Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 3
"Early Hearing Detection and Intervention Program"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 135.131
State or federal law(s) implemented by the rulemaking: Iowa Code section 135.131

Public Hearing

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

July 29, 2025 10 a.m.	Microsoft Teams Meeting ID: 242 459 066 176 7 Passcode: Wu3Kc9DH

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed chapter was reviewed pursuant to Executive Order 10. Chapter 3 implements Iowa's Early Hearing Detection and Intervention (EHDI) program, which provides for universal hearing screening for all newborns and infants in Iowa. The goal of the program is early detection of hearing loss to allow children and their families the earliest possible opportunity to obtain appropriate early intervention services.

As a result of the Red Tape Review, the Department is proposing to eliminate restrictive terms and language duplicative of the Iowa Code. The Department is also proposing to eliminate sections of the chapter for which there is no rulemaking authority.

Finally, the Department updated language in rules 641—3.7(135) and 641—3.8(135) to conform to 2025 Iowa Acts, Senate File 418.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

There are no costs associated with this proposed rulemaking.

- **Classes of persons that will benefit from the proposed rulemaking:**

Iowa newborns and infants and their families will benefit from this proposed rulemaking. The proposed rulemaking also benefits providers that conduct newborn hearing screenings since it gives the direction on how to submit screening data to the Department.

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

- **Quantitative description of impact:**

Hearing loss is the most frequently occurring birth defect. Approximately 2 to 3 per 1,000 babies born in the U.S. have some level of hearing difference. Another 3 per 1,000 will develop hearing differences in early childhood (late onset). Without early intervention, children with hearing differences are at risk of falling behind typically hearing peers in language, social-emotional, and academic skills.

- **Qualitative description of impact:**

Iowa newborns and infants and their families will benefit from this proposed rulemaking. The proposed rulemaking also benefits providers that conduct newborn hearing screenings since it gives the direction on how to submit screening data to the Department.

3. **Costs to the State:**

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

The Department incurs personnel and other administrative costs to implement the proposed chapter.

- **Anticipated effect on State revenues:**

This proposed rulemaking has no impact on State revenues.

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

Rules are required to be promulgated under Iowa Code section 135.131.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

Not applicable.

6. **Alternative methods considered by the agency:**

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

Not applicable.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

Not applicable.

Small Business Impact

If the rulemaking 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 rulemaking on small business:

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

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

This proposed rulemaking has no impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 3 and adopt the following **new** chapter in lieu thereof:

CHAPTER 3
EARLY HEARING DETECTION AND INTERVENTION (EHDI) PROGRAM

641—3.1(135) Definitions. For the purposes of this chapter, the following definitions will apply:

"Audiologist" means a person licensed pursuant to Iowa Code chapter 147 or certified by the Iowa board of educational examiners pursuant to 282—Chapter 14 or a person appropriately licensed in the state where the person practices.

"Audiology assistant" means a person who works under the supervision of an Iowa-licensed speech pathologist or audiologist, does not meet the requirements to be licensed as a speech pathologist or audiologist, and meets the minimum requirements set forth in 481—Chapter 781.

"Audiometrist" means a technician who has received special training in the use of pure-tone audiometry equipment. An audiometrist conducts the hearing tests selected and interpreted by an audiologist, who supervises the process.

"Birth center" means the same as defined in Iowa Code section 10A.711.

"Birthing hospital" means the same as defined in Iowa Code section 135.131.

"Congenital cytomegalovirus" or *"cCMV"* means an infection where cytomegalovirus is transmitted to the fetus in the prenatal period.

"Cytomegalovirus" or *"CMV"* means a kind of herpes virus that usually produces very mild symptoms in an infected person but may cause severe neurological damage in a person with a weakened immune system and in a newborn.

"Diagnostic audiologic assessment" means physiologic or behavioral procedures completed by an audiologist to evaluate and diagnose hearing loss.

"Discharge" means a release from a birthing hospital to the parent or legal guardian of the child.

"Early ACCESS" means Iowa's Individuals with Disabilities Education Act (IDEA), Part C, program for infants and toddlers. It is a statewide, comprehensive, interagency system of integrated early intervention services that supports eligible children and their families as defined in 281—Chapter 120.

"Guardian" means a person who is not the parent of a minor child, but who has legal authority to make decisions regarding life or program issues for the child. A guardian may be a court or a juvenile court. "Guardian" does not mean conservator as defined in Iowa Code section 633.3, although a person who is appointed to be a guardian may also be appointed to be a conservator.

"Health care professional" means a licensed physician, nurse practitioner, physician assistant, certified midwife, registered nurse, licensed practical nurse, patient care technician, certified nursing assistant, licensed audiologist, audiology assistant, audiometrist, hearing aid specialist, speech-language pathologist or other licensed or certified professional for whom hearing screening is within the professional's scope of practice.

"Hearing loss" means a permanent unilateral or bilateral hearing loss of greater than 30 dB HL in the frequency region important for speech recognition (500-4000 Hz).

"Hearing screening" means a physiological measurement of hearing of a newborn or infant with a "pass" or "refer" result. Screening is used to determine the newborn's or infant's need for further testing and must be performed bilaterally, when applicable.

"Initial screening" or *"newborn hearing screening"* means a screening performed in a birthing hospital, birth center or facility other than a birthing hospital within the first month of life.

"Newborn hearing screening" means a physiological test to separate those newborns with normal hearing from those newborns who may have hearing thresholds of greater than 30 dB HL in either ear in the frequency region important for speech recognition (500-4000 Hz).

"Normal hearing" means hearing thresholds in both ears of 30 dB HL or less in the frequency region important for speech recognition (500-4000 Hz).

"Parent" means:

1. A biological or adoptive parent of a child;

2. A guardian, but not the state if the child is a ward of the state;

3. A person acting in the place of a parent, such as a grandparent or stepparent with whom a child lives, or a person who is legally responsible for the child's welfare;

4. A surrogate parent who has been assigned in accordance with 281—120.422(34CFR303); or

5. A foster parent, if:

- A biological parent's authority to make the decisions required of parents under state law has been terminated; and
- The foster parent has an ongoing, long-term parental relationship with the child; is willing to make the decisions required of a parent; and has no interest that would conflict with the interests of the child.

"Physician" means an individual licensed under Iowa Code chapter 148.

"Primary care provider" means a licensed physician, nurse practitioner, physician assistant or certified midwife who undertakes primary pediatric care responsibility for an infant or child to provide ongoing medical care and referrals to promote overall health and well-being.

"Protocol" means a document that guides decision making and provides the criteria to be used regarding screening, diagnosis, management, and treatment of children related to hearing health care. Early hearing detection and intervention protocols not otherwise specified in this chapter are available on the department's website.

"Provider" means a licensed audiologist, otolaryngologist or hearing aid specialist who agrees to provide hearing aids or audiologic services to eligible patients.

"Rescreen" means a newborn hearing screening performed after two weeks of age on an infant who did not pass the initial screening.

641—3.2(135) Program components.

3.2(1) The EHDI coordinator assigned within the department provides administrative oversight, including follow-up activities, for the EHDI program within Iowa.

3.2(2) The EHDI advisory committee represents the interests of the people of Iowa and assists in the development of programming that ensures the availability and access to quality hearing health care for Iowa children.

3.2(3) The EHDI program has an association with the Iowa Title V maternal and child health programs to promote comprehensive services for infants and children with special health care needs.

3.2(4) The EHDI program provides hearing screening surveillance and follow-up for infants and children under the age of three. Follow-up may include:

a. Contact with the parent or legal guardian of an infant who was not screened or does not pass the initial hearing screening, outpatient hearing screening or diagnostic audiologic assessment.

b. Contact with the infant's primary care provider to ensure the infant receives appropriate follow-up no later than the recommended timeline as outlined in the Joint Committee on Infant Hearing position statement at www.jcih.org as amended to August 1, 2025.

c. Contact with the birthing hospital or health care professional for inquiries on missing results, data entry discrepancies and recommendations for additional referrals.

d. Referrals to family support or early intervention service providers for infants or toddlers diagnosed with a hearing loss.

e. Technical assistance to birthing facilities, primary care providers and health care professionals regarding best practices related to newborn hearing screening, diagnosis and follow-up best practices.

641—3.3(135) Screening the hearing of all newborns. All newborns and infants born in Iowa, except those born with a condition that is incompatible with life, shall be screened for hearing loss. The person required to perform the screening shall use at least one of the following procedures:

1. Automated or screening auditory brainstem response, or
2. Evoked otoacoustic emissions.

641—3.4(135) Procedures required of birthing hospitals. Each birthing hospital in Iowa shall follow these procedures:

3.4(1) Each birthing hospital shall designate an employee of the hospital to be responsible for the newborn hearing screening program in that institution. If a birthing hospital contracts with a third party for newborn screening services, the hospital retains ultimate responsibility for screening and reporting.

3.4(2) Prior to the discharge of the newborn, each birthing hospital shall provide hearing screening to every newborn delivered in the hospital, except in the following circumstances:

a. The newborn is transferred for acute care prior to completion of the hearing screening.

b. The newborn is born with a condition that is incompatible with life.

3.4(3) If a newborn is transferred for acute care, the birthing hospital shall notify the receiving facility of the status of the hearing screening. The receiving facility shall then be responsible for completion of the newborn hearing screening prior to discharge of the newborn from the nursery.

3.4(4) Newborn hearing screening shall be performed by a health care professional.

3.4(5) The birthing hospital shall report newborn hearing screening results to the parent or guardian in written form.

3.4(6) The birthing hospital shall report newborn hearing screening results to the department pursuant to 641—3.7(135).

3.4(7) The birthing hospital shall report the results of the hearing screening to the primary care provider of the newborn or infant upon the newborn's or infant's discharge from the birthing hospital. If the newborn or infant was not tested prior to discharge, the birthing hospital shall report the status of the hearing screening to the primary care provider of the newborn or infant.

3.4(8) The birthing hospital shall follow the hearing screening protocols prescribed by the department.

641—3.5(135) Procedures required of birth centers. Each birth center in Iowa shall follow these procedures:

3.5(1) Each birth center shall designate an employee of the birth center to be responsible for the newborn hearing screening program in that institution.

3.5(2) Prior to discharge of the newborn, each birth center shall refer every newborn delivered in the birth center to a health care professional for a newborn hearing screening. Before discharge of the newborn, the birth center shall arrange an appointment for the newborn hearing screening no more than 15 days from the date of discharge and report the appointment time, date and location to the parent.

3.5(3) The health care professional to whom the newborn is referred for screening shall complete the screening within 30 days of the newborn's discharge from the birth center, unless the parent fails to attend the appointment. If the parent fails to attend the appointment, the health care professional shall document such failure in the medical or educational record and shall report such failure to the department.

3.5(4) The health care professional who completes the newborn hearing screening shall report screening results to the parent in written form.

3.5(5) The health care professional who completes the newborn hearing screening shall report screening results to the department pursuant to 641—3.7(135).

3.5(6) The health care professional who completes the newborn hearing screening shall report the results of the hearing screening to the primary care provider of the newborn or infant.

3.5(7) The person who completes the screening shall follow the hearing screening protocols prescribed by the department.

641—3.6(135) Procedures to ensure that children born in locations other than a birth center or birthing hospital receive a hearing screening.

3.6(1) The physician or other health care professional who undertakes primary pediatric care of a newborn delivered in a location other than a birthing hospital or birth center shall ensure a hearing screening is performed pursuant to Iowa Code section 135.131(5). The health care professional shall arrange an appointment for the newborn hearing screening and report to the parent the appointment time, date, and location.

3.6(2) The health care professional who completes the newborn hearing screening shall report screening results to the parent in written form.

3.6(3) The health care professional who completes the newborn hearing screening shall report screening results to the department pursuant to 641—3.7(135). If the parent fails to attend the appointment, the facility shall document such failure in the medical or educational record and shall report such failure to the department.

3.6(4) The health care professional who completes the newborn hearing screening shall report the results of the hearing screening to the primary care provider of the newborn or infant.

3.6(5) The person who completes the newborn hearing screening shall follow the hearing screening protocols prescribed by the department.

641—3.7(135) Reporting hearing screening results and information to the department and child's primary care provider.

3.7(1) Any birthing hospital, birth center, physician, audiologist or other health care professional required to report information pursuant to Iowa Code section 135.131 shall report all of the following information to the department relating to each newborn's hearing screening within six working days of the birth of the newborn and within six working days of any hearing rescreen, utilizing the department's designated reporting system:

a. The name, date of birth, and sex of the newborn.

b. The name, address, and telephone number, if available, of the mother of the newborn. If the mother is not the person designated as legally responsible for the child's care, the name, address, and telephone number of the parent, as defined in 641—3.1(135), shall be reported.

c. The name of the primary care provider for the newborn upon the newborn's discharge from the birthing hospital or birth center.

d. The results of the newborn hearing screening, either "pass," "refer," or "not screened," for each ear separately.

e. The results of any rescreening, either "pass" or "refer," and the diagnostic audiologic assessment procedures used for each ear separately.

f. Known risk indicators for hearing loss of the infant or child.

3.7(2) If the parent fails to attend the appointment, the facility shall document such failure in the medical or educational record and shall report such failure to the department.

3.7(3) The person who completes the newborn hearing screening shall report the results of the hearing screening to the primary care provider of the infant or child.

641—3.8(135) Conducting and reporting screening results and diagnostic audiologic assessments to the department and child's primary care provider. Any health care professional conducting newborn hearing screens, rescreens, or diagnostic audiologic assessments shall report the results within six working days for any child under three years of age to the department utilizing the department's designated reporting system. The health care professional shall conduct the diagnostic hearing assessment in accordance with the Pediatric Audiologic Diagnostic Protocol as amended to August 1, 2025, posted on the department's website. Results of a hearing screen, rescreen or diagnostic audiologic assessment shall be reported as follows.

3.8(1) Reports shall include:

a. The name, date of birth, and sex of the child.

b. The name, address, and telephone number, if available, of the mother of the child. If the mother is not the person designated as legally responsible for the child's care, the name, address, and telephone number of the parent, as defined in 641—3.1(135), shall be reported.

c. The name of the primary care provider for the child.

d. Known risk indicators for hearing loss.

e. The date the child is fit with a hearing aid(s) or a cochlear implant(s), if applicable.

f. The date of referral to early intervention, if applicable.

g. The date of referral to family support, if applicable.

3.8(2) Results of the newborn hearing screening shall be reported as either "pass" or "refer" for each ear separately.

3.8(3) Results of the hearing rescreen shall be reported as either "pass" or "refer" for each ear separately.

3.8(4) If an assessment results in a diagnosis of normal hearing for both ears, this shall be reported.

3.8(5) Any diagnosis of hearing loss shall also be reported except for transient conductive hearing loss lasting for less than 90 days in the professional judgment of the practitioner. This exception will apply only if the child passed the initial hearing screening or rescreening or had a diagnostic assessment resulting in normal hearing for both ears.

3.8(6) Diagnostic audiologic assessment results shall include a statement of the severity (mild, moderate, moderately severe, severe, profound, or undetermined) and type (sensorineural, conductive, mixed, or undetermined) of hearing loss.

3.8(7) Any health care professional conducting newborn hearing screens, rescreens, or diagnostic audiologic assessments shall report the results to the primary care provider of the infant or child.

641—3.9(135) Congenital cytomegalovirus (cCMV) testing for newborns who do not pass the initial newborn hearing screening. If the newborn hearing screen indicates potential hearing loss, as evidenced when a newborn does not pass the initial newborn hearing screening, the birthing hospital, birth center, physician, or other health care professional required to ensure that the hearing screening is performed shall follow the procedures related to cCMV testing outlined in Iowa Code section 135.131(9). If a parent objects to the testing, the birthing hospital, birth center, physician, or other health care professional required to ensure that the hearing screening is performed shall follow the procedures in 641—3.11(135).

641—3.10(135) Information sharing and confidentiality. Reports, records, and other information collected by or provided to the department relating to a child's newborn hearing screening, rescreen, diagnostic audiologic assessment, and early intervention enrollment are confidential records pursuant to Iowa Code section 22.7.

3.10(1) Personnel of the department shall maintain the confidentiality of all information and records used in the review and analysis of newborn hearing screenings, rescreens, diagnostic audiologic assessments, and early intervention enrollment, including information which is confidential under Iowa Code chapter 22 or any other provisions of state law.

3.10(2) No individual or organization providing information to the department in accordance with this rule shall be deemed to be or held liable for divulging confidential information.

3.10(3) The department shall not release confidential information except to the following persons and entities under the following conditions:

a. The parent or guardian of an infant or child for whom the report is made.

b. A local birth-to-three coordinator with the Early ACCESS program or an agency under contract with the department to administer the children with special health care needs program.

c. A health care professional or primary care provider.

d. A representative of a federal or state agency, to the extent that the information is necessary to perform a legally authorized function of that agency.

e. A representative of a state agency, or an entity bound by that state, to the extent that the information is necessary to perform newborn hearing screening follow-up. The state agency or the entity bound by that state shall be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa. The state agency or the entity bound by that state shall not use the information obtained from the department to market services to patients or nonpatients or identify patients for any purposes other than those expressly provided in this rule.

3.10(4) Research purposes. All proposals for research using the department's data to be conducted by persons other than program staff shall first be submitted to and accepted by the researchers' institutional review board. The department will then review and approve programs before research can commence.

641—3.11(135) Procedure to accommodate parental objection. These rules will not apply if the parent objects to the hearing screening, diagnostic audiologic assessment, or cCMV testing.

3.11(1) If a parent objects to the screening, the birthing hospital, birth center, physician, or other health care professional shall obtain a written refusal from the parent or guardian on the department newborn hearing screening or diagnostic audiologic assessment refusal form and shall maintain the original copy of the written refusal in the newborn's, infant's or child's medical record.

3.11(2) The birthing hospital, birth center, physician, or other health care professional shall send a copy of the written newborn hearing screening or diagnostic audiologic assessment refusal form to the department within six days of the birth of the newborn.

3.11(3) If a parent objects to a hearing rescreen or diagnostic audiologic assessment orally to a department EHDI staff member during follow-up, the staff member shall document the refusal in the department's designated reporting system and mail to the parent or guardian the department newborn hearing screening or diagnostic audiologic assessment refusal form in an attempt to obtain a written refusal to be maintained in the newborn's, infant's or child's medical record.

3.11(4) If a parent objects to cCMV testing, the birthing hospital, birth center, physician, or other health care professional required to ensure cCMV testing shall obtain, on the department cCMV testing refusal form, a written refusal from the parent or guardian, shall maintain the original copy of the written refusal in the child's medical record, and shall send a copy of the written refusal to the department within 21 days of the child's birth.

641—3.12(135) Civil/criminal liability. A person who acts in good faith in complying with these rules shall not be held civilly or criminally liable for reporting the information required.

These rules are intended to implement Iowa Code section 135.131.