ARC 2290C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 135.131, the Department of Public Health hereby amends Chapter 3, "Early Hearing Detection and Intervention," Iowa Administrative Code.

This chapter contains rules for the universal hearing screening of all newborns and infants in Iowa and the transfer of data to the Department to enhance the capacity of agencies and practitioners to provide services to children and their families. The goal of universal hearing screening of all newborns and infants in Iowa is early detection of hearing loss to allow children and their families the earliest opportunity to obtain appropriate early intervention services.

These amendments further define roles and responsibilities of the Department and providers for infants who did not receive a newborn hearing screening or did not pass their hearing screening and require follow-up; clarify who is eligible to perform hearing screens on infants and children under the age of three; add language to accommodate parental objection beyond the newborn hearing screening if an infant does not pass the hearing screening at birth; update Iowa Code citations; and outline the role of the Early Hearing Detection and Intervention (EHDI) Advisory Committee members, including service, attendance and voting. The changes facilitate timely follow up for infants in need of a hearing screening, rescreening or diagnostic assessment and help avoid unnecessary contact with parents and providers. The proposed changes also allow the Iowa EHDI program to monitor the quality of care and assist the Department in providing recommendations for improving care. These amendments further define the composition and role of the EHDI Advisory Committee and bring language into alignment with Iowa Code chapter 17A to offer better transparency in the operations of the Committee. All amendments have been reviewed by and input gathered from the EHDI Advisory Committee members.

Notice of Intended Action was published in the Iowa Administrative Bulletin on August 5, 2015, as **ARC 2082C**. A public hearing was held on August 26, 2015. No comments were received. The adopted amendments are identical to those published under Notice.

The State Board of Health adopted these amendments on November 12, 2015.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 135.131.

These amendments will become effective on January 13, 2016.

The following amendments are adopted.

ITEM 1. Amend **641—Chapter 3**, title, as follows:

EARLY HEARING DETECTION AND INTERVENTION (EHDI) PROGRAM

ITEM 2. Adopt the following **new** definitions in rule **641—3.1(135)**:

"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 645—Chapter 300.

"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.

"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.

"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.

ITEM 3. Amend rule **641—3.1(135)**, definitions of "Discharge," "Initial screening," "Protocol" and "Provider," as follows:

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

"Initial screening" or *"newborn hearing screening"* means a ~~newborn hearing~~ screening performed ~~during the birth admission for an infant born~~ in a birthing hospital, birth center or ~~the first newborn hearing screening performed on a newborn born in a~~ facility other than a birthing hospital within the first month of life.

"Protocol" means a document which 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 Web site at ~~http://www.idph.state.ia.us/iaehdi/professionals.asp~~ www.idph.iowa.gov.

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

ITEM 4. Amend rule 641—3.2(135) as follows:

641—3.2(135) Purpose. The overall purpose of this chapter is to establish administrative rules in accordance with Iowa Code section 135.131 ~~as amended by 2009 Iowa Acts, House File 314, division II,~~ relative to the following:

1. Universal hearing screening of all newborns and infants in Iowa.
2. Facilitating the transfer of data to the department to enhance the capacity of agencies and practitioners to provide services to children and their families.
3. Establishing procedures for infants who were not screened or do not pass their initial hearing screening to receive appropriate follow-up to determine if the infants have normal hearing or have hearing loss.

~~3.~~ 4. Establishing the procedure for distribution of funds to support the purchase of hearing aids and audiologic services for children ~~in accordance with 2009 Iowa Acts, House File 811, section 60(2)*"c."*~~.

ITEM 5. Amend subrule 3.4(1) as follows:

3.4(1) The ~~early hearing detection and intervention (~~EHDI~~)~~ coordinator assigned within the department provides administrative oversight ~~to~~, including follow-up activities, for the ~~early hearing detection and intervention~~ EHDI program within Iowa.

ITEM 6. Rescind paragraphs **3.4(2)"a"** and **"b."**

ITEM 7. Amend subrule 3.4(3) as follows:

3.4(3) The ~~early hearing detection and intervention~~ 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.

ITEM 8. Adopt the following **new** subrule 3.4(4):

3.4(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 time line as outlined in the Joint Committee on Infant Hearing position statement at www.jcih.org.

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.

ITEM 9. Amend subrule 3.6(1) as follows:

3.6(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.

ITEM 10. Amend subrules 3.6(4) to 3.6(7) as follows:

3.6(4) Newborn hearing screening shall be performed by ~~an audiologist, audiology assistant, audiometrist, registered nurse, licensed physician, or other person for whom newborn hearing screening is within the person's scope of practice~~ a health care professional.

3.6(5) The birthing hospital shall report newborn hearing screening results to the parent or guardian in written form.

3.6(6) The birthing hospital shall report newborn hearing screening results to the department ~~in a manner prescribed in~~ pursuant to 641—3.9(135).

3.6(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.

ITEM 11. Amend subrules 3.7(2) to 3.7(5) as follows:

3.7(2) Prior to discharge of the newborn, each birth center shall refer every newborn delivered in the birth center to ~~an audiologist, physician, or hospital~~ 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 ~~the appointment time, date, and location~~.

3.7(3) The ~~facility~~ health care professional to ~~which~~ 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 ~~facility~~ health care professional shall document such failure in the medical or educational record and shall report such failure to the department.

3.7(4) The ~~person~~ health care professional who completes the newborn hearing screening shall report screening results to the parent in written form.

3.7(5) The ~~person~~ health care professional who completes the newborn hearing screening shall report screening results to the department ~~in the manner prescribed in~~ pursuant to 641—3.9(135).

ITEM 12. Renumber subrule **3.7(6)** as **3.7(7)**.

ITEM 13. Adopt the following **new** subrule 3.7(6):

3.7(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.

ITEM 14. Amend subrules 3.8(1) to 3.8(3) as follows:

3.8(1) ~~A physician or other health care professional~~ The primary care provider who undertakes primary pediatric care of a newborn delivered in a location other than a birthing hospital or birth center shall refer the newborn to ~~an audiologist, physician, or hospital~~ a health care professional for completion of the newborn hearing screening ~~within three months of the newborn's birth~~ no later than one month of age. The health care professional ~~who undertakes primary pediatric care of the newborn~~ shall arrange an appointment for the newborn hearing screening and report to the parent the appointment time, date, and location.

3.8(2) The ~~person~~ health care professional who completes the newborn hearing screening shall report screening results to the parent in written form.

3.8(3) The ~~person~~ health care professional who completes the newborn hearing screening shall report screening results to the department ~~in the manner prescribed in~~ pursuant to 641—3.9(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.

ITEM 15. Renumber subrule **3.8(4)** as **3.8(5)**.

ITEM 16. Adopt the following **new** subrule 3.8(4):

3.8(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.

ITEM 17. Amend rule 641—3.9(135), introductory paragraph, as follows:

641—3.9(135) Reporting hearing screening results and information to the department and child's primary care provider. Any birthing hospital, birth center, physician, audiologist or other health care professional required to report information pursuant to Iowa Code section 135.131 ~~as amended by 2009 Iowa Acts, House File 314, division II,~~ 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.

ITEM 18. Amend subrules 3.9(1) and 3.9(6) as follows:

3.9(1) The name ~~and~~, date of birth, and gender of the newborn.

3.9(6) Known risk indicators for hearing loss of the ~~newborn or~~ infant or child.

ITEM 19. Adopt the following **new** subrules 3.9(7) and 3.9(8):

3.9(7) 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.

3.9(8) 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.

ITEM 20. Amend rule 641—3.10(135), introductory paragraph, as follows:

641—3.10(135) Conducting and reporting screening results and diagnostic audiologic assessments to the department and child's primary care provider. Any ~~facility, licensed audiologist or~~ 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 ~~facility~~ health care professional shall conduct the diagnostic hearing assessment in accordance with the Pediatric Audiologic Diagnostic Protocol ~~contained at Appendix A~~ prescribed by the department at www.idph.iowa.gov. Results of a hearing screen, rescreen or diagnostic audiologic assessment shall be reported as follows.

ITEM 21. Amend paragraph **3.10(1)"a"** as follows:

a. The name ~~and~~, date of birth, and gender of the child.

ITEM 22. Adopt the following **new** paragraphs **3.10(1)"e"** to **"g"**:

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.

ITEM 23. Amend subrule 3.10(5) as follows:

3.10(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.

ITEM 24. Adopt the following **new** subrule 3.10(7):

3.10(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.

ITEM 25. Amend rule 641—3.11(135), introductory paragraph, as follows:

641—3.11(135) Sharing of information and confidentiality. Reports, records, and other information collected by or provided to the department relating to a child's newborn hearing screening, rescreen, ~~and~~

diagnostic audiologic assessment, and early intervention enrollment are confidential records pursuant to Iowa Code section 22.7.

ITEM 26. Amend subrule 3.11(1) as follows:

3.11(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, ~~and~~ diagnostic audiologic assessments, and early intervention enrollment, including information which is confidential under Iowa Code chapter 22 or any other provisions of state law.

ITEM 27. Amend paragraph **3.11(3)"c"** as follows:

c. A ~~local~~ health care professional or primary care provider.

ITEM 28. Amend subrules 3.13(1) and 3.13(2) as follows:

3.13(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 assessment refusal form and shall maintain the original copy of the written refusal in the newborn's ~~or~~, infant's or child's medical record.

3.13(2) The birthing hospital, birth center, physician, or other health care professional shall send a copy of the written newborn hearing screening or diagnostic assessment refusal form to the department within six days of the birth of the newborn.

ITEM 29. Adopt the following **new** subrule 3.13(3):

3.13(3) If a parent objects to a hearing rescreen or diagnostic 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 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.

ITEM 30. Adopt the following **new** rule 641—3.15(135):

641—3.15(135) Early hearing detection and intervention advisory committee.

3.15(1) *Membership.* The membership of the advisory committee shall be geographically representative of stakeholders with an interest in and concern for newborn hearing screening and follow-up. The advisory committee shall be appointed by the department director and consist of no more than 25 members and include the state EHDI coordinator. The EHDI coordinator will assist in facilitation of committee meetings. Membership will include a minimum of one representative from each of the following areas:

a. Advocate (e.g., office of deaf services).
b. Audiology.
c. Children with special health care needs program.
d. Deaf/hard-of-hearing community.
e. Early intervention services.
f. Ears, nose and throat specialist/otolaryngologists.
g. Family support.
h. Iowa Hospital Association or designee.
i. Hospitals (preferably hearing screening coordinator).
j. Parent(s) of deaf or hard-of-hearing child.
k. Family practice physician.
l. Pediatrician.
m. Representation from a state agency that is not the department.

3.15(2) *Meetings.* The committee shall meet three times per year. Location and times will be prescribed by the department.

3.15(3) *Voting.* The committee will make its recommendations by consensus. In the event that consensus cannot be reached within a reasonable time frame, there will be a majority rule, as in a simple majority of those present or more than 50 percent. At least 50 percent of the members must be present.

3.15(4) *Service, vacancies and attendance.*

a. Each committee member is appointed to serve a term of three years. Members may serve longer at the request of the department director unless their absence at meetings exceeds that permitted by the attendance policy. Terms for existing members will begin at the first of the year or as positions vacate. The term for a new member replacing a member before the member's term is up will begin when the vacancy is filled.

b. Vacancies will be filled within six months. The term will begin when the vacancy is filled. The EHDI coordinator will work with advisory committee members, EHDI program staff and associations to identify new members. Names and short biographies will be given to the department director to make a final determination for committee member vacancies.

c. Committee members are expected to be present in person for advisory committee meetings with the exception of extenuating circumstances that have been communicated to the state EHDI coordinator. Any member who cannot attend the scheduled meetings should notify the state EHDI coordinator at least 24 hours prior to the start of the regularly scheduled meeting. If there are extenuating circumstances and a member can send a representative, the member is encouraged to do so. Appointed members may be recommended for dismissal from the committee if the members miss more than two meetings per year.

ITEM 31. Amend subrule 3.18(2) as follows:

3.18(2) Funding does not pay for services ~~denied~~ covered by insurance ~~because the applicant received services outside the provider network~~.

ITEM 32. Amend paragraph **3.19(2)"g"** as follows:

g. Parent/guardian's or child's medical insurance plan ~~name~~ coverage.

ITEM 33. Amend paragraph **3.21(7)"a"** as follows:

a. ~~Health Care Financing Administration Form HCFA 1500~~ Centers for Medicare and Medicaid Services Form CMS 1500. Forms will be furnished by the providers and will include the applicant's enrollee number in the upper right-hand corner of the form.

ITEM 34. Rescind and reserve **641—Chapter 3**, **Appendix A**.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/9/15.