

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Center for Health and Environmental Data**

**NEWBORN HEARING SCREENING**

**6 CCR 1009-6**

*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

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**Adopted by the Board of Health January 15, 2020; effective March 16, 2020.**

**SECTION 1: AUTHORITY AND DEFINITIONS**

1.1 These rules and regulations are established under the authority § 25-4-1004.7, C.R.S.

1.2 Definitions

The following terms, whenever used in or referred to in these regulations, shall have the following respective meanings, unless a different meaning clearly appears from the context:

“Attending a birth” means delivery of a newborn and postpartum medical services provided to the newborn until the date of discharge, or for births occurring outside a birthing facility, until the health professional’s services have concluded.

“Audiological intervention” means any management of hearing loss performed by an audiologist, including but not limited to fitting for any amplification device designed to compensate for hearing loss, such as hearing aids or cochlear implants, as well as auditory training to aid in recognition of speech sounds once an amplification device is in place.

“Audiologist” means a person licensed pursuant to Article 210 of Title 12, of the Colorado

Revised Statutes, who has specialized training in hearing testing and intervention for newborns. These professionals may perform initial hearing screens or rescreens on newborns, but their role is primarily focused on audiological evaluation, diagnosis and audiological intervention for newborns with suspected or confirmed hearing loss. Audiologists may establish standards of care and provide consultation and supervision for hearing screening programs in birthing facilities.

“Auditory Brainstem Response” means a hearing test in which electrodes are placed strategically on the baby’s head and record brain wave activity in response to sounds heard through an earphone.

“Birthing Facility” means a general hospital or birthing center licensed or certified pursuant to §25-1.5-103, C.R.S.

“Department” means the Colorado Department of Public Health and Environment.

“Early Intervention” for purposes of this rule, means the services, education and support to children who are deemed to have a hearing loss, or who are evaluated and deemed to have a diagnosed physical or mental condition with a high probability of resulting in a developmental delay.

“Failed Screen” means any result from a completed hearing screening test or a rescreening test that is not “pass.”

“Follow-up services” for purposes of the newborn hearing screening program means, 1) identification of newborns at risk for hearing loss through the screening process; 2) coordination among medical and audiology providers, and families (the newborn’s parent(s) or legal guardian(s)); 3) providing information and timely referral for audiological evaluation; 4) providing information and timely referral for early intervention services; 5) confirming the connection to early intervention services; and; 6) monitoring screening for a missed screen, rescreening, and audiological evaluation and early intervention connection. Follow-up services facilitate rapid connection of newborns to early intervention, but are not intended to serve as clinical case management services. Follow-up services does not include the delivery of early intervention services except as described in Section 4.

“Health professional” means a physician, nurse, midwife, or other health professional attending the birth. The definition of health professional also includes other health professionals providing medical services to the newborn prior to discharge, including professionals that perform newborn hearing screening, serve as newborn hearing hospital coordinators, connect infants to hearing evaluation and early intervention resources, perform or report the date of the first CO-Hear’s Home Visit, and develop or report the date of initial Individualized Family Services Plan.

“Hearing rescreen” means a hearing screening performed on a newborn who received a failed screen result for an initial hearing screen.

“Initial hearing screen” means an otoacoustic emissions or auditory brainstem response screen performed on a newborn who has not previously received a screen.

“Missed Screen” means that the newborn missed receiving their initial hearing screen, and an initial hearing screen is pending.

“Named Submitter” means the entity or individual who submits initial hearing screen or hearing rescreen reports to the Department electronically. This can include, but is not limited to hospitals, birthing facilities, audiologists, health professionals or providers trained to perform a newborn hearing screening.

“Newborn” means an infant between 0 and 1 year of life.

“Otoacoustic Emissions” means a hearing test in which a small earphone emits sounds into the ear and measures the sounds that are produced by the vibration of hair cells in the inner ear in response to that sound.

“Passed Screen” means that the newborn passed a hearing screening and no further testing is currently required for purposes of the newborn hearing screening program.

**SECTION 2: REQUIREMENTS FOR HEALTH PROFESSIONALS ATTENDING A BIRTH IN A SETTING OTHER THAN A BIRTHING FACILITY**

- 2.1 A. For health professionals attending a birth in a setting other than a birthing facility who perform the initial hearing screen and hearing rescreen “professional effort” means:

1. Providing the parent or guardian with information about the importance of performing a newborn hearing screening in a timely manner within 30 days of the newborn's birth. The information provided must explain that appropriate testing and identification of newborn at risk for hearing loss facilitates early intervention and supports the linguistic and cognitive development of children, including the value of a hearing screen later in life if there is a concern with a newborn's hearing, speech or language development. The information provided must also explain how often a failed screen occurs and next steps for a parent or guardian when rescreening and follow-up services are necessary. The health professional may distribute information that has been developed by the Department to comply with this requirement;
  2. Performing the initial hearing screen in a manner that comports with the health professional's scope of practice or newborn hearing screening training to ensure accurate test results. The initial hearing screen will occur no sooner than 12 hours after birth and prior to the health professional terminating care of the newborn. If the newborn is unavailable for screening due to serious health problems that prevent hearing screening, hearing screening will be performed prior to discharge from services;
  3. Performing a hearing rescreen for a "failed screen" result on the initial hearing screening. The hearing rescreen will be performed in a manner that comports with the health professional's scope of practice or newborn hearing screening training to ensure accurate test results. The hearing rescreen will occur within 30 days of birth;
  4. Reporting the initial hearing screen and if applicable, the hearing rescreen result to the newborn's parent or guardian at the time of the screening;
  5. Reporting the initial hearing screen and, if applicable, the hearing rescreen result to the newborn's primary care provider within 30 days of birth, and;
  6. Reporting any missed screen or hearing rescreen failed screen result to the Department pursuant to Section 3 of this rule;
  7. Referring the parent or legal guardian for further diagnostic testing as appropriate based on screen results and risk factors for hearing loss.
- B. For health professionals attending a birth in a setting other than a birthing facility who do not perform the initial hearing screen or hearing rescreen, the health professional does not constitute a named submitter and "professional effort" shall mean:
1. Providing the parent or guardian with information about the importance of performing a newborn hearing screening within 30 days of the newborn's birth. The information provided must explain that appropriate testing and identification of newborns at risk for hearing loss facilitates early intervention and supports the appropriate language and cognitive development of children, including the value of hearing screen later in life if there is a concern with a child's hearing, speech or language development. The information provided must also explain how often a failed screen occurs and next steps for a parent or guardian when rescreening and follow-up services are necessary. The health professional may distribute information that has been developed by the Department to comply with this requirement;

2. Providing the newborn's parent or legal guardian with a list of providers that can perform the initial hearing screen and hearing rescreen. The list will include providers that have newborn hearing screening within their scope of practice or providers known to the health professional to have received training to perform newborn hearing screening. To the extent practicable, the list will identify providers that are within a reasonable travel distance of the newborn's parent or legal guardian;
  3. Asking the newborn's parent or guardian at a postpartum appointment whether the newborn received an initial hearing screen, and if the parent or legal guardian indicates the initial screening has not occurred, discussing the importance of screening at the postpartum appointment and notifying the newborn's primary care provider, within 14 to 30 days after the postpartum appointment, that screening needs to be scheduled.
- C. Nothing in this definition or the rule should be construed to require that screening services be performed if the parent or legal guardian objects, as the statute directs that screening for hearing loss is not required if the parent or legal guardian objects. If a parent or legal guardian objects, the health professional should document this in the newborn's medical record.

### **SECTION 3. REPORTING INITIAL HEARING SCREENING AND HEARING RESCREEN RESULTS TO THE DEPARTMENT**

- 3.1 Results that are included in the approved data system(s) include:
- A. Initial hearing screen reported in the Electronic Birth Certificate: Passed screen results. These results are available to the newborn hearing screening program when the Department determines the pass result needs to be confirmed or reviewed;
  - B. Initial hearing screen: Failed screen results;
  - C. Initial hearing screen: Missed screen results;
  - D. Initial hearing screen reported to the health information data system rather than the Electronic Birth Certificate as described in section 3.2.A.1.b. This entry resolves a missed screen result.
  - E. Hearing rescreen: Failed screen results, and
  - F. Hearing rescreen: Passed screen results.
- 3.2 The result will be reported electronically to the approved data system(s).
- A. 1. a. Named submitters attending a birth in a birthing facility will submit all initial hearing screening results electronically through the Electronic Birth Certificate. Initial hearing screening results submitted through the Electronic Birth Certificate will include passed, missed, and failed screen results.
    - b. The initial screening result will be submitted to the Department prior to the newborn's discharge from the birthing facility, unless extenuating circumstances are present.

When there are extenuating circumstances, such as the newborn receiving medical care through a neonatal intensive care unit, the initial screening result will be submitted through the Electronic Birth Certificate no later than 14 days after the newborn's birth or such later time as is medically appropriate and documented in the newborn's medical record. Reporting after 14 days must be submitted to the health information data system.

2. a. All other named submitters who perform the initial newborn screening will submit initial hearing results electronically through the Electronic Birth Certificate or through the Department approved health information data system.
- b. Reports will be submitted in a timely manner, no later than 30 days after the newborn's birth, unless extenuating circumstances are present.

When there are extenuating circumstances, the initial screening result will be submitted by the health professional at such a time as is deemed safe and practicable for the infant to receive the screening.

- B. Named submitters may enter newborn information and newborn hearing results for newborns that moved to Colorado after their birth to support the provision of follow-up services. This information is submitted to the health information data system. It is not part of the Electronic Birth Certificate.
- C. Named submitters who perform hearing rescreening will provide hearing rescreen results electronically through the Department approved data system. Results will be submitted in a timely manner. Unless there are unusual extenuating circumstances, rescreening results will be provided within 30 days of the newborn's birth. When there are extenuating circumstances, the rescreen result will be submitted by the health professional at such a time as is deemed safe and practicable for the infant to receive the screening.

#### **SECTION 4. FOLLOW-UP SERVICES FOR NEWBORNS AT RISK OF HEARING LOSS**

- 4.1 A. Screening to resolve a missed screen, rescreening, audiological evaluation and similar diagnostic testing services are not provided by the Department's newborn hearing screening program. These services are provided through other government agencies, community partners and private entities. Any costs incurred for these services is the responsibility of the parent or service provider.

The Department's newborn hearing screening program only monitors the result of these services for the limited purpose of rapidly connecting newborns and their families to early intervention services, and for the purposes of program evaluation and quality improvement.

- B. A parent or legal guardian, and their newborn's participation in the follow-up services is voluntary.
- 4.2 A. The Department monitors reporting pursuant to Section 3. For screen missed and screen fail results, the Department will send the parent or legal guardian information about the importance of screening and screening services. This information is sent when or soon after the 30 day reporting requirements have passed.
  - B. For newborns that are screened to address a missed screen:

1. A health professional resolves a missed screen by performing a hearing screen and reporting the result as required by Section 3 of these rules.
  2.
    - a. If the result is screen pass, no further action is required but health professionals are encouraged to provide information about value of hearing screen later in life if there is a concern with a child's hearing, speech or language development.
    - b. If the result is screen fail, a hearing rescreen or more comprehensive hearing evaluation as deemed necessary by the health provider, is required.

The health professional who performed the hearing screen will provide the parent or legal guardian with the screening result, information about the importance of newborn hearing screening and will perform the rescreen or provide information about which providers can perform hearing rescreening. To extent practicable, the list will identify providers that are within a reasonable travel distance of the newborn's parent or legal guardian.
- C. For newborns that are rescreened to confirm the initial screening result:
1. A health professional performs the hearing rescreen and reporting the result as required by Section 3 of these rules.
  2.
    - a. If the rescreen result is screen pass, no further action is needed.
    - b. If the rescreen result is screen fail, the health professional that performed the hearing rescreen will refer the newborn for a comprehensive audiological evaluation. To the extent practicable, the list will identify providers that are within a reasonable travel distance of the newborn's parent or legal guardian.
- D. An audiologist will provide a comprehensive hearing evaluation or diagnostic services within the first three months of life or, for newborns that experience delays in screening or follow-up services, as soon the need for audiological services becomes known to the audiologist. After the evaluation is completed, the audiologist should communicate the results of the evaluation and any recommendations to the parent or legal guardian, and other health professionals as authorized by the parent or legal guardian, and the Department, and; refer the newborn to early intervention services. When the audiologist confirms that the newborn has a permanent hearing loss, the referral for early intervention services will occur within 48 hours. To the extent practicable, the referral will identify early intervention service providers that are within a reasonable travel distance of the newborn's parent or legal guardian.
- E. Early intervention service providers will submit the date of the newborn's first CO-Hear Home Visit and the date of the initial Individualized Family Service Plan.
- 4.3 In addition to coordination through the referral process, coordination among medical and audiology providers, and families (the newborn's parent(s) or legal guardian(s) occurs when:
- A. A health professional attending a birth in a setting other than a hospital facility provides the screen result to the newborn's primary care provider, and;

- B. Individuals granted access to the health information data system enter or review screening results, rescreening results and audiological evaluation results as authorized in Section 5.

4.4 The Department shall monitor:

- A.
  - 1. The number of newborns with screen pass results reported in the Electronic Birth Certificate.
  - 2. To the extent it can be assessed, the number of pass results that were entered incorrectly and subsequently corrected, and the number of days it took for the initial screen result correction to be entered. This analysis only concerns the accuracy of initial screen results data entry.
- B. The number of newborns with missed screen results, failed initial screen results, hearing rescreen fail results and hearing rescreen pass results;
- C. The number of newborns that receive any follow-up services;
- D. The number of newborns who are eligible but opt to not participate in follow-up services;
- E. The length of time between the last failed screening and the first audiological evaluation;
- F. The number of newborns that receive an early intervention described in Section 4.2(E), and;
- G. The length of time between the audiological evaluation and the early intervention described in Sections 4.2(D) and 4.2(E).
- H. Such other monitoring the Department deems appropriate to monitor the effectiveness of newborn hearing screening program and support the statutory duties of the Colorado Infant Hearing Advisory Committee (CIHAC) as defined in § 25-4-1004.7(2)(a)(I), C.R.S.

4.5 The Department may provide educational material or materials developed by the CIHAC pursuant to § 25-4-1004.7(2)(a)(I), C.R.S., on the Department website to assist parents, legal guardians, and newborn hearing screening providers, coordinators and partners.

The Department may assist a health professional, parent or guardian seeking a referral for screening, audiological evaluation or early intervention; however, the Department cannot endorse any service provider. The Department may provide a health professional, parent or legal guardian with the contact information for the applicable licensing board when the individual seeks to file a complaint.

**SECTION 5: HEALTH INFORMATION DATA SYSTEM STANDARDS**

- 5.1
  - A. Only reports of initial hearing screens, hearing rescreens, and follow up services for newborns at risk of hearing loss as described in Section 3.1 and 4.1 of these rules will be maintained in the Department's health information data system.
  - B. The Department will limit the reported data to the minimum information necessary for a health professional attending the birth or providing follow-up services for newborns at risk of hearing loss to execute their obligations under the statute and this rule. A health professional will only be able to input and view records for patients from their own facility.

- C. The Department approves all access to its health information data system. To receive access, the health professional attending the birth or providing follow-up services for newborns at risk of hearing loss will sign the Department's confidentiality agreement. A health professional attending the birth or providing follow-up services for newborns at risk of hearing loss may access the Department health information data system to input or retrieve their patient care data. A primary care provider of a newborn receiving follow-up services may access the system for the purpose of coordinating care regardless of whether the primary care provider is performing follow up services. The Department will log and monitor health information data system use. The only authorized use of the data is to connect newborns at risk for hearing loss to appropriate follow-up services, pursuant to § 25-4-1004.7(5) and § 25-4-1004.7(8), C.R.S., and these rules.

The Department may revoke access to the health information data system at any time, including when the patient is no longer under the health professional's care, follow-up services have concluded, the individual has violated the terms of the signed confidentiality agreement, or the data are being used for a purpose that is outside the statutory and regulatory authorization.

- D. Entities, including but not limited to the Department and the Colorado School for the Deaf and the Blind, Article 80, Title 22, C.R.S., CO-Hears Program may access and input data into the health information data system to coordinate care, provide referrals and similar follow-up services.
- E. Entities and individuals granted access have the ability to run facility-level reports for the purpose of improving the facility or individual's newborn hearing screening practices and service delivery.
- F. The Department may access the health information data system to identify an appropriate follow-up services provider for a child with a failed screen result when:
1. Requested by the parent, named submitter, newborn's primary care provider or follow-up service provider and the relationship with the newborn has been confirmed.
  2. The Department communicates to the requestor that identifying a potential provider is not an endorsement for the provider or their services.
- 5.2 Except as authorized in Section 5.1, newborn hearing screening program data, whether recorded on paper or electronically, shall be strictly confidential and shall not be released. § 25-4-1004.7(9)(d), C.R.S., allows the Department to provide statistical reports with aggregate data; such reports will not include the name or any other patient specific data that could reasonably lead to identification of the patient. To ensure accurate assessment of prevalence, statistical reports will be comprised of data for newborns born in Colorado.
- A. The Department will provide statistical reports to the CIHAC to support the CIHAC's execution of its statutorily assigned duties in § 25-4-1004.7(2)(a)(I), C.R.S.
- B. The Department will submit de-identified, aggregate data to entities such as Centers for Disease Control and Prevention for comparison to national standards and outcomes. When appropriate, de-identified, aggregate data may also be used for the purpose of improving newborn hearing screening, evaluation, and connection to follow-up services.



- C. The statistical reports and de-identified, aggregate data identified in Section 5.2.A and 5.2.B can be made available to named submitters, entities with access to the health information data system and other interested persons for the purpose of comparing an entity or individual's services to state outcomes and national standards, or improving practice.

5.3 Quality Control

The Department will ensure quality newborn hearing screening data by:

- A. Training individuals granted access to the system to report screening results pursuant to Section 3 and follow-up services pursuant to Section 4. Training will be provided annually and more often as determined by the Department to be appropriate. Such training may be offered in conjunction with the periodic training required by § 25-4-1004.7(9)(c), C.R.S.
- B. Training individuals entering hearing screening data in the electronic birth certificate. Such training can be offered in conjunction with other Department training related to completing the electronic birth certificate.
- C. Utilizing the data identified in Rule 4.4(H) to implement quality improvement activities.

Nothing in this subsection should be read to limit the CIHAC's ability to recommend best practices and guidelines as delineated in § 25-4-1004.7(2)(a)(I), C.R.S. as those activities may also concern quality improvement.

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**Editor's Notes**

**History**

New rule eff. 03/16/2020.