall enter an appropriate written appearance.

441—7.17(17A) Continuation and reinstatement of benefits.

7.17(1) *Programs for which no federal or state law applies.* For all assistance programs for which there is no contravening federal or state law, benefits or services shall not be suspended, reduced, restricted, or discontinued, nor shall a license, registration, certification, approval, or accreditation be revoked or other adverse action taken pending a final decision when:

a. An appeal is filed before the effective date of the intended action; or

b. The appellant requests a hearing within ten days of receipt of a notice to suspend, reduce, restrict, or discontinue benefits or services. The date on which the notice is received is considered to be five days after the date on the notice, unless the appellant shows the notice was not received within the five-day period.

7.17(2) *Sole issue is state or federal law or policy.* Benefits or services continued pursuant to subrule 7.17(1) may be suspended, reduced, restricted, or discontinued if the presiding officer determines at the contested case hearing that the sole issue is one of state or federal law or policy and the department has notified the enrollee in writing that services are to be suspended, reduced, restricted, or discontinued pending the proposed decision.

7.17(3) *Recoup cost of services or benefits.* The department or managed care organization may recoup the cost of benefits or services provided pursuant to this chapter if the adverse action appealed from is affirmed, consistent with state and federal law.

441—7.18(17A) Emergency adjudicative proceedings.

7.18(1) *Necessary emergency action.* When and to the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with state and federal law, a contested case hearing presiding officer may issue a written order 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. In determining the necessity of such an action, the presiding officer shall consider factors including, but not limited to, the following:

a. Whether there has been sufficient investigation and evidentiary support to ensure the order is proceeding based on reliable information;

b. Whether the specific circumstances giving rise to the potential order have been specifically identified and determined to be continuing;

c. Whether the person who is required to comply with the emergency adjudicative order may continue to engage in other activities without risk of immediate danger to the public health, safety, or welfare;

d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety, or welfare; and

e. Whether the specific action contemplated is necessary to avoid the immediate danger.

7.18(2) *Issuance of order.* An emergency adjudicative order shall contain, or shall be expeditiously followed by, a written analysis, including findings of fact, conclusions of law, and policy reasons to justify the order. The agency shall provide written notice that best ensures prompt, reliable delivery. Such order shall be immediately delivered to the persons required to comply with the order.

7.18(3) *Completion of proceedings.* Upon issuance of an order under this rule, the department shall proceed as quickly as reasonably practicable to complete any proceedings that would be required if the matter did not involve an immediate danger. An order issued under this rule shall include notice of the date on which proceedings under this chapter are to be completed. After issuance of an order under this rule, continuance of further proceedings under this chapter shall only be granted in compelling circumstances upon application in writing. Before issuing an emergency adjudicative order, the presiding officer shall consider factors including, but not limited to, the following:

a. Whether there has been sufficient investigation and evidentiary support to ensure the order is proceeding based on reliable information;

b. Whether the specific circumstances giving rise to the potential order have been specifically identified and determined to be continuing;

c. Whether the person who is required to comply with the emergency adjudicative order may continue to engage in other activities without risk of immediate danger to the public health, safety, or welfare;

d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety, or welfare; and

e. Whether the specific action contemplated is necessary to avoid the immediate danger.

441—7.19(17A) Supplemental Nutrition Assistance Program (SNAP) administrative disqualification hearings. The department acts on alleged intentional program violations either through an administrative disqualification hearing or referral to a court of appropriate jurisdiction. An individual accused of an intentional program violation may waive the individual's right to an administrative disqualification hearing in accordance with the procedures outlined in this rule and in 7 CFR 273.16(e) and (f) as amended to December 8, 2021.

7.19(1) When a case is referred for an administrative disqualification hearing, the appeals section shall mail written notification to the individual that the individual can waive the right to an administrative disqualification hearing by signing and returning, Waiver of Right to an Administrative Disqualification Hearing.

7.19(2) By signing Waiver of Right to an Administrative Disqualification Hearing, the individual:

a. Waives the right to an administrative disqualification hearing;

b. Consents to the SNAP disqualification period designated, Waiver of Right to an Administrative Disqualification Hearing, and a reduction of benefits for the period of disqualification; and

c. Acknowledges that remaining household members, if any, may be held responsible for repayment of the resulting claim.

7.19(3) An administrative disqualification hearing shall be scheduled if the individual does not sign and mail or fax Waiver of Right to an Administrative Disqualification Hearing, to the appeals section within ten days of receipt of the written notification stating the individual can waive the right to an administrative disqualification hearing. The date on which the written notification is received is considered to be five days after the date on the notification, unless the individual shows the notification was not received within the five-day period.

7.19(4) An individual who waives the right to an administrative disqualification hearing will be subject to the same penalties as an individual found to have committed an intentional program violation in an administrative disqualification hearing.

7.19(5) No further administrative appeal procedure exists after an individual waives the individual's right to an administrative disqualification hearing and a disqualification penalty has been imposed. The disqualification penalty shall not be changed by a subsequent fair hearing decision.

DIVISION II
APPEALS BASED ON THE COMPETITIVE PROCUREMENT BID PROCESS

441—7.41(17A) Scope, bidder and applicability. The rules in Division II apply to appeals based on the department's competitive procurement bid process. A bidder is an entity that submits a proposal in response to a solicitation issued through the department's competitive procurement process.

441—7.42(17A) Requests for timely filing of an appeal. Any bidder that receives either a notice of disqualification or a notice of award, and has first exhausted the reconsideration process, is considered an aggrieved party and may file a written appeal with the department.

7.42(1) An aggrieved party in a competitive procurement must seek reconsideration of a disqualification or a notice of award prior to filing any appeal. The request for reconsideration must be received by the department within five calendar days of the date of either a disqualification notice or notice of award, exclusive of Saturdays, Sundays and legal state holidays. The department will expeditiously address the request for reconsideration and issue a decision on the reconsideration. If the party seeking reconsideration continues to be an aggrieved party following receipt of the decision on reconsideration, the aggrieved party may file an appeal within five calendar days of the date of the department's decision on reconsideration, exclusive of Saturdays, Sundays and legal state holidays.

7.42(2) The written appeal shall state the grounds upon which the appellant challenges the department's decision.

7.42(3) The day after the department's decision on reconsideration is issued is the first day of the period in which the appeal may be filed. The mailing address is: Department of Human Services, Appeals Section,

1305 East Walnut Street, Des Moines, Iowa 50319-0114. Appeals may also be sent by email, or in-person delivery.

When an appeal is submitted through an electronic delivery method, such as electronic mail or facsimile, the appeal is filed on the date it is submitted. The electronic delivery method shall record the date and time the appeal request was submitted. If there is no date recorded by the electronic delivery method or the appeal was filed via in-person delivery, the date of filing is the date the appeal is stamped received by the agency. Receipt date of all appeals shall be documented by the office where the appeal is received.

When the time limit for filing falls on a holiday or a weekend, the time will be extended to the next workday.

441—7.43(17A) Bidder appeals. The bidder appeal shall be a contested case proceeding and shall be conducted in accordance with the provisions of Division II. Division I of this chapter does not apply to competitive procurement bid appeals, unless otherwise noted.

7.43(1) *Hearing time frame.* The presiding officer shall hold a hearing on the bidder appeal within 60 days of the date the notice of appeal was received by the department.

7.43(2) *Registration.* Upon receipt of the notice of appeal, the department shall register the appeal.

7.43(3) *Acknowledgment.* Upon receipt of the notice of appeal, the department shall send a written acknowledgment of receipt of the appeal to the appellant, representative, or both.

7.43(4) *Granting a hearing.* The department shall determine whether an appellant may be granted a hearing and the issues to be discussed at the hearing in accordance with the applicable rules, statutes or federal regulations or request for proposal.

a. The appeals of those appellants who are granted a hearing shall be certified to the department of inspections and appeals for the hearing to be conducted. The department shall indicate at the time of certification the issues to be discussed at the hearing.

b. Appeals of those appellants that are denied a hearing shall not be closed until a letter is sent to the appellant and the appellant's representative advising of the denial of the hearing and the basis upon which that denial is made. Any appellant that disagrees with a denial may present additional information relative to the reason for denial and request reconsideration by the department over the denial.

7.43(5) *Hearing scheduled.* For those records certified for hearing, the department of inspections and appeals shall establish the date, time, method and place of the hearing, with due regard for the convenience of the appellant as set forth in the department of inspections and appeals rules in 481—Chapter 10 unless otherwise designated by federal or state statute or regulation.

7.43(6) *Method of hearing.* The department of inspections and appeals shall determine whether the appeal hearing is to be conducted in person, by videoconference or by teleconference call. The parties to the appeal may participate from multiple sites for videoconference or teleconference hearings. Any appellant is entitled to an in-person hearing if the appellant requests one. All parties shall be granted the same rights during a teleconference hearing as specified in rule 441—7.8(17A).

7.43(7) *Reschedule requests.* Requests made by the appellant or the department to set another date, time, method or place of hearing shall be made to the department of inspections and appeals, except as otherwise noted. The granting of the requests will be at the discretion of the department of inspections and appeals. All requests concerning the scheduling of a hearing shall be made to the department of inspections and appeals directly.

7.43(8) *Notification.* For those appeals certified for hearing, the department of inspections and appeals shall send a notice to the appellant at least ten calendar days in advance of the hearing date.

a. The notice shall comply with Iowa Code section 17A.12(2), and include a statement that opportunity shall be afforded to all parties to respond and present evidence on all issues involved and to be represented by counsel at their own expense.

b. A copy of this notice shall be made available to the department employee who took the action and to any other parties to the appeal.

[**ARC 1206C**, IAB 12/11/13, effective 1/15/14; **ARC 4972C**, IAB 3/11/20, effective 4/15/20]

441—7.44(17A) Procedures for bidder appeal.

7.44(1) Discovery. The parties shall serve any discovery requests upon other parties at least 30 days prior to the date set for the hearing. The parties must serve responses to discovery at least 15 days prior to the date set for the hearing.

7.44(2) Witnesses and exhibits. The parties shall contact each other regarding witnesses and exhibits at least ten days prior to the date set for the hearing. The parties must meet prior to the hearing regarding the evidence to be presented in order to avoid duplication or the submission of extraneous materials.

7.44(3) Amendments to notice of appeal. The aggrieved bidder may amend the grounds upon which the bidder challenges the department's award no later than 15 days prior to the date set for the hearing.

7.44(4) If the hearing is not conducted in person, the parties must deliver all exhibits to the office of the presiding officer at least three days prior to the time the hearing is conducted.

7.44(5) The presiding officer shall issue a proposed decision in writing that includes findings of fact and conclusions of law stated separately. The decision shall be based on the record of the contested case and shall conform to Iowa Code chapter 17A. The presiding officer shall send the proposed decision to the appellant and representative by mail.

7.44(6) The record of the contested case shall include all materials specified in Iowa Code subsection 17A.12(6).

441—7.45(17A) Stay of agency action for bidder appeal.

7.45(1) *When a stay may be requested.*

a. Any party appealing the issuance of a notice of disqualification or notice of award may petition for stay of the decision pending its review. The petition for stay shall be filed with the notice of appeal, shall state the reasons justifying a stay, and shall be accompanied by an appeal bond equal to 120 percent of the contract value.

b. Any party adversely affected by a final decision and order may petition the department for a stay of that decision and order pending judicial review. The petition for stay shall be filed with the director within five days of receipt of the final decision and order and shall state the reasons justifying a stay.

7.45(2) *When a stay is granted.* In determining whether to grant a stay, the director shall consider the factors listed in Iowa Code section 17A.19(5)*"c."*

7.45(3) *Vacation.* A stay may be vacated by the issuing authority upon application of the department or any other party.

[**ARC 1206C**, IAB 12/11/13, effective 1/15/14]

441—7.46(17A) Request for review of the proposed decision. A request for review of the proposed decision shall follow the provisions outlined in rule 441—7.11(17A).

[**ARC 1206C**, IAB 12/11/13, effective 1/15/14; **ARC 3787C**, IAB 5/9/18, effective 7/1/18; **ARC 4972C**, IAB 3/11/20, effective 4/15/20]

441—7.47(17A) Other procedural considerations.

7.47(1) *Consolidation—severance.*The rules regarding consolidation and severance in 481—10.10 apply.

7.47(2) *Rights of appellants during hearings.* All rights afforded appellants at rule 441—7.8(17A) shall apply.

441—7.48(17A) Appeal record.

7.48(1) The appeal record shall consist of all items specified in Iowa Code section 17A.16.

7.48(2) The party that requests a transcription of the proceedings shall bear the cost.

441—7.49(17A) Pleadings. The rules regarding pleadings in 441—10.11 apply.

441—7.50(17A) Ex parte communications. The rules regarding ex parte communications specified in subrule 7.9(1) and Iowa Code section 17A.17apply.

441—7.51(17A) Right of judicial review. The rules regarding right of judicial review specified in subrule 7.12(3) and Iowa Code section 17A.19 apply.
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CHAPTER 9
PUBLIC RECORDS AND FAIR
INFORMATION PRACTICES

441—9.1(17A,22) Statement of policy, purpose and scope of chapter.

9.1(1) The purpose of this chapter is to facilitate public access to open records. It also seeks to facilitate department determinations with respect to the handling of confidential records and the implementation of the fair information practices Act. The department is committed to the policies set forth in Iowa Code chapter 22; department staff shall cooperate with members of the public in implementing the provisions of that chapter.

These rules also implement the federal Health Insurance Portability and Accountability Act (HIPAA) regulations at 45 CFR Parts 160 and 164 as amended to August 14, 2002. These rules set forth the standards the department must meet to protect the privacy of protected health information. The department is a hybrid entity for purposes of HIPAA. The rules on protected health information apply only to those parts of the department that are considered part of the covered entity.

9.1.(2) This chapter does not:

a. Require the agency to index or retrieve records which contain information about individuals by that person's name or other personal identifier.

b. Make available to the general public records which would otherwise not be available under the public records law, Iowa Code chapter 22.

c. Govern the maintenance or disclosure of, notification of or access to, records in the possession of the agency which are governed by the rules of another agency.

d. Apply to grantees, including local governments or subdivisions thereof, administering state-funded programs.

e. Make available records compiled by the agency in reasonable anticipation of court litigation or formal administrative proceedings. The availability of such records to the general public or to any subject individual or party to such litigation or proceedings shall be governed by applicable constitutional principles, statutes, rules of discovery, evidentiary privileges, and applicable rules of the agency.

f. Require the agency to create, compare or procure a record solely for the purpose of making it available.

441—9.1(17A,22) Definitions. As used in this chapter:

"Business associate" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

"Client" means a person who has applied for or received services or assistance from the department.

"Confidential record" in these rules means a record which is not available as a matter of right for examination and copying by members of the public under applicable provisions of law. Confidential records include records or information contained in records that the agency is prohibited by law from making available for examination by members of the public, and records or information contained in records that are specified as confidential by Iowa Code section 22.7, or other provision of law, but that may be disclosed upon order of a court, the lawful custodian of the record, or by another person duly authorized to release the record. Mere inclusion in a record of information declared confidential by an applicable provision of law does not necessarily make that entire record a confidential record.

"Covered entity" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

"Custodian" means the director of the department or the director's designee.

"Data aggregation" is the same as defined in 45 CFR §164.501 as amended to January 25, 2013.

"Designated record set" is the same as defined in 45 CFR §164.501 as amended to January 25, 2013, including:

1. The medical records about subjects that are maintained for facilities;
2. The enrollment, payment, and eligibility record systems maintained for Medicaid; or
3. The enrollment, payment, and eligibility record systems maintained for the HAWK-I program that are used, in whole or in part, by the HAWK-I program to make decisions about subjects.

For purposes of this definition, the term "record" means the same as defined in 45 CFR §164.501 as amended to January 25, 2013.

"Disclosure" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

"Facility" or *"facilities*" means, with respect to HIPAA rules about health information, one or more of these department institutions: Cherokee Mental Health Institute, Clarinda Mental Health Institute, Glenwood Resource Center, Independence Mental Health Institute, Mount Pleasant Mental Health Institute, and Woodward Resource Center.

"Health care" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014. *"Health care clearinghouse*" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014

"Health care operations" for covered entities in the department has the same definition as that stated in 45 CFR 164.501 as amended to January 25, 2013.

"Health care provider" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

"Health information" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

"Health oversight agency" means the same as defined in 45 CFR §164.501 as amended to January 25, 2013.

"Health plan" means an individual or group plan that provides or pays the cost of medical care, as defined at 45 CFR 160.103 as amended to June 27, 2014. In the department, "health plan" means Medicaid or hawk-i.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

"Law enforcement official" means an officer or employee of any agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, or an Indian tribe, who is empowered by law to:

1. Investigate or conduct an official inquiry into a potential violation of law; or
2. Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

"Legal representative" is a person recognized by law as standing in the place or representing the interests of another for one or more purposes.

"Mental health information" means oral, written, or otherwise recorded information which indicates the identity of a person receiving professional services (as defined in Iowa Code section 228.1(8)) and which relates to the diagnosis, course, or treatment of the person's mental or emotional condition.

"Open record" means a record other than a confidential record.

"Payment," with respect protected health information, has the same definition as that stated in45 CFR §164.501 as amended to January 25, 2013. In the department, "payment" applies to subjects for whom health care coverage is provided under the Medicaid program or the HAWK-I program.

"Personally identifiable information" means information about or pertaining to the subject of a record which identifies the subject and which is contained in a record system.

"Personal representative" means someone designated by another as standing in the other's place or representing the other's interests for one or more purposes. The term "personal representative" includes, but is not limited to, a legal representative. For disclosure of protected health information, the definition of "personal representative" is more restrictive, as described at rule 441—9.15(17A,22).

"Protected health information" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

"Psychotherapy notes" means the same as defined in 45 CFR §164.501 as amended to January 25, 2013.

"Public health authority" means the same as defined in 45 CFR §164.501 as amended to January 25, 2013.

"Record" means the whole or a part of a "public record" as defined in Iowa Code section 22.1 that is owned by or in the physical possession of the department.

"Record system" means any group of records under the control of the department from which a record may be retrieved by a personal identifier such as the name of a subject, number, symbol, or other unique identifier assigned to a subject.

"Subject" means the person who is the subject of the record, whether living or deceased.

"Substance abuse information" means information which indicates the identity, diagnosis, prognosis, or treatment of any person in an alcohol or drug abuse program.

"Transaction" means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

"Treatment," means the same as defined in 45 CFR §164.501 as amended to January 25, 2013.

"*Use,*" with respect to protected health information, means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

"Workforce" with respect to protected health information, means the same as defined in 45 CFR 160.103 as amended to June 27, 2014.

441—9.2(17A,22) Requests for access to records.

9.2(1) *Location of record.* A request for access to a record should be directed to the director's office 1305 East Walnut, Des Moines, IA, 50319. If a request for access to a record is misdirected, department personnel will promptly forward the request to the department's records officer.

9.2(2) *Office hours.* Open records shall be made available during all customary office hours, which are 8 a.m. to 4:30 p.m. daily, excluding Saturdays, Sundays and legal holidays.

9.2(3) *Request for access.* Requests for access to open records may be made in writing, in person, or by telephone. Requests shall identify the particular records sought by name or description. Mail or telephone requests shall include the name, address, and telephone number of the person requesting the information.

9.2(4) *Response to requests.* Access to an open record will be provided upon request unless the size or nature of the request makes prompt access infeasible. If the size or nature of the request for access to an open record requires time for compliance, the custodian shall comply with the request as soon as feasible. Access to an open record may be delayed for one of the purposes authorized by Iowa Code section 22.8(4) or 22.10(4).

The custodian of a record may deny access to the record by members of the public only on the grounds that such a denial is warranted under Iowa Code sections 22.8(4) and 22.10(4), or that it is a confidential record, or that its disclosure is prohibited by a court order. Access by members of the public to a confidential record is limited by law and, therefore, may generally be provided only in accordance with the provisions of rule 441—9.4(17A,22) and other applicable provisions of law.

9.3(5) *Security of record.* No person may, without permission from the custodian, search or remove any record from department files. Examination and copying of department records shall be supervised by the custodian or a designee of the custodian. Records shall be protected from damage and disorganization.

9.3(6) *Copying.* A reasonable number of copies of an open record may be made in the department office. If photocopy equipment is not available in the department office where an open record is kept, the custodian shall permit its examination in that office and shall arrange to have copies promptly made elsewhere.

9.3(7) *Fees.* The department may charge fees as permitted by Iowa Code chapter 22. The department will publish a fee schedule for open records on its website. The department may charge a fee for the cost of preparing an explanation or summary of health information. The department and the subject requesting the information shall agree to the amount of any fee imposed before the department prepares the explanation or summary.

441—9.4(17A,22) Access to confidential records. Under Iowa Code section 22.7 or other applicable provisions of law, the lawful custodian may disclose certain confidential records to one or more members of the public. Other provisions of law authorize or require the custodian to release specified confidential records under certain circumstances or to particular persons. In requesting the custodian to permit the examination and copying of such a confidential record, the following procedures apply and are in addition to those specified for requests for access to records in rule 441—9.3(17A,22)

9.4(1) *Proof of identity.* A person requesting access to a confidential record may be required to provide proof of identity or authority to secure access to the record.

9.4(2) *Requests.* The custodian may require a request to examine and copy a confidential record to be in writing. A person requesting access to such a record may be required to sign a certified statement or affidavit enumerating the specific reasons justifying access to the confidential record and to provide any proof necessary to establish relevant facts.

9.4(3) *Notice to subject of record and opportunity to obtain injunction.* Except as provided in 441—subrule 175.41(2), after the custodian receives a request for access to a confidential record, and before the custodian releases such a record, the custodian may make reasonable efforts to notify promptly any person who is a subject of that record, is identified in that record, and whose address or telephone number is contained in that record. To the extent such a delay is practicable and in the public interest, the custodian may give the subject of such a confidential record to whom notification is transmitted a reasonable opportunity to seek an injunction under Iowa Code section 22.8, and indicate to the subject of the record the specific period of time during which disclosure will be delayed for that purpose.

9.4(4) *Request denied.* When the custodian denies a request for access to a confidential record, the custodian shall promptly notify the requester. If the requester indicates to the custodian that a written notification of the denial is desired, the custodian shall promptly provide such a notification that is signed by the custodian and that includes:

a. The name and title or position of the custodian responsible for the denial; and

b. A citation to the provision of law vesting authority in the custodian to deny disclosure of the record and a brief statement of the reasons for the denial to this requester.

9.4(5) *Request granted.* Except as provided in 441—subrule 175.41(2), when the custodian grants a request for access to a confidential record, the custodian shall notify the requester or the person who is to receive the information and include any limits on the examination and copying of the record.

9.4(6) *Records requiring special procedures.* Special procedures are required for access to:

a. Child abuse information. Access to child abuse information is obtained according to rules 441—175.41(235A) and 441—175.42(235A).

b. Dependent adult abuse information. Access to adult abuse information is governed by rule 441—176.9(235A).

441—9.5(17A,22) Requests for treatment of a record as a confidential record and its withholding from examinations. The custodian may treat a record as a confidential record and withhold it from examination only to the extent that the custodian is authorized by Iowa Code section 22.7, another applicable provision of law, or a court order, to refuse to disclose that record to members of the public.

9.5(1) *Persons who may request.* Any person who would be aggrieved or adversely affected by disclosure of a record and who asserts that Iowa Code section 22.7, another applicable provision of law, or a court order, authorizes the custodian to treat the record as a confidential record, may request the custodian to treat that record as a confidential record and to withhold it from public inspection.

9.5(2) *Request.* A request that a record be treated as a confidential record and be withheld from public inspection shall be in writing and shall be filed with the custodian.

a. The request must set forth the legal and factual basis justifying such confidential record treatment for that record, and the name, address, and telephone number of the person authorized to respond to any inquiry or action of the custodian concerning the request.

b. A person requesting treatment of a record as a confidential record may also be required to sign a certified statement or affidavit stating the specific reasons justifying the treatment of that record as a confidential record and to provide any proof necessary to establish relevant facts.

c. Requests to temporarily treat a record as a confidential record shall specify the precise period of time for which that treatment is requested.

d. A person filing such a request shall, if possible, provide a copy of the record in question from which those portions for which such confidential record treatment has been requested have been deleted. If the original record is being submitted to the department by the person requesting confidential treatment at the time the request is filed, the person shall indicate conspicuously on the original record that all or portions of it are confidential.

9.5(3) *Failure to request.* Failure of a person to request confidential record treatment for a record does not preclude the custodian from treating it as a confidential record. However, if a person who has submitted business information to the department does not request that it be withheld from public inspection under Iowa Code sections 22.7(3) and 22.7(6), the custodian of records containing that information may proceed as if that person has no objection to its disclosure to members of the public.

9.5(4) *Timing of decision.* A decision by the custodian with respect to the disclosure of a record to members of the public may be made when a request for its treatment as a confidential record that is not available for public inspection is filed, or when the custodian receives a request for access to the record by a member of the public.

9.5(5) *Request granted or deferred.* If a request for such confidential record treatment is granted, or if action on such a request is deferred, a copy of the record from which the matter in question has been deleted and a copy of the decision to grant the request or to defer action upon the request will be made available for public inspection in lieu of the original record. If the custodian subsequently receives a request for access to the original record, the custodian will make reasonable and timely efforts to notify any person who has filed a request for its treatment as a confidential record that is not available for public inspection of the pendency of that subsequent request.

9.5(6) *Request denied and opportunity to seek injunction.* If a request that a record be treated as a confidential record and be withheld from public inspection is denied, the custodian shall notify the requester in writing of that determination and the reasons therefor. On application by the requester, the custodian may engage in a good faith, reasonable delay in allowing examination of the record so that the requester may seek injunctive relief under the provisions of Iowa Code section 22.8, or other applicable provision of law. However, such a record shall not be withheld from public inspection for any period of time if the custodian determines that the requester had no reasonable grounds to justify the treatment of that record as a confidential record. The custodian shall notify requester in writing of the time period allowed to seek injunctive relief or the reasons for the determination that no reasonable grounds exist to justify the treatment of that record as a confidential record. The custodian may extend the period of good faith, reasonable delay in allowing examination of the record so that the requester may seek injunctive relief only if no request for examination of that record has been received, or if a court directs the custodian to treat it as a confidential record, or to the extent permitted by another applicable provision of law, or with the consent of the person requesting access.

9.5(7) *Requesting privacy protection for protected health information.*

a. Requesting restrictions on protected health information use or disclosure. Subjects may complete a Request to Restrict Use or Disclosure of Health Information form. The department will follow the requirements of 45 CFR §164.522 as amended to January 25, 2013 in responding to these requests.

b. Requesting the receipt of communications of protected health information by alternative means or at alternative locations. Subjects may complete a Request to Change How Health Information Is Provided form. The department will follow the requirements of 45 CFR §164.522 as amended to January 25, 2013 in responding to these requests. For Medicaid and hawk-i, the subject is required to clearly indicate the reason for requesting the confidential communication. Facilities shall not require the subject to explain the basis for the request as a condition of providing confidential communications.

441—9.6(17A,22) Procedure by which additions, dissents, or objections may be entered into certain records.

9.6(1) *All programs.* Except as otherwise provided by law, a subject may file a request with the custodian to review, and to have a written statement of additions, dissents, or objections entered into, a record containing personally identifiable information pertaining to that subject. However, the subject is not authorized to alter the original copy of the record or to expand the official record of any department proceeding.

a. The subject shall send the request to review such a record or the written statement of additions, dissents, or objections to the department.

b. The request to review such a record or the written statement of additions, dissents, or objections must be dated and signed by the subject, and shall include the current address and telephone number of the subject or the subject's representative.

9.6(2) *Additional procedures for protected health information.* The department will follow the protected health information right to amend standards as outlined in 45 CFR §164.526 as amended to January 15, 2013. A subject shall submit a request for amendment to the department on a Request to Amend Health Information form published on the department's website. The subject shall provide a reason to support the requested amendment.

441—9.7(17A,22,228) Consent to disclosure by the subject of a confidential record. To the extent permitted by any applicable provision of law, the subject of a confidential record may have a copy of the portion of that record concerning the subject disclosed to a third party. A request for such a disclosure must be in writing and must identify the particular record or records to be disclosed, the particular person or class of persons to whom the record may be disclosed, and the time period during which the record may be disclosed. The subject of the record and, where applicable, the person to whom the record is to be disclosed may be required to provide proof of identity. Appearance of counsel before the department on behalf of a person who is the subject of a confidential record is deemed to constitute consent for the department to disclose records about that person to the person's attorney. No confidential information about clients of the department shall be released without the client's consent, except as otherwise provided in these rules. Release of confidential information includes granting access to or allowing the copying of a record, providing information either in writing or orally, or acknowledging information to be true or false.

9.7(1) *Release Forms.*

a. Releases allowing the department to provide confidential information. Subjects should complete the Authorization for the Department to Release Information for releases that do not involve protected health information.

b. Releases allowing the department to provide confidential information, including protected health information. When consent or authorization for use or disclosure of health information is required, the department shall use Form 470-3951, Authorization to Obtain or Release Health Care Information, or a HIPAA authorization form from another source that meets HIPAA requirements. The department shall not require a subject to sign a HIPAA authorization form as a condition of treatment, payment, enrollment in a health plan, or eligibility for benefits. The department as a health care provider may require a subject to sign a HIPAA authorization form for the use or disclosure of protected health information for research, as a condition of the subject's receiving research-related treatment. A subject may revoke a HIPAA authorization at any time, provided that the revocation is in writing using the Request to End an Authorization form, except to the extent that the department has taken action in reliance thereon.

(2) Except as provided in subparagraph 9.7(1)*"c"*(1), department staff shall release mental health or substance abuse information only with authorization on the Consent to Obtain and Release Information form, or a form from another source that meets requirements of law.

c. Releases allowing the department to obtain confidential information from a third party. The department is required to obtain confidential information from third parties. The department may make these requests only when the client has authorized the release on one of the following forms.

(1) Authorization for Release of Information
(2) Household Member Questionnaire
(3) Bank or Credit Union Information
(4) Addendum for Application and Review Forms for Release of Information
(5) Request for School Verification
(6) Employer's Statement of Earnings.
(7) Verification of Educational Financial Aid.
(8) Financial Institution Verification.
(9) Authorization to Obtain or Release Health Care Information.

d. Releases for p*hotographs and recordings.* The department uses Authorization to Take and Use Photographs, and Authorization to Take and Use Photographs of Minor or Ward forms, for permission to use photographs in department publications. The department shall obtain authorization from the subject or person responsible (such as a guardian, custodian, or personal representative) for the subject before taking

photographs or making any type of recording for any purpose other than those specifically allowed by law or for internal use within an institution.

9.7(2) *Exceptions to use of release forms.*

a. Public official. A letter from the subject to a public official which seeks the official's intervention on behalf of the subject in a matter that involves the department shall be treated as an authorization to release information. The department shall release sufficient information about the subject to the official to resolve the matter.

b. *Medical emergency.* Department staff may authorize release of confidential information to medical personnel in a medical emergency if the subject is unable to give or withhold consent. As soon as possible after the release of information, the subject shall be advised of the release.

d. Abuse information. Consent to release information is not required to gather information for investigations of child abuse or dependent adult abuse.

9.7(3) *Opportunity for subject to agree or object.* This subrule describes when the department may use or disclose protected health information, without a written authorization, to persons involved in the subject's care and for notification purposes. However, the department shall give the subject an opportunity to agree or object, unless this requirement is waived as specified in paragraph 9.7(3)*"e."*

a. Involvement in the subject's care. The department may disclose protected health information that is directly relevant either to a subject's care or to payment related to the subject's care, provided payment is relevant to the person's involvement in the subject's care. The person involved must be:

(1) A family member;

(2) Another relative;

(3) A close personal friend of the subject; or

(4) Any other person identified by the subject.

b. Notification purposes. The department may use or disclose protected health information to notify, or assist in notifying, identifying or locating a family member, a personal representative of the subject, or another person responsible for the care of the subject of the subject's location, general condition or death. For disaster relief purposes, the use or disclosure shall be in accordance with paragraph 9.7(3)*"f."*

c. Uses and disclosures with the subject present. If the subject is present for, or available before, a use or disclosure permitted by this subrule and has the capacity to make health care decisions, the department may use or disclose the protected health information if the department:

(1) Obtains the subject's agreement;

(2) Provides the subject with the opportunity to object to the disclosure, and the subject does not express an objection; or

(3) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the subject does not object to the disclosure.

d. Informing the subject. The department may orally inform the subject of and obtain the subject's oral agreement or objection to a use or disclosure permitted by this subrule.

e. Limited uses and disclosures when the subject is not present. When the subject is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the subject's incapacity or an emergency circumstance, the department may, in the exercise of professional judgment, determine that disclosure is in the best interest of the subject.

(1) When the department determines that disclosure is in the subject's best interest, the department may disclose only the protected health information that is directly relevant to the person's involvement with the subject's health care.

(2) The department may use professional judgment and its experience with common practice to make reasonable inferences of the subject's best interest in allowing a person to act on behalf of the subject to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

f. For disaster relief purposes. The department may use protected health information or disclose protected health information to a public or private organization authorized by law or by its charter to assist in disaster relief efforts for the purpose of coordinating with these organizations the uses or disclosures permitted by paragraph 9.7(3)*"b."* The requirements in paragraphs 9.7(3)*"c"* and *"d"* apply to these uses and

disclosures to the extent that the department, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

441—9.8(17A,22) Notice to suppliers of information. When the department requests a person to supply information about that person, the department shall notify the person of how the information will be used, which persons outside the department might routinely be provided this information, which parts of the requested information are required and which are optional, and the consequences of a failure to provide the information requested. This notice may be given in these rules, on the written form used to collect the information, on a separate fact sheet or letter, in brochures, in formal agreements, in contracts, in handbooks, in manuals, verbally, or by other appropriate means. The notice shall generally be given at the first contact with the department and need not be repeated. Where appropriate, the notice may be given to a person's legal or personal representative. Notice may be withheld in an emergency or where it would compromise the purpose of a department investigation.

441—9.9(17A,22) Release to subject.

9.9(1) *Access by subjects to protected health information.* The department will follow the access of individuals to protected health information standards as outlined in 45 CFR §164.524 as amended to February 6, 2014. Subjects shall submit all requests for access to the department using the Request for Access to Health Information form. If the department does not maintain the protected health information that is the topic of the subject's request for access, and the department knows where the requested information is maintained, the department shall inform the subject where to direct the request for access.

441—9.10(17A,22) Use and disclosure without consent of the subject. Open records are routinely disclosed without the consent of the subject. To the extent allowed by law, the department may also use and disclose confidential information without the consent of the subject or the subject's representative.

9.10(1) *Internal use.* Confidential information may be disclosed to employees and agents of the department as needed for the performance of their duties. The custodian of the record shall determine what constitutes legitimate need to use confidential records.

9.10(2) *Audits and health oversight activities.*

a. Audits. Information concerning program expenditures and client eligibility is released to staff of the state executive and legislative branches who are responsible for ensuring that public funds have been managed correctly. Information is also released to auditors from federal agencies when those agencies provide program funds.

b. Health oversight activities. The department will follow the uses and disclosures standards for health oversight activities as outlined in 45 CFR §164.512 as amended to January 6, 2016.

9.10(3) *Program review.* Information concerning client eligibility and benefits is released to state or federal officials responsible for determining whether the department is operating a program lawfully. These officials include the ombudsman office under Iowa Code section 2C.9, the auditor of state under Iowa Code section 11.2, the Office of Inspector General in the federal Department of Health and Human Services, and the Centers for Medicare and Medicaid Services.

9.10(4) *Contracts and agreements with agencies and persons.*

a. The department may enter into contracts or agreements with public or private agencies to carry out the department's official duties. Information necessary to carry out these duties may be shared with these agencies. The department may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the department obtains satisfactory assurance that the business associate will appropriately safeguard the information.

b. The department may enter into agreements to share information with agencies administering federal or federally assisted programs which provide assistance or services directly to persons on the basis of need. Only information collected in the family investment program, the child care assistance program, the food assistance program, the refugee resettlement program, or the child support recovery program may be shared under these agreements.

c. To meet federal income and eligibility verification requirements, the department has entered into agreements with the department of workforce development, the United States Internal Revenue Service, and the United States Social Security Administration. The department obtains information regarding persons whose income or resources are considered in determining eligibility and the amount of benefits for the family investment program, refugee cash assistance, child care assistance, food assistance, Medicaid, state supplementary assistance and foster care. Identifying information regarding clients of these programs is released to these agencies. The information received may be used for eligibility and benefit determinations.

d. To meet federal requirements under the Immigration Reform and Control Act of 1986 (IRCA) relating to the Systematic Alien Verification for Entitlements (SAVE) program, the department has entered into an agreement with the Bureau of Citizenship and Immigration Service (BCIS). Under the agreement, the department exchanges information necessary to verify alien status for the purpose of determining eligibility and the amount of benefits for the family investment program, refugee cash assistance, food assistance, Medicaid, state supplementary assistance and foster care assistance. Identifying information regarding these subjects is released to the BCIS. The information received may be used for eligibility and benefit determinations.

e. The department has entered into an agreement with the department of workforce development to provide services to family investment program clients participating in the PROMISE JOBS program as described at 441—Chapter 93. Information necessary to carry out these duties shall be shared with the department of workforce development, as well as with its subcontractors.

f. The department has entered into an agreement with the department of education, vocational rehabilitation, disability determination services, to assist with Medicaid disability determinations.

g. The department has entered into an agreement with the department of education to share information that assists both schools and department clients in carrying out the annual verification process required by the United States Department of Agriculture, Food and Nutrition Service. That federal agency requires the department of education and local schools to verify eligibility of a percentage of the households approved for free-meal benefits under the school lunch program. When a department office receives a written request from the local school, the department office responds in writing with the current family investment program and food assistance program status of each recipient of free meals listed in the request. Other client-specific information is made available only with written authorization from the client.

9.10(5) *Release for judicial and administrative proceedings.* Information is released to the court as required in Iowa Code sections 125.80, 125.84, 125.86, 229.8, 229.10, 229.13, 229.14, 229.15, 229.22, 232.48, 232.49, 232.52, 232.71B, 232.81, 232.97, 232.98, 232.102, 232.111, 232.117 and 235B.3.

a. The department may disclose protected health information in the course of any judicial or administrative proceeding in response to an order of a court or administrative tribunal, provided that the department discloses only the protected health information expressly authorized by the order and the court makes the order knowing that the information is confidential.

b. When a court subpoenas information that the department is prohibited from releasing, the department shall advise the court of the statutory and regulatory provisions against disclosure of the information and shall disclose the information only on order of the court.

9.10(6) *Fraud.* Information concerning suspected fraud or misrepresentation to obtain department services or assistance is disclosed to the department of inspections and appeals and to law enforcement authorities.

9.10(7) *Service referrals.* Information concerning clients may be shared with purchase of service providers under contract to the department.

a. Information concerning the client's circumstances and need for service is shared with prospective providers to obtain placement for the client. If the client is not accepted for service, all written information released to the provider shall be returned to the department.

b. When the information needed by the provider is mental health information or substance abuse information, the subject's specific consent is required.

9.10(8) *Medicaid billing.* Only the following information shall be released to bona fide providers of medical services in the event that the provider is unable to obtain it from the subject and is unable to complete the Medicaid claim form without it:

a. Patient identification number.

b. Health coverage code as reflected on the subject's medical card.

c. The subject's date of birth.

d. The subject's eligibility status for the month that the service was provided.

e. The amount of spenddown.

f. The bills used to meet spenddown.

9.10(9) *County billing.* Information necessary for billing is released to county governments that pay part of the cost of care for intermediate care facility services under 441—subrule 82.14(2) or Medicaid waiver services under rule 441—83.70(249A) or 441—83.90(249A). This information includes client names, identifying numbers, provider names, number of days of care, amount of client payment, and amount of payment due.

9.10(10) *Child support recovery.* The child support recovery unit has access to information from most department records for the purpose of establishing and enforcing support obligations. Information about absent parents and recipients of child support services is released according to the provisions of Iowa Code chapters 234, 252A, 252B, 252C, 252D, 252E, 252F, 252G, 252H, 252I, 252J, 252K, 598, 600B, and any other support chapter. Information is also released to consumer reporting agencies as specified in rule 441—98.116(252B).

9.10(11) *Refugee resettlement program.* Contacts with both sponsor and resettlement agencies are made as a part of the verification process to determine eligibility or the amount of assistance. When a refugee applies for cash or Medicaid, the refugee's name, address, and telephone number are given to the refugee's local resettlement agency.

9.10(12) *Abuse investigation.* The central abuse registry disseminates child abuse information and dependent adult abuse information as provided in Iowa Code sections 235A.15 and 235B.7, respectively. Reports of child abuse and dependent adult abuse investigations are submitted to the county attorney as required in Iowa Code sections 232.71B and 235B.3. Results of the investigation of a report by a mandatory reporter are communicated to the reporter as required in Iowa Code sections 235A.17(2) and 235A.15(2)*"b"*(5).

9.10(13) *Foster care.* Information concerning a child's need for foster care is shared with foster care review committees or foster care review boards and persons named in the case permanency plan.

9.10(14) *Adoption.* Adoptive home studies completed on families who wish to adopt a child are released to licensed child-placing agencies, to the United States Immigration and Naturalization Service, and to adoption exchanges. Information is released from adoption records as provided in Iowa Code sections 600.16 and 600.24.

9.10(15) *Disclosures to law enforcement.*

a. Disclosures by workforce members who are crime victims. The department is not considered to have violated the requirements of this chapter if a member of its workforce who is the victim of a criminal act discloses confidential information to a law enforcement official, provided that:

(1) The confidential information disclosed is about the suspected perpetrator of the criminal act and intended for identification and location purposes; and

(2) The confidential information disclosed is limited to the following information:

1. Name and address.
2. Date and place of birth.
3. Social security number.
4. ABO blood type and Rh factor.
5. Type of injury.
6. Date and time of treatment.
7. Date and time of death, if applicable.

8. A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

b. Crime on premises. The department may disclose to a law enforcement official protected health information that the department believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the department.

c. Decedents. The department may disclose protected health information to a law enforcement official about a subject who has died when the death resulted from child abuse or neglect or the death occurred in a department facility.

d. Other. The department may disclose confidential information to a law enforcement official when otherwise required or allowed by this chapter, such as disclosures about victims of child abuse or neglect; disclosures to avert a threat to health or safety, or to report suspected fraud; disclosures required by due process of law, such as disclosures for judicial and administrative proceedings; or other disclosures required by law.

9.10(16) *Response to law enforcement.* The address of a current recipient of family investment program benefits may be released upon request to a federal, state or local law enforcement officer if the officer provides the name of the recipient, and the officer demonstrates that:

a. The recipient is a fugitive felon who is fleeing prosecution, custody or confinement after conviction under state or federal law, or who is a probation or parole violator under state or federal law, or

b. The recipient has information that is necessary for the officer to conduct the officer's official duties, and

c. The location or apprehension of the recipient is within the officer's official duties.

9.10(17) *Research.* Information that does not identify individual clients may be disclosed for research purposes with the consent of the custodian responsible for the records.

a. Mental health information may be disclosed for purposes of scientific research as provided in Iowa Code section 228.5 and section 229.25. Requests to do research involving records of a department facility shall be approved by the designated authority.

b. Abuse registry information may be disclosed for research purposes as provided in rules 441—175.42(235A) and 441—176.12(235B) and authorized by Iowa Code sections 235A.15(2)*"e"*(1) and 235B.6(2)*"e"*(1).

c. For research relating to protected health information, the researcher shall provide the department with information about the nature of the research, the protocol, the type of information being requested, and any other relevant information that is available concerning the request. If the researcher feels that contact with the subject is needed, the researcher shall demonstrate to the department that the research cannot be conducted without contact with the subject. The researcher shall pay for the costs of obtaining authorizations needed to contact the subjects and for the cost of files and preparation needed for the research.

9.10(18) *Threat to health or safety.*

a. All programs. A client's name, identification, location, and details of a client's threatened or actual harm to department staff or property may be reported to law enforcement officials. Other information regarding the client's relationship to the department shall not be released. When a department staff person believes a client intends to harm someone, the staff person may warn the intended victim or police or both. Only the name, identification, and location of the client and the details of the client's plan of harm shall be disclosed.

b. Protected health information. The department will follow the disclosure standards in 45 CFR §164.512 as amended to January 6, 2016.

9.10(19) *Required by law.*

a. Information is shared with other agencies without a contract or written agreement when federal law or regulations require it.

b. The department may use or disclose protected health information to the extent that use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of the law.

c. State law shall preempt rules in this chapter about protected health information when any one of the following conditions exists:

(1) Exception granted by Secretary of Health and Human Services under 45 CFR 160.204 as amended to January 25, 2013.

(2) State law more stringent. The provision of state law relates to the privacy of protected health information and is more stringent than a requirement of this chapter, within the meaning of "more stringent" found at 45 CFR 160.202 as amended to January 25. 2013.

(3) Reporting requirements. The provision of state law, including state procedures established under the law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(4) Requirements related to audits, monitoring, evaluation, licensing, and certification. The provision of state law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities and persons.

9.10(20) *Treatment, payment, or health care operations.*

a. The department may use or disclose protected health information for treatment, payment, or health care operations, as permitted by 45 CFR 164.506 as amended to January 25, 2013, except for psychotherapy notes, which are subject to the limits described in paragraph 9.10(21)*"b."* The use or disclosure shall be consistent with other applicable requirements of this chapter.

b. The department may use or disclose psychotherapy notes without an authorization for any one of the following reasons:

(1) To carry out the following treatment, payment, or health care operations:

1. Use by the originator of the psychotherapy notes for treatment.

2. Use or disclosure by the department for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling.

3. Use or disclosure by the department to defend itself in a legal action or other proceeding brought by the subject.

(2) When required by the Secretary of Health and Human Services to investigate or determine the department's compliance with federal HIPAA regulations.

(3) For health oversight activities with respect to the oversight of the originator of the psychotherapy notes.

(4) When necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public as described in this chapter.

(5) When required by law as described in this chapter.

(6) To disclose protected health information in the designated record set to a coroner or medical examiner as described in this chapter.

9.10(21) Other uses and disclosures for which an authorization or opportunity to agree or object is not required. The department may use or disclose protected health information Other uses and disclosures for which an authorization or opportunity to agree or object is not required, as permitted by 45 CFR 164.512 as amended to January 25, 2013.

9.10(22) *Victims of domestic violence.* The department shall disclose confidential information about an individual whom the department reasonably believes to be a victim of domestic violence when required by state law.

9.10(23) *Whistle blowers.* The department is not considered to have violated the requirements of this chapter when a member of its workforce or a business associate discloses protected health information, provided that:

a. The workforce member or business associate has a good-faith belief that the department or a business associate has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or has provided care, services, or conditions that potentially endanger one or more patients, workers, or the public; and

b. The disclosure is made to one of the following:

(1) A health oversight agency or public health authority authorized by law to investigate or oversee conduct or conditions for the purpose of reporting the allegation of failure to meet professional standards or misconduct.

(2) An appropriate health care accreditation organization.

(3) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate.

9.10(24) *Secondary to a use or disclosure of protected health information.* The department may use or disclose protected health information that is secondary to a use or disclosure otherwise permitted or required by these rules, such as when a visitor in a facility overhears a doctor speaking to a subject about the subject's health.

9.10(25) *De-identified data or a limited data set.* The department may use or disclose protected health information to create information that is de-identified or a limited data set under the conditions specified in 45 CFR 164.514 as amended to August 14, 2002.

441—9.11(22) Availability of records.

9.11(1)*Open records.* Department records are open for public inspection and copying unless otherwise provided by rule or law.

9.11(2) *Confidential records.* Iowa Code chapters governing the operations of the department establish the confidential nature of many department records. The department also administers several federally funded programs and is authorized by Iowa Code section 22.9 to enforce confidentiality standards from federal law and regulation as required for receipt of the funds where the department has determined that the right to examine and copy public records under Iowa Code section 22.2 would cause the denial of funds, services, or essential information from the United States government that would otherwise be available to the department.

9.11(3) *Authority to release confidential records.* The department may have discretion to disclose some confidential records which are exempt from disclosure under Iowa Code section 22.7 or other provision of law.

441—9.12(22,252G) Personally identifiable information. The nature and extent of personally identifiable information collected by the department varies by the type of record. This rule describes personally identifiable information collected, maintained, and retrieved by the department by personal identifiers in record systems and the legal authority for the collection of that information. This rule also identifies the legal authority for keeping some or all of the collected personally identifiable information confidential.

9.12(1) Department administrative records.

a. Personnel records. These records contain information about employees, families and dependents, and applicants for positions with the department. Some of this information is confidential under Iowa Code sections 22.7(11) and 22.7(18).

b. Fiscal records. These records contain itemized vouchers collected from individuals pursuant to Iowa Code section8A.514. Some of this information is confidential under Iowa Code sections 22.7(11) and 22.7(18).

d. *Litigation files.* These files or records contain information regarding litigation or anticipated litigation, which includes judicial and administrative proceedings. The records include briefs, depositions, docket sheets, documents, correspondence, attorney's notes, memoranda, research materials, witness information, investigation materials, information compiled under the direction of the attorney, and case management records. The files contain materials which are confidential as attorney work product and attorney-client communications. Some materials are confidential under other applicable provisions of law or because of a court order. Persons wishing copies of pleadings and other documents filed in litigation should obtain them from the clerk of the appropriate court which maintains the official copy. These records are confidential as outlined in Iowa Code sections 217.30, 22.7(4) and 622.10.

9.12(2) Program records.

a. Adoption investigator certification. These records are collected pursuant to Iowa Code chapter 600.

b. Adoption program records. These records are collected pursuant to Iowa Code sections 600.8 and 600.16. These records are confidential as outlined in Iowa Code sections 600.16 and 600.24.

c. Appeals. These records are collected pursuant to Iowa Code section 217.1. Some of these records are confidential as outlined in Iowa Code section 217.1.

d. AIDS drug reimbursement program. These records are collected for purposes of implementing a federal grant program authorized by HR 1827. Certain patient records are confidential as outlined in Iowa Code section 141A.9.

e. Brain injury service program recipients. These records are collected pursuant to Iowa Code section 135.22B. These records are confidential as outlined in Iowa Code section 135.22(2).

f. Center for congenital and inherited disorders. These records are collected pursuant to Iowa Code chapter 136A. These records are confidential as outlined in Iowa Code section 136A.7.

g. Central registry for brain or spinal cord injuries. These records are collected pursuant to Iowa Code section 135.22. Except for statistical reports, these records are maintained as confidential pursuant to Iowa Code section 135.22.

h. Child abuse program. These records are collected pursuant to Iowa Code section 235A.14. These records are confidential as outlined in Iowa Code sections 235A.13, 235A.15, 235A.16, and 235A.17.

i. Childcare assistance client records. These records are collected pursuant to Iowa Code section 237A. These records are confidential as outlined in Iowa Code section 237A.13.

j. Childcare facility licensing. These records are collected pursuant to Iowa Code chapter 237A. Some of these records are confidential as outlined in Iowa Code section 237A.7.

k. Childhood lead poisoning prevention program. These records are collected pursuant to Iowa Code sections 135.100 to 135.105. Certain of these records are confidential as outlined in Iowa Code section 139A.

l. Child support recovery program. These records are collected pursuant to Iowa Code chapters 252A, 252B, 252C, 252D, 252E, 252F, 252G, 252H, 252I, 252J, 252K, and Iowa Code sections 144.13, 144.26, 232.147, 234.39, 595.4, 598.22B and 600.16A. These records are confidential as outlined in Iowa Code sections 252B.9 and 252G.5, 42 U.S.C. §654(26), 42 U.S.C. §654a(d), 45 CFR §303.21 and 307.13.

m. Chronic disease prevention and management programs. These records are collected pursuant to Iowa Code section 135.11(1). Certain medical information in these records is confidential as outlined in Iowa Code section 22.7(2).

n. Collection service center payment. These records are collected pursuant to Iowa Code sections 252B.9, 252B.13A and 252B.16. These records are confidential as outlined in Iowa Code section 252B.9(2), 42 U.S.C. § 654a(d) and 45 CFR §307.13.

o. Criminal and juvenile justice information. These records are collected pursuant to Iowa Code sections 216A.136 and 216A.138 and through interagency agreements.

p. Dental health program. These records are collected pursuant to Iowa Code section 135.11(19). Certain medical information in these records is confidential as outlined in Iowa Code section 22.7(2).

q. Dependent adult abuse program. These records are collected pursuant to Iowa Code section 235B.1. These records are confidential as outlined in Iowa Code section 235B.1.

r. Domestic abuse death review team. These records are collected pursuant to Iowa Code section 135.110. These records are confidential as outlined in Iowa Code section 135.11.

s. Emergency Medical Services. These records are collected pursuant to Iowa Code chapter 147A. Some of these records are confidential as outlined in Iowa Code section 147A.25.

t. Environmental health program. These records are collected pursuant to Iowa Code section 135.11(1) and PL 96-510, Section 104(d)(1), 40 CFR 763 effective June 28, 1983, and 40 CFR 761 effective May 31, 1979, dealing with asbestos, PCB and other environmental health factors. Certain medical information in the work-related disease program file may be confidential as outlined in Iowa Code section 22.7(2). Certain asbestos and PCB inspection records are collected under contract with the federal Environmental Protection Agency, and requests for such records will be referred to that agency.

u. Family investment program client records. These records are collected pursuant to Iowa Code section 234.6. These records are confidential as outlined in Iowa Code section 217.30, 42 U.S.C. §602(a)(1) and §1306a.

v. Food assistance client files. These records are collected pursuant to Iowa Code section 234.6. These records are confidential as outlined in Iowa Code section 217.30, 7 U.S.C. §2020(e)8 and 7 CFR 272.1(c) and (d) as amended to January 1, 1987.

w. Foster care client/service files. These records are collected pursuant to Iowa Code sections 237.3 to 237.5. These records are confidential as outlined in Iowa Code section 237.9.

x. Foster care facility licensing. These records are collected pursuant to Iowa Code chapter 237. Some of these records are confidential as outlined in Iowa Code section 237.9.

y. Foster care review board files. These records are collected pursuant to Iowa Code sections 237.17. Some of these records are confidential as outlined in Iowa Code section 237.21.

z. hawk-I client files. These records are collected pursuant to Iowa Code section 514I.4. These records are confidential as outlined in Iowa Code section 514I.4, and 42 CFR 457.1110 as amended to January 1, 2001.

aa. Human rights advocacy files. These records are collected pursuant to Iowa Code chapter 216A; the Omnibus Budget Reconciliation Act, P.L. 97-35; Juvenile Justice and Delinquency Prevention Act, P.L. 93-415; and the Victims Compensation and Assistance Act, P. L. 98-473. These records are confidential as outlined in Iowa Code section 22.7(18).

bb. Long term and managed care ombudsman complaints. These records are collected pursuant to Iowa Code sections 135C.37 and 231.42. These records are confidential as outlined in Iowa Code sections 135C.37 and 231.42.

cc. Maternal and child health program. These records are collected pursuant to Iowa Code section 135.11(20). Records that contain medical information are confidential pursuant to Iowa Code section 22.7(2).

dd. Medicaid clients. These records are collected pursuant to Iowa Code section 249A.4. These records are confidential as outlined in Iowa Code section 217.30, 42 U.S.C. §1396a(7), and 42 CFR 431.300 to 307 as amended to November 13, 1996.

ee. Medicaid provider information. These records are collected pursuant to Iowa Code section 249A.4. Some of these records are confidential as outlined in Iowa Code section 217.30, and 42 U.S.C. §1396a(7), 42 CFR 431.300 to 307 as amended to November 13, 1996.

ff. Newborn and infant hearing screening program. These records are collected pursuant to Iowa Code section 135.131. Information which identifies an individual patient is confidential as outlined in Iowa Code section 135.131.

gg. Nutrition and WIC (supplemental food program for women, infants and children) program. These records are collected pursuant to Iowa Code section 135.11(1)and Chapter 17 of the federal Child Nutrition Act of 1966 as amended. These records are confidential as outlined in 7 CFR 246 and Iowa Code section 22.7(2).

hh. Radiological health program. These records are collected pursuant to Iowa Code chapters 136B and 136C. Certain of these records are confidential as outlined in 641—39.4(24).

ii. Refugee health program. These records are collected pursuant to Iowa Code section 135.11(1) and Section 412(c)(3) of the federal Immigration and Naturalization Act. Records that contain medical information are confidential pursuant to Iowa Code section 22.7(2).

jj. Refugee resettlement client records. These records are collected pursuant to Iowa Code section 217.1. These records are confidential as outlined in Iowa Code section 217.30, and 45 CFR 400.27 as amended to March 22, 2000.

kk. Reportable diseases and other diseases and health conditions, including lead and other heavy metal poisonings. These records are collected pursuant to Iowa Code chapter 139A. Except for statistical reports, these records are confidential as required by Iowa Code chapter 139A.

ll. Reportable sexually transmitted diseases or infections. These records are collected pursuant to Iowa Code chapter 139A. Except for statistical reports, these records are confidential as required by Iowa Code chapter 139A.

mm. State institution resident records. These records are collected pursuant to Iowa Code section 218.1. These records are confidential as outlined in Iowa Code sections 218.22, 229.24 and 229.25

nn. State supplementary assistance clients. These records are collected pursuant to Iowa Code chapter 249. Some of these records are confidential as outlined in Iowa Code section 217.30.

oo. Substance abuse client records. These records are collected pursuant to Iowa Code chapter 125, 218, 219 and Iowa Code sections 234.6 and 249A.4. These records are confidential as outlined in Iowa Code section 125.37 and 125.93, 42 U.S.C. §29 dd.3 and ee.3, 42 CFR Part 2 as amended to October 1, 2002, 38 U.S.C. §4132.

pp. Substance abuse program licensing complaints. These records are collected pursuant to Iowa Code chapter 125. Certain information in these records may be confidential as outlined in Iowa Code sections 22.7(2), 22.7(18) and 125.37.

qq. Title IV-E foster care and adoption assistance client files. These records are collected pursuant to Iowa Code sections 217.1, and 600.17 to 600.22. These records are confidential as outlined in Iowa Code section 217.30, 42 U.S.C. §671(a)(8), and 45 CFR 1355.30(1) as amended to November 23, 2001.

rr. Veterinary public health. These records are collected pursuant to Iowa Code chapter 139A. Certain medical information in these records may be confidential as outlined in Iowa Code chapter 139A.

ss. Vital records. These records are collected pursuant to Iowa Code chapter 144, including records of births, deaths, fetal deaths, adoptions, marriages, divorces, annulments and related data and correspondence. These records are confidential as outlined in Iowa Code section 144.43.

9.12(3) Other restricted data contained in department client records includes:

a. Department of revenue information. These records are collected pursuant to Iowa Code sections 252B.5 and 252B.9. These records are confidential as outlined in Iowa Code section 421.17 and 422.20(1).

b. Department of workforce development information. These records are collected pursuant to Iowa Code chapters 239B, 249A, 249C and Iowa Code section 252B.9. These records are confidential as outlined in Iowa Code sections 217.30, and 42 U.S.C. §503(d) and (e).

c. Income and eligibility verification system. These records are collected pursuant to Iowa Code chapters 239B, 249A and Iowa Code sections 217.1, 234.6(7). These records are confidential as outlined in Iowa Code section 217.30 and 42 U.S.C. §1230b-7.

d. Department of public safety information. These records are collected pursuant to Iowa Code sections 237.8, 237A.5 and 252B.9. These records are confidential as outlined in Iowa Code sections 692.2, 692.3, 692.8 and 692.18.

e. Federal tax return information. These records are collected pursuant to Iowa Code chapters 239B, 249A and 252B and Iowa Code sections 217.1, 234.6(7). These records are confidential as outlined in Iowa Code section 422.20(2) and 26 U.S.C. §6103.

f. Juvenile court information. These records are collected pursuant to Iowa Code chapter 232 and Iowa Code section 234.6. These records are confidential as outlined in Iowa Code sections 232.48, 232.97 and 232.147 to 232.151.

g. Peer review organization. These records are collected pursuant to Iowa Code section 249A.4. These records are confidential as outlined in Iowa Code section 217.30 and 42 U.S.C. §1320c-9.

h. United States department of health and human services information. These records are collected pursuant to Iowa Code chapters 239B, 249, 249A and 252B and Iowa Code sections 217.1, 234.6(7). These records are confidential as outlined in Iowa Code section 217.30, 42 CFR Part 401.134(c) as amended to October 1, 2002.

441—9.14(17A,22) Special policies and procedures for protected health information. The department will follow all special policies and procedures for using and disclosing protected health information as outlined in 45 CFR part 164 as amended through December 31, 2023, including the minimum necessary standard, uses and disclosures for premium rating and related purposes, verification and documentation requirements, notice of privacy practices, the right to receive an accounting of disclosures, complaint procedures, appeal rights and record retention.

441—9.15(17A,22) Person who may exercise rights of the subject.

9.15(1) *Adults.* When the subject is an adult, including an emancipated minor, the subject's rights under this rule may also be exercised by the subject's legal or personal representative, except as provided in subrule 9.15(3).

9.15(2) *Minors.* Within the limits of subrule 9.15(3), when the subject is an unemancipated minor, the subject's rights under this rule shall be exercised only by the subject's legal representative, except as follows:

a. When the department otherwise deals with the minor as an adult, as in the case of minor parents under the family investment program.

b. When otherwise specifically provided by law. However, minor subjects shall be granted access to their own records upon request, subject to the limits in rule 441—9.9(17A,22).

9.15(3) *Exceptions.*

a. Scope of authority. Legal and personal representatives may act only within the scope of their authority. For protected health information, the designation must reflect the subject's ability to make health care decisions and receive protected health information. For example, court-appointed conservators shall have access to and authority to release only the following information:

(1) Name and address of subject.

(2) Amounts of assistance or type of services received.

(3) Information about the economic circumstances of the subject.

b. Mental health information. Only an adult subject or a subject's legal representative may consent to the disclosure of mental health information. Records of involuntary hospitalization shall be released only as provided in Iowa Code section 229.24. Medical records of persons hospitalized under Iowa Code chapter 229 shall be released only as provided in Iowa Code section 229.25.

c. Substance abuse information. Only the subject may consent to the disclosure of substance abuse information, regardless of the subject's age or condition.

d. Failure to act in good faith. If the department has reason to believe that the legal or personal representative is not acting in good faith in the best interests of the subject, the department may refuse to release information on the authorization of the legal or personal representative.

e. Abuse, neglect, and endangerment situations. Notwithstanding a state law or any other requirement of this chapter, the department, in the exercise of professional judgment, may elect not to treat a person as a subject's personal representative if:

(1) The department has reason to believe that the subject has been or may be subjected to domestic violence, abuse, or neglect by the person; or

(2) The department has reason to believe that treating the person as a personal representative could endanger the subject.

f. Protected health information. A parent, guardian, or other person acting in place of a parent who does not represent the minor for protected health information may still access protected health information about the minor if required by law.

g. Deceased subjects. If, under applicable law, an executor, administrator, or other person has authority to act on behalf of a deceased subject or of the subject's estate, the department shall treat that person as a personal representative.

h. Other. If, under applicable law, the subject of a confidential record is precluded from having a copy of a record concerning the subject disclosed to a third party, the department shall not treat the third party as a personal representative.

These rules are intended to implement Iowa Code chapters 17A, 22, 135, 217, 228, 252G, and the Health Insurance Portability and Accountability Act of 1996.

CHAPTER 16
NOTICES

441—16.1(17A) Definitions.

"Adequate notice" means any notice of decision or notice of action that includes all of the following information:

a. A description of the action taken;

b. The effective date of the action;

c. The specific reasons supporting the action, stated language likely to be understood by the average program applicant or enrollee;

d. References to applicable provisions of law supporting the action;

e. An explanation of the right to appeal; and

f. The circumstances under which assistance is continued when an appeal is filed.

"Adverse benefit determination" means any adverse action taken by the department regarding assistance program benefits administered by the department or on the department's behalf, excluding department decisions about requests for exceptions to policy.

"Assistance program" means a program administered by the department or on the department's behalf through which qualifying individuals receive benefits or services.

"Enrollee" means any applicant for, or recipient of, benefits or services pursuant to an assistance program.

"Timely" means that the notice is sent at least ten calendar days before the date the adverse benefit determination would become effective. The timely notice period shall begin on the day after the notice is sent.

441—16.2(17A) Notices.

16.3(1) Written t*imely and adequate notice.* When required by federal or state law, the department will provide written timely and adequate notice of the right to appeal any adverse benefit determination that affects an individual who is applying for, or receiving benefits from, an assistance program. The department will also provide written timely notice of pending actions for a state or federal tax or debtor offset.

16.3(2) *Adequate notice.* The department shall give adequate notice of the approval or denial of assistance or services; the approval or denial of a license, certification, approval, registration, or accreditation.

16.3(3) *Dispensing with timely notice.* Timely notice may be dispensed with, but adequate notice shall be sent no later than the date benefits would have been issued, when:

a. There is factual information confirming the death of the enrollee or of the family investment program payee and there is no relative available to serve as a new payee.

b. The enrollee provides a clear written, signed statement that the enrollee no longer wishes to receive assistance, or gives information which requires termination or reduction of assistance, and the enrollee has indicated, in writing, that the enrollee understands that the consequence of supplying the information is termination or reduction of assistance.

c. The enrollee has been admitted or committed to an institution that does not qualify for payment under an assistance program.

d. The enrollee has been placed in skilled nursing care, intermediate care, or long-term hospitalization.

e. The whereabouts of the enrollee are unknown and mail directed to the enrollee has been returned by the post office indicating no known forwarding address. When the whereabouts of the enrollee become known during the payment period covered by the returned warrant, the warrant shall be made available to the enrollee.

f. The department establishes that the enrollee has been accepted for assistance in another state.

g. Cash assistance or food assistance is changed because a child is removed from the home as a result of a judicial determination or is voluntarily placed in foster care.

h. A change in the level of medical care is prescribed by the enrollee's physician.

i. A special allowance or service granted for a specific period is terminated and the enrollee has been informed in writing at the time of initiation that the allowance or service shall terminate at the end of the specified period.

j. The notice involves an adverse determination made with regard to the preadmission screening requirements.

k. The department terminates or reduces benefits or makes changes as described at 441—subrule 40.27(3) or rule 441—75.52(249A).

l. The department terminates benefits for failure to return a completed report form, as described in paragraph 16.3(3)*"k."*

m. The department approves or denies an application for assistance.

n. The department implements a mass change based on law or rule changes that affect a group of enrollees.

Regulatory Analysis Template

ARC 7062C

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Proposing rulemaking related to agency reorganization and providing an opportunity for public comment

The Health and Human Services Department hereby proposes to amend Chapter 1, "Departmental Organization and Procedures," and Chapter 9, "Public Records and Fair Information Practices," Iowa Administrative Code.

Legal Authority for Rulemaking

This rulemaking is proposed under the authority provided in Iowa Code section 217.6 and 2023 Iowa Acts, Senate File 514.

State or Federal Law Implemented

This rulemaking implements, in whole or in part, 2023 Iowa Acts, Senate File 514.

Purpose and Summary

The purpose of this proposed rulemaking is to update language in legacy agency chapters to reflect the agency changes made in 2023 Iowa Acts, Senate File 514, as part of the state government reorganization. This rulemaking updates language in subrule 9.12(1) to reflect changes in the legislation and rescinds rule 441—1.8(17A,217), which is duplicative of uniform rules of agency procedure previously adopted by the legacy agencies. The Iowa Department of Health and Human Services' uniform rules on agency procedure will be contained under agency ID number [441]. Notice **ARCs 7063C** and **7064C**, IAB 8/23/23, also propose to rescind and reserve chapters to reduce confusion among the public and regulated community regarding uniform rules for the Iowa Department of Health and Human Services.

Fiscal Impact

This rulemaking has no fiscal impact to the State of Iowa.

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rulemaking would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 441—Chapter 6.

Public Comment

Any interested person may submit written comments concerning this proposed rulemaking. Written comments in response to this rulemaking must be received by the Department no later than 4:30 p.m. on September 12, 2023. Comments should be directed to:

Sarah Reisetter
Lucas State Office Building, 6th Floor

321 East 12th Street
Des Moines, Iowa 50319
Email: compliancerules@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rulemaking may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rulemaking by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rulemaking at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rulemaking action is proposed:

ITEM 1. Rescind and reserve rule **441—1.8(17A,217)**.

ITEM 2. Amend subrule 9.12(1), introductory paragraph, as follows:

9.12(1) *Nature and extent.* The personally identifiable information collected by the department in its administration of human services programs varies by the type of record. The nature and extent of personally identifiable information is described below:

ARC 7063C

HUMAN RIGHTS DEPARTMENT[421]

Notice of Intended Action

Proposing rulemaking related to agency reorganization and providing an opportunity for public comment

The Department of Health and Human Services (Department) hereby proposes to amend Chapter 1, "Organization and Operations," and rescind Chapter 2, "Public Records and Fair Information Practices," Chapter 3, "Petitions for Rule Making," Chapter 4, "Agency Procedure for Rule Making," Chapter 5, "Declaratory Orders," Chapter 6, "Contested Cases," and Chapter 7, "Waiver Rules," Iowa Administrative Code.

Legal Authority for Rulemaking

This rulemaking is proposed under the authority provided in Iowa Code section 217.6 and 2023 Iowa Acts, Senate File 514.

State or Federal Law Implemented

This rulemaking implements, in whole or in part, 2023 Iowa Acts, Senate File 514.

Purpose and Summary

The purpose of this proposed rulemaking is to update language in legacy agency chapters to reflect the agency changes made in 2023 Iowa Acts, Senate File 514, as part of the state government reorganization. This rulemaking updates language in the Human Rights Department chapters to reflect the changes in the legislation and rescinds a number of rules and chapters that are duplicative of uniform rules of agency procedure previously adopted by the legacy agencies. The Iowa Department of Health and Human Services' uniform rules on agency procedure will be contained under agency ID number [441]. This rulemaking rescinds and reserves chapters to reduce confusion among the public and regulated community regarding uniform rules for the Iowa Department of Health and Human Services.

Fiscal Impact

This rulemaking has no fiscal impact to the State of Iowa.

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rulemaking would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 441—Chapter 6.

Public Comment

Any interested person may submit written comments concerning this proposed rulemaking. Written comments in response to this rulemaking must be received by the Department no later than 4:30 p.m. on September 12, 2023. Comments should be directed to:

Sarah Reisetter
Health and Human Services
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Email: compliancerules@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rulemaking may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rulemaking by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rulemaking at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rulemaking action is proposed:

ITEM 1. Rescind and reserve rule **421—1.2(17A,216A)**.

ITEM 2. Rescind and reserve rule **421—1.3(17A,216A)**.

ITEM 3. Amend rule 421—1.4(17A,216A) as follows:

421—1.4(17A,216A) Mission. The ~~mission of the department~~ department's mission related to human rightsis to ensure basic rights, freedoms, and opportunities for all by empowering underrepresented Iowans and eliminating economic, social, and cultural barriers. The department helps individuals attain economic independence by ensuring access to government services and advancing educational achievement and entrepreneurial success consistent with their aspirations.

ITEM 4. Amend rule 421—1.5(17A,216A) as follows:

421—1.5(17A,216A) ~~Organization~~ Contact information.

~~1.5(1)~~ ~~*Contact information.*~~Requests for assistance, information, inquiries, submissions, petitions, and other communications related to human rightsmay be directed to the department as follows: The office is located at 321 E. 12th Street, Des Moines, Iowa 50319. The main telephone number is (515)242-5655. The fax number is (515)242-6119. Regular office hours are Monday through Friday, 8 a.m.to 4:30 p.m., excluding legal holidays. The department's website is ~~humanrights.iowa.gov~~ hhs.iowa.gov.

~~**1.5(2)** *Director.* The duties and responsibilities of the director are described in Iowa Code section 216A.2. The director is appointed by the governor, subject to confirmation by the senate. The director serves at the pleasure of the governor. The director is the chief administrative officer of the department and, in that capacity, administers the programs and services of the department in compliance with applicable federal and state laws and regulations. The duties of the director include preparing a budget, managing the internal operations of the department, appointing the deputy director and administrators of the divisions, and employing personnel. The director serves as an ex officio member of all of the commissions or councils within the department, as well as an ex officio, nonvoting member of the human rights board.~~

~~**1.5(3)** *Central administration.* The central administration office is responsible for the overall~~

planning, policy, management, communications, finances, and operations of the department.

1.5(4) *Divisions.* The department is composed of the following divisions and offices:

a. Division of community action agencies. A description of the division is contained in 421—Chapter 20.

b. Division of criminal and juvenile justice planning. A description of the division is contained in 421—Chapter 30.

c. Division of community advocacy and services. The division of community advocacy and services contains the following offices: the office of Latino affairs, the office on the status of women, the office of persons with disabilities, the office of deaf services, the office on the status of African Americans, the office of Asian and Pacific Islander affairs, and the office of Native American affairs. A description of the division is contained in 421—Chapter 40.

ITEM 5. Amend rule 421—1.6(216A) as follows:

421—1.6(216A) Human rights board. The authority , and duties and composition of the human rights board are specified in Iowa Code section 216A.3. The department shall provide staff support to the board.

1.6(1) The board shall consist of 16 members, including 11 voting members and 5 nonvoting members and determined as follows:

a. The voting members shall consist of nine voting members selected by each of the permanent commissions within the department, and two voting members appointed by the governor. For purposes of this subrule, "permanent commissions" means the commission of Latino affairs, commission on the status of women, commission of persons with disabilities, commission on community action agencies, commission of deaf services, justice advisory board, commission on the status of African Americans, commission of Asian and Pacific Islander affairs, and commission of Native American affairs. The term for voting members is four years. The board shall select a chairperson from the voting members of the board.

b. The nonvoting members shall consist of the department director; two state representatives, one appointed by the speaker of the house of representatives and one by the minority leader of the house of representatives; and two state senators, one appointed by the majority leader of the senate and one by the minority leader of the senate. The regular term of an appointment made by a member of the general assembly shall be two years pursuant to Iowa Code section 69.16B.

1.6(2) A majority of the voting members of the board shall constitute a quorum, and the affirmative vote of two-thirds of the voting members present is necessary for any substantive action taken by the board.

1.6(3) The board shall meet not less than four times a year. Meetings shall comply with the open meetings law, Iowa Code chapter 21. Agendas and approved minutes will be posted on the department's website.

1.6(4) The board shall have the following duties:

a. Develop and monitor implementation of a comprehensive strategic plan to remove barriers for underrepresented populations and, in doing so, to increase Iowa's productivity and inclusivity, including performance measures and benchmarks.

b. Approve, disapprove, amend, or modify the budget recommended by the director for the operation of the department, subject to the budget requirements pursuant to Iowa Code chapter 8.

c. Adopt administrative rules pursuant to Iowa Code chapter 17A, upon the recommendation of the director, for the operation of the department.

d. By November 1 of each year, approve the department report to the general assembly and the governor that covers activities during the preceding fiscal year.

ITEM 6. Rescind and reserve **421—Chapter 2**.

ITEM 7. Rescind and reserve **421—Chapter 3**.

ITEM 8. Rescind and reserve **421—Chapter 4**.

ITEM 9. Rescind and reserve **421—Chapter 5**.

ITEM 10. Rescind and reserve **421—Chapter 6**.

ITEM 11. Rescind and reserve **421—Chapter 7**.

ARC 7064C

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Proposing rulemaking related to agency reorganization and providing an opportunity for public comment

The Department of Health and Human Services (Department) hereby proposes to rescind Chapter 170, "Organization of the Department," Chapter 171, "Petitions for Rule Making," Chapter 172, "Declaratory Orders," Chapter 173, "Contested Cases," Chapter 174, "Agency Procedure for Rule Making," and Chapter 175, "Fair Information Practices and Public Records," and amend Chapter 176, "Criteria for Awards or Grants," Iowa Administrative Code.

Legal Authority for Rulemaking

This rulemaking is proposed under the authority provided in Iowa Code section 217.6 and 2023 Iowa Acts, Senate File 514.

State or Federal Law Implemented

This rulemaking implements, in whole or in part, 2023 Iowa Acts, Senate File 514.

Purpose and Summary

The purpose of this proposed rulemaking is to update language in legacy agency chapters to reflect the agency changes made in 2023 Iowa Acts, Senate File 514, as part of the state government reorganization. This rulemaking rescinds a number of chapters that are duplicative of uniform rules of agency procedure previously adopted by the legacy agencies. The Iowa Department of Health and Human Services' uniform rules on agency procedure will be contained under agency ID number [441]. This rulemaking rescinds and reserves chapters to reduce confusion among the public and regulated community regarding uniform rules for the Iowa Department of Health and Human Services.

Fiscal Impact

This rulemaking has no fiscal impact to the State of Iowa.

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rulemaking would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 441—Chapter 6.

Public Comment

Any interested person may submit written comments concerning this proposed rulemaking. Written comments in response to this rulemaking must be received by the Department no later than 4:30 p.m. on September 12, 2023. Comments should be directed to:

Sarah Reisetter

Lucas State Office Building, 6th Floor
321 East 12th Street
Des Moines, Iowa 50319
Email: compliancerules@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rulemaking may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rulemaking by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rulemaking at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rulemaking action is proposed:

ITEM 1. Rescind and reserve **641—Chapter 170**.

ITEM 2. Rescind and reserve **641—Chapter 171**.

ITEM 3. Rescind and reserve **641—Chapter 172**.

ITEM 4. Rescind and reserve **641—Chapter 173**.

ITEM 5. Rescind and reserve **641—Chapter 174**.

ITEM 6. Rescind and reserve **641—Chapter 175**.

ITEM 7. Rescind and reserve rule **641—176.1(135,17A)**.

ITEM 8. Rescind and reserve rule **641—176.2(135,17A)**.

ITEM 9. Rescind and reserve rule **641—176.3(135,17A)**.

ITEM 10. Rescind and reserve rule **641—176.4(135,17A)**.

ITEM 11. Rescind and reserve rule **641—176.5(135,17A)**.

ITEM 12. Rescind and reserve rule **641—176.8(135,17A)**.

ARC 7065C

CHILD ADVOCACY BOARD[489]

Notice of Intended Action

Proposing rulemaking related to agency reorganization and providing an opportunity for public comment

The Child Advocacy Board hereby proposes to amend Chapter 1, "Purpose and Function," Chapter 2, "Rules and Operation for the State Board," Chapter 3, "Local Foster Care Review Boards," and Chapter 4, "Court Appointed Special Advocate Program," and rescind Chapter 5, "Public Records and Fair Information Practices," Iowa Administrative Code.

Legal Authority for Rulemaking

This rulemaking is proposed under the authority provided in Iowa Code section 237.18.

State or Federal Law Implemented

This rulemaking implements, in whole or in part, 2023 Iowa Acts, Senate File 514.

Purpose and Summary

The purpose of this proposed rulemaking is to update language in the Board's rules to reflect the movement of the Child Advocacy Board to the Department of Health and Human Services pursuant to the state government reorganization legislation passed during the 2023 Legislative Session of the Iowa General Assembly.

This rulemaking updates references to the administrator, who will be an employee of the Department of Health and Human Services as of July 1, 2023; updates references to the "Department of Human Services" to be the "Department of Health and Human Services" and rescinds the Public Records and Fair Information Practices chapter from this agency number to remove duplicative uniform rules. The specific rules describing "personally identifiable information" in rule 489—5.14(22) was previously moved to new rule 441—9.17(22).

Fiscal Impact

This rulemaking has no fiscal impact to the State of Iowa.

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rulemaking would result in hardship or injustice to that person may petition the Department of Health and Human Services for a waiver of the discretionary provisions, if any, pursuant to 441—Chapter 6.

Public Comment

Any interested person may submit written comments concerning this proposed rulemaking. Written comments in response to this rulemaking must be received by the Department no later than 4:30 p.m. on September 12, 2023. Comments should be directed to:

Sarah Reisetter

Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Phone: 515.242.6392
Email: compliancerules@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rulemaking may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

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The following rulemaking action is proposed:

ITEM 1. Amend subrule 1.1(1) as follows:

1.1(1) *Location.* The child advocacy board is located in the Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0083; telephone (866)448-4608. Office hours are 8 a.m. to 4:30 p.m., Monday through Friday, except on state holidays. The child advocacy board is created within the department of ~~inspections and appeals~~ health and human services.

ITEM 2. Amend subrule **1.1(2)**, definitions of "Department" and "Person or court responsible for the child," as follows:

"Department" means the department of health and human services.

"Person or court responsible for the child" means the department, including but not limited to the department of health and human services, agency, or individual who is the guardian of a child by court order issued by the juvenile or district court and has the responsibility of the care of the child, or the court having jurisdiction over the child.

ITEM 3. Amend subrule 2.1(1) as follows:

2.1(1) *Membership and terms.* The child advocacy board is created within the department of ~~inspections and appeals~~ health and human services. The state board consists of nine members appointed by the governor, subject to confirmation by the senate and directly responsible to the governor. One member shall be an active court appointed special advocate volunteer, one member shall be an active member of a local citizen foster care review board, and one member shall be a judicial branch employee or judicial officer appointed from nominees submitted by the judicial branch. The appointment is for a term of four years that begins and ends as provided in Iowa Code section 69.19. Vacancies on the state board shall be filled in the same manner as original appointments are made. An employee of the department of health and human services ~~or of the department of inspections and appeals~~, an employee of a child-placing agency, an employee of an agency with which the department of health and human services contracts for services for children under foster care, a foster parent providing foster care, or an employee of the district court is not eligible to serve on the state board. However, the judicial branch employee or judicial officer appointed from nominees submitted by the judicial branch in accordance with Iowa Code section 237.16(1) shall be eligible to serve on the state board.

ITEM 4. Amend subrule 2.2(1) as follows:

2.2(1) The ~~state board~~ director appoints an administrator for the child advocacy board. The administrator is responsible for the ongoing administration of the state and local boards' activities and of the court appointed special advocate program.

ITEM 5. Amend subrule 3.2(2) as follows:

3.2(2) A person employed by the department of health and human services or the judicial department, an employee of an agency with which the department of health and human services contracts for services for children under foster care, a foster parent providing foster care, or a child-placing agency shall not serve on a local board.

ITEM 6. Amend subrule **4.1(1)**, definition of "Administrator," as follows:

"Administrator" means the person selected by the ~~child advocacy board~~ director to lead, direct and manage the staff and programs established by the board.

ITEM 7. Amend paragraph **4.2(3)"g"** as follows:

g. Not be a person employed by the state board, the department of health and human services, the district court, or an agency with which the department of health and human services contracts for services for children.

ITEM 8. Rescind and reserve **489—Chapter 5**.