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To: Members of the State Board of Health

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Through: Chris Wells, Director, Center for Health and Environmental Data (CHED) *CW*

Date: October 16, 2019

Subject: **Request for Rulemaking Hearing**
Proposed new rule 6 CCR 1009-6, *Newborn Hearing Screening*

The newborn hearing screening program began in 1997. The program is required to collect reports on all 63,000 - 68,000 Colorado newborns first and second hearing screens (live birth population in 2018: 63,454), Section 25-4-1004.7, C.R.S. These hearing screens are typically taken shortly after birth and are entered into the newborn's medical record. The report is entered and transmitted to the Electronic Birth Registry System (EBRS) and a data extract on newborn hearing screening results is delivered daily to the Birth Defects Monitoring and Prevention Program. If a newborn is at risk for hearing loss, the program contacts parents and families in a timely fashion (currently by sending a letter at 1 month of age) so they can locate appropriate diagnostic and intervention services for the newborn.

Hearing loss occurs in newborns more frequently than any other health condition for which newborn screening is required. Appropriate testing and identification of newborn infants with hearing loss facilitates early intervention and therefore serves the public purpose of promoting the appropriate linguistic and cognitive development of children and reducing the need for additional public supports and expenditures. Early detection, comprehensive evaluation, and appropriate intervention for hearing loss in a child are highly effective in facilitating a child's language development.

House Bill 18-1006, *Infant Newborn Screening*, updates and expands the statutes related to newborn hearing screening in Colorado. The legislation clarifies the roles and responsibilities of the Colorado Infant Hearing Advisory Committee, expands the Colorado Infant Hearing Advisory Committee membership from seven to nine, requires the Department to provide (on a periodic basis) training to birthing facilities and midwives on the newborn screening program, and requires the Board of Health promulgate rules related to newborn hearing screening. The Department proposes these new rules to implement the statutory directive related to rulemaking.

The Department respectfully requests that this matter be set for rulemaking.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for New Rule
6 CCR 1009-6, Newborn Hearing Screening

Basis and Purpose.

House Bill 18-1006, *Infant Newborn Screening*, updated and expanded the statutes related to newborn hearing screening in Colorado. The legislative declaration in Section 25-4-1004.7(1), C.R.S., reads, "Hearing loss occurs in newborn infants more frequently than any other health condition for which newborn screening is required." Hearing loss occurs in 1 to 2 newborns born in Colorado per 1000. HB 18-1006 codified current newborn hearing screening practice. Similarly, much of the rule codifies current practice.

In Colorado, newborn hearing practice is informed by the Colorado Infant Hearing Advisory Committee (CIHAC), a Type II advisory board. Per statute and the CIHAC Bylaws, "the purpose of the CIHAC is to provide scientific expertise and advice to the Colorado Department of Public Health and Environment related to newborn hearing screening (NBH) services/practices in the state, to inform programs and influence policies for improving newborn hearing screening services in Colorado, to provide a channel for input from appropriate official and voluntary agencies, professionals, and citizens in matters related to newborn hearing screening services in Colorado and to assist in presenting information about the newborn screening program to professionals, citizens, agencies, and other interested parties." The statute does not assign the CIHAC a role in developing or recommending newborn hearing screening program rules; however, the Department may use CIHAC recommendations to inform the rule language. Doing this helps those responsible for implementing the rule as they receive valuable resources and consistent information; however the Department also recognizes there may be instances where the rulemaking authority and the CIHAC best practices recommendations do not overlap.

While the statute contemplates newborn hearing screening for all newborns, the rulemaking authority is specific. Excerpts of the legislation that delineate the rulemaking requirement are provided below. This is followed by an explanation of how the proposed rule implements the rulemaking requirement.

Nothing in 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.

Section 25-4-1004.7(5), C.R.S., states,

A physician, nurse, midwife, or other health professional attending a birth outside a hospital or institution shall make every **professional effort, as defined by the board**, including following up at scheduled postpartum appointments, to ensure that the hearing screening is performed within thirty days of the birth and shall provide **information, as established by rule of the Department**, to parents regarding the importance of the screening. The physician, nurse, midwife, or other health professional who performs the screening shall provide a report of any screening to the parent or guardian of the infant, the primary care provider of the infant, and the Department. Screening for hearing loss under this subsection (5) is not required

if the parent or legal guardian objects. (Emphasis added herein.)

Rule to Define Professional Effort

The Board of Health is directed to define professional effort for health professionals attending a birth outside a hospital or institution.

Important considerations when developing the proposed rule:

- Rather than listing the professionals identified in statute each time, “Health professional” was defined to include the physician, nurse, midwife, or other health professionals attending the birth. The definition of health professional also includes other health professionals providing medical services to the newborn prior to discharge, including newborn hearing hospital coordinators and any health professionals who connect infants to evaluation and intervention resources.
- The term “institution” is not defined in Sections 25-4-1004.7 or 25-4-1004.2, C.R.S. Section 25-4-1002, C.R.S., does define “birthing facility” as a hospital or birthing center licensed or certified pursuant to Section 25-1.5-103, C.R.S. Birthing Center licensing is governed by 6 CCR 1011-1, Chapter 22, also promulgated through the Board of Health. To harmonize the statute, the Department has interpreted this rulemaking requirement to apply to health professionals attending a birth outside a birthing facility.
- There is no parallel rulemaking authority for health professionals operating within a birthing facility. Though there is no rule, health professionals attending a birth at a birthing facility must comply with Section 25-4-1004.7, C.R.S., as well as any health facility licensing or professional licensing standards, including the professional standard of care.
- While professional effort is defined for health professionals attending a birth outside a birthing facility, this effort is in addition to any facility or professional licensing requirements and the professional standard of care.

Proposed Section 2 of the rule defines “Professional Effort” (for health professionals attending a birth outside a birthing facility) as timely screening for health providers that perform screening, referral for comprehensive audiological evaluation, rescreening, informing the newborn’s parent or guardian about the importance of hearing screening, and reporting screening results to parents, primary care providers, and the Department. If a newborn passes a hearing screening in both ears, the parent or guardian should be counseled that hearing should be rechecked if there are ever speech, language, or hearing concerns.

For newborns born outside of a birthing facility, screens may be completed by a health professional in that setting or the newborn may be referred to another site to complete the hearing screen.

- For health professionals operating outside a birthing facility who will perform the screening: Screening shall occur no sooner than 12 hours after birth and in a manner that comports with the health professional’s scope of practice or newborn hearing screening training. Reporting to the Department, the parent or guardian and the newborn’s primary care provider will occur within 30 days of birth and, if a failed screen is received within 30 days of birth, the health professional shall provide or refer the newborn for follow-up services. If the newborn is unavailable within 30 days of birth for screening due to serious health problems that prevent hearing screening, hearing screening will be performed prior to discharge from services.

- For health professionals who do not perform the hearing screening on-site due to lack of access to hearing screening equipment, or early discharge or release from services: The health professional will provide the newborn's parent or guardian with a list of providers that can perform the screening services, educate the parent or guardian as to the importance of timely hearing screening, confirm with the newborn's parent or legal guardian that screening has occurred at a postpartum appointment, and if screening has not occurred, subsequently notify the newborn's primary care provider.

If newborns have missed an initial hearing screen due to serious health problems requiring admission to a hospital, hearing screening should be performed prior to discharge from the hospital.

Rule to Provide Information to Parents

The Department establishes what information health professionals attending a birth outside a hospital or institution provide parents.

Important considerations when developing the proposed rule:

- See previous discussion of "health professionals."
- See previous discussion of "institution."
- While Section 25-4-1004.7, C.R.S. uses the terms "Board of Health" and "Department" in relation to rulemaking, the statute does not refer to Executive Director rulemaking; thus, rulemaking by the Board of Health is appropriate.

During the development of the rule, stakeholders shared that providing the information required by the statute (see above) should be included in the definition of "professional effort." As discussed above, the Board defines "professional effort." In addition, Section 25-4-1004.7(9), C.R.S., directs the Board of Health promulgate rules concerning follow-up services for newborns identified as being at risk for hearing loss. Section 25-4-1004.7(9)(b), C.R.S., requires that information to parents be included in follow-up services. To act on stakeholder feedback and harmonize the statute, the Department is recommending the Board promulgate the rule governing the information health professionals attending a birth outside a facility provide parents. This ensures there is alignment between this statutory and regulatory requirement and the follow-up services requirements for newborns identified as at risk for hearing loss.

- The statute uses the term "parent," "guardian" and "legal guardian." The Department has interpreted the term "guardian" to include "legal guardian." Parents and legal guardians may receive protected identifying information and protected health information (screening results). Parents and guardians may receive general, non-patient specific information about the importance of screening. Reading the statute in its entirety and reviewing the plain language of this rulemaking requirement, the proposed rule requires this information be provided to the parent or guardian.

Proposed Section 2.1.A.1 and 2.1.B.1 state that health professionals attending a birth outside a birthing facility will provide the parent or guardian with the information or will explain that appropriate testing and identification of newborns with hearing loss facilitates early intervention and supports appropriate linguistic and cognitive development of children. The information provided will also explain how often a screening result suggests a newborn is at risk for hearing loss and next steps for a parent or guardian when the rescreening and follow-up services are necessary. The information provided will also include information on the value of hearing screening later in life if there is a concern

with a newborn's hearing, speech or language development. The health professional may distribute information that has been developed by the Department to comply with this requirement.

- For health professionals attending a birth outside a birthing facility who perform the newborn hearing screening, this information will be provided in a timely manner within 30 days of the newborn's birth. It is anticipated it will occur prior to or contemporaneously with the hearing screening.
- For health professionals attending a birth outside a birthing facility who do not perform the newborn hearing screening, this information is to be provided within 30 days of the birth of the newborn. These health professionals are also required under Rule 2.1.B.2 to provide the parent or guardian with a list of providers that are able to perform the newborn hearing screening services. 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. (Training is available for individuals who want to perform newborn hearing screening through any health professional with trained experience with the newborn hearing screening program, including but not limited to: hearing screening equipment manufacturers, CNAs, nurses, and audiologists.) The list will also include providers that are within a reasonable travel distance of the newborn and their family to the extent practicable.

Section 25-4-1004.7(8), C.R.S., states:

- (a) The state board of health shall promulgate rules that require each of the following with information pertinent to this section to report the results of individual screening to the department:
 - (I) A birthing facility; or
 - (II) Another facility or provider.
- (b) The rules must include a requirement that the birthing facility include the results of the hearing screening in the electronic medical record of the newborn. The information system required in subsection (7) of this section must allow the results of outpatient rescreenings to be reported to the department and to the parent or guardian of the newborn.

Reporting Requirements to the Department

Proposed rule Section 3 addresses what is reported to the Department and the manner in which it is reported. Important considerations when developing the proposed rule:

- The entities and individuals required to report initial hearing screens and hearing rescreens to the Department are identified in the proposed rule as "the named submitter."
- There is no rulemaking authority related to reporting to the parent or guardian. The Department recognizes that "guardian" as used in this section may be limited to the "legal guardian." Entities and individuals required to report may need to harmonize this statutory requirement with other statutes governing protected health information.
- For births at a birthing facility, Section 25-4-1004.7(8), C.R.S., the birthing facility already has processes in place for informing primary care providers. For births occurring outside of a birthing facility, Section 25-4-1004.5(5), C.R.S., directs the health professional to report screening results to the newborn's primary care provider.

Proposed rule Section 3 requires the named submitter to report a “pass result” or a “failed result.” The named submitter will also report when a newborn hearing screen is missed. Screening results are for the limited purpose of identifying whether a newborn is at risk for hearing loss so follow-up services can be initiated. The terminology required in rule is based on the data elements entered and transmitted to the Electronic Birth Registry System (EBRS). EBRS uses the terms “pass,” “fail,” and “missed.” A pass means no further action is needed by the health professional or the newborn’s primary care provider. Newborn hearing screen results are extracted from EBRS and delivered daily to the Birth Defects Monitoring and Prevention Program. While the newborn hearing screening program may access EBRS to review a screen pass result, the extraction is for failed and missed results. A missed or failed screen would necessitate referrals to additional screening, or early intervention, as needed. This standard ensures that parents or guardians of newborns at risk for hearing loss are alerted to the need for comprehensive audiological evaluation or early intervention. Hearing screen results do not reflect the current or future quality of life for the newborn. It is only an indicator for whether there is a risk for hearing loss and follow-up services are appropriate.

The initial hearing screening result will be submitted through the EBRS within 14 days of a newborn’s birth. Any additional screening results including hearing rescreen results will be submitted to the Department through the health information data system described in the Proposed rule Section 5. When the screening result is not reported on the Electronic Birth Certificate, the passed screen result is reported to the health information data system. This is necessary to resolve a missed screen or potential missed screen. Screening results will be provided within 30 days of the newborn’s birth, unless extenuating circumstances exist. When there are extenuating circumstances in which the newborn cannot be screened, such as the newborn receiving medical care through a neonatal intensive care unit, the initial screening result in the Electronic Birth Certificate will be submitted as a “missed” result and the newborn will be screened at such a time as is deemed safe and practicable for the infant to receive screening. That result will be submitted to the Department via the health information data system. Similarly, if extenuating circumstances prevent a hearing rescreen from happening within 30 days after a newborn’s birth, the hearing rescreen will be submitted to the health information data system at such a time when the health professional deems it medically safe and practicable to screen the infant and submit the result.

The proposed rule requires information be reported to the Department electronically prior to the newborn’s discharge, or, for newborns born in a setting other than a hospital or birthing facility, within 30 days of the newborn’s birth to align with the screening requirements directed by Section 25-4-1004.7(5), C.R.S., and support timely initiation of follow-up services. A hospital or birthing facility must also include this information in the newborn’s electronic medical record pursuant to Section 25-4-1004.7(8), C.R.S. When health professionals do not perform the screening on-site and they provide a list of referral resources for hearing screening, the health professional to which the newborn was referred will report the results of the hearing screen.

Section 25-4-1004.7(9), C.R.S., states:

- (a) The state board of health shall promulgate rules to establish and maintain appropriate follow-up services for newborns at risk of hearing loss. The follow-up services must include identification of newborns at risk for hearing loss, coordination among medical and audiology providers and families, connecting newborns to timely intervention, appropriate referrals to specialists for follow-up and diagnostic testing, and additional duties as determined by the

department.

- (b) The follow-up services must provide the parents with information and resources so that the parents can, in a timely manner, locate appropriate diagnostic and intervention services for the newborn.

Rule for Follow-up Services for Newborns At-risk for Hearing Loss

Important considerations when developing the proposed rule:

- The Board of Health is assigned responsibility for promulgating the rule. The statute then identifies certain activities that must be included in follow-up services for newborns at risk of hearing loss. The statute then states follow-up services for newborns at risk for hearing loss includes “additional duties as determined by the Department.” To harmonize the Board and the Department’s authority, the Department reads the statute as indicating that the Board cannot independently assign the Department additional duties. This is important for the program to operate within the existing personnel and resource allocation. The Department recognizes that when the Department and Board agree to add additional duties, there is an efficiency with including it in the rule promulgated by the Board of Health.
- Screening to resolve a missed screen, rescreening, audiological evaluations, and early intervention services are not provided by the Department’s newborn hearing screening program. These services are provided by 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 monitors the results of these services for the purpose of rapidly connecting newborns and their families to early intervention services, and for the purposes of program evaluation and quality improvement.
- 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 to facilitate continuity of care. The information is submitted to the health information data system. It is not part of the Electronic Birth Certificate record and, therefore, will not be included in any analysis of Colorado data.
- The rule is limited to the Department’s newborn hearing screening program. Nothing in the rule limits a health professional’s or facility’s ability to coordinate care. The Department recognizes that the Health Resources and Services Administration (HRSA) provides federal funds for early hearing detection and intervention through the HRSA EHDI program. Entities participating in this program may link a newborn to early intervention, special education and assistive technology. The Department does not participate in the Colorado CDC EHDI program. While there is an overlap between the follow-up services for newborns at risk of hearing loss, the Department’s program is narrower in scope. Where there is overlap, the proposed rules align with EHDI standards. The rule does not create a conflicting standard for health professionals serving newborns and newborns’ hearing needs. The proposed rule requires the minimum data entry needed to ensure a newborn at risk for hearing loss or with confirmed hearing loss is connected to early intervention services but once connected, the purpose of the newborn hearing screening program is satisfied and no further monitoring occurs.

Proposed Section 4 delineates the standards for follow-up services for newborns at risk of hearing loss for purposes of the Department’s newborn hearing screening program. It includes:

- *Identification of newborns at risk for hearing loss:* Follow-up newborn hearing screening is either an initial hearing screening due to a missed screen result, or a hearing rescreen after a failed result on the initial hearing screen. These services are provided by health professionals with training in newborn hearing screening, as discussed above. If there is a failed screen result on a second screen or if an infant is determined to be at risk for hearing loss, the newborn receives an audiological evaluation to determine their hearing levels and facilitate appropriate referrals if a hearing loss is confirmed. The health professional who performed the hearing screen will provide information about providers who can perform an audiological evaluation, if deemed to be applicable to the newborn. This testing should be completed by an audiologist with training with newborn populations.
- *Coordination, Connection to Intervention and Referral:* To facilitate connection to referral resources, the Department monitors reports of screen missed and screen failed results in order to give requested referral information to parents or guardians after the 30 day reporting period has passed. Timely referral for diagnostic and intervention consists of a referral for a comprehensive audiological evaluation completed after a failed screening result, or referral for early intervention services after hearing loss is confirmed. Audiologists are responsible for referring a child to the appropriate early intervention services. The provision of intervention services includes facilitation of the family's communication goals for their child by a provider with training in early intervention services. The purpose of the newborn hearing screening program is achieved when early intervention service providers submit the date of the newborn's first CO-Hear Home Visit and the date of the initial Individualized Family Service Plan.

Providers with access to the health information data system will submit information on key dates when the newborn received evaluation and intervention services to ensure that newborns are connected to early intervention. Referrals should be completed as soon as possible with the goal of completion based upon the American Academy of Pediatrics (AAP) Early Hearing Detection and Intervention guidelines (EHDI 1- 3-6 guidelines). The EHDI 1-3-6 guidelines recommend screening for hearing loss by 1 month of age, completing follow-up diagnostic testing by 3 months of age, and beginning intervention for a confirmed hearing loss by 6 months of age.

The EHDI guidelines are recommended by the Joint Committee on Infant Hearing (JCIH). The JCIH is comprised of organizations such as representatives from the American Academy of Pediatrics, the American Academy of Otolaryngology and Head and Neck Surgery, the American Speech Language Hearing Association, the American Academy of Audiology, the Council on Education of the Deaf, and Directors of Speech and Hearing Programs in State Health and Welfare Agencies. The JCIH's guidelines are informed by audiology, otolaryngology, pediatrics, and nursing professionals. The JCIH guidelines are commonly accepted across the United States.

- *Providing information to parents:* Parents are to be provided information and resources to locate appropriate diagnostic and treatment services for a newborn. This is comprised of information related to audiological evaluation and early intervention services.
- *Additional duties:* The Department will monitor the data entered into the health information data system to ensure the screening and follow-up services are working well, and to support the Colorado Infant Hearing Advisory Committee (CIHAC) in the execution of its statutory duties. The rule also allows the Department to provide educational material developed by the Colorado Infant Hearing Advisory Committee (CIHAC) on the Department website to assist parents, legal guardians, and newborn

hearing screening providers, coordinators and partners and allows the Department to assist those seeking a referral for screening, audiological evaluation or early intervention. However, the Department cannot endorse any service provider and may provide contact information for the applicable licensing board when an individual seeks to file a complaint against a health professional.

Section 25-4-1004.7(7), C.R.S., states:

Upon receipt of sufficient financial resources in the newborn hearing screening cash fund, as determined by the department, to support a new information technology system for the purpose of managing the newborn hearing screening program, the department shall procure an information technology system and promulgate rules in order to implement the system.

Section 25-4-1004.7(9)(d), C.R.S., states:

The information gathered by the department, other than statistical information and information that the parent or guardian of a newborn allows to be released through the parent's or guardian's informed consent, is confidential. Public access to newborn patient data is limited to data compiled without the newborn's name. Audiologists and other health professionals providing diagnostic services to newborns and their families may access the information, on a newborn-specific basis, for the purpose of entering follow-up information. The information gathered in accordance with this subsection (9)(d) does not restrict the department from performing follow-up services with newborns, their parents or guardians, and healthcare providers.

Rule for Information Technology System Standards

Proposed rule Section 5 includes standards to implement the data system in a manner that protects patient identifying data. Important considerations when developing the proposed rule:

- The Department will support the provider community's ability to comply with the rule by providing a training video, as well as an annual in-person training. The video will be used for onboarding users to the data system and can be accessed anytime. This video will be utilized for training those who will be accessing the system, primarily hospital coordinators, audiologists, and CO-Hears (CO-Hears are Colorado School for the Deaf and the Blind employees who help connect families to early intervention). Additional training on the data system may be provided by the Newborn Hearing Screening Coordinator, as deemed necessary by the Department. This training differs from the general newborn hearing screening program training that occurs pursuant to Section 25-4-1004.7(9)(c), C.R.S. The general newborn hearing screening program training is delivered in-person once per year. At a minimum, a webinar is available for those who can't attend. The training occurs in conjunction with the Vital Records Program, as it includes instruction for completing the hearing screening portion of the Electronic Birth Certificate Worksheet. Training ensures that individuals granted access to the system can accurately enter screening results and follow-up services data.
- Section 24-4-1004.7(9)(d), C.R.S., states that the information gathered by the Department, other than statistical information is confidential. The same

subsection then goes on to read, "Public access to newborn patient data is limited to data compiled without the newborn's name." The Department recognizes that if the only data element excluded is the newborn's name, the data is likely identifying, and would include protected health information and personally identifiable information. Reading the statute in its entirety and in relation to other laws, such as the Health Insurance Portability and Accountability Act, the proposed rule states that identifying information cannot be provided. Section 25-4-1004.7(9)(d), C.R.S., allows the Department to provide statistical reports with aggregate data, but such reports will not include any patient specific data that could lead to identification of a patient. Identifying data shall be strictly confidential.

Proposed Section 5 includes confidentiality requirements, access and revocation standards and data use standards.

- The new health information data system will be HIPAA-compliant; all data will be confidential pursuant to Section 25-4-1004.7(9)(d), C.R.S. Only health professionals performing and entering data on hearing screens, audiologists and other professionals providing follow-up services for newborns at risk of hearing loss may access identifying information in the database. This includes appropriate personnel with the Colorado School for the Deaf and the Blind, Article 80, Title 22, C.R.S., CO-Hears program. When individuals from a healthcare facility apply for access to the data system, they will specify the facility they work for, and their request for access will be sent to their supervisor or facility's designee for approval. They will only be granted access once they have signed a confidentiality agreement and their identity is verified. They will then only be able to access records for patients from their own facility and will not be able to search for or view any other facility's records. If a patient is transferred to another facility, the individual health professional whom they are transferred to will be able to access the newborn's record.

Limited CDPHE Employees, directly supporting and managing the newborn hearing screening program, will have access to all of the records in the Department's health information data system. While the Department is authorized to provide assistance, the Department cannot endorse a provider or their services.

- The rule also delineates specific instances where statistical information and de-identified, aggregate data reported pursuant to Section 3 and monitored pursuant to Rule 4.4. can be provided. This information will be provided to the Colorado Infant Hearing Advisory Committee (CIHAC) and the Centers for Disease Control and Prevention. Facility-level data can also be accessed by those with access to the system so they can assess and improve their service delivery.

Consistent with proposed rule 4.4, aggregate data reported to public entities will only include data for newborns born in Colorado to ensure accurate assessment of: 1) the number of newborns with passed, missed, or failed initial screen results; 2) the number of newborns with passed or failed hearing rescreens; 3) the number of newborns that receive an audiological evaluation; 4) the number of newborns that receive any follow-up services; 5) the number of newborns who are eligible but opt-out of follow-up services; 6) the average

length of time between a failed rescreen and an audiological evaluation; 7) the average length of time between the audiological evaluation and connection to early intervention; and 8) any such other monitoring the Department, such as data mis-entry, deems appropriate to monitor the effectiveness of the newborn hearing screening program.

Section 25-4-1004.7(4)(b), C.R.S., reads:

(a) Repealed.

(b) Such rules, if promulgated, shall address those hospitals with a low volume of births, as determined by the state board of health based upon recommendations by the advisory committee on hearing in newborn infants, which may arrange otherwise for newborn infant hearing screening.

HB 18-1006 struck (4)(a) which read, "if the number of infants screened falls below eighty-five percent, the board of health shall promulgate rules requiring screening of newborn infants pursuant to Section 24-4-103, C.R.S., of the "State Administrative Procedure Act.""

No rulemaking related to Section 25-4-1004.7(4)(b), C.R.S., is proposed at this time. Reading subsection (4)(b) without (4)(a), however, it appears that such rulemaking is discretionary and at this time such rules appear unnecessary. This will continue to be monitored.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

Yes, the bill number is HB18-1006. Rules are ___ authorized required.
 No

Does this rulemaking incorporate materials by reference?

Yes URL or Sent to State Publications Library
 No

Does this rulemaking create or modify fines or fees?

Yes
 No

Does the proposed rule create (or increase) a state mandate on local government?

Yes
 No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed.

REGULATORY ANALYSIS
for New Rule
6 CCR 1009-6, Newborn Hearing Screening

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/S/B
Hospitals/Hospital networks and Birthing Facilities (and their Administrators)	69	C
Midwives	523	C
Audiologists	505	C
Pediatricians	1,905	C
Family Medicine Offices	3,336	C
Colorado newborns and their families	63,000 to 68,000	C, B
Colorado newborns that need diagnostic and/or interventions, and their families	Varies from year to year	C, B
Colorado Commission for the Deaf, Hard of Hearing and Deafblind	TBD	S
Colorado Association of the Deaf	TBD	S
National Association of the Deaf	TBD	S
Colorado School for the Deaf and the Blind/CO-Hears	30	C/S
Hearing screening advocacy organizations	2	S
Colorado Hands & Voices	1200	C/S

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

- C = individuals/entities that implement or apply the rule.
- S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
- B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and

qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Economic outcomes

Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, and any Department measures taken to reduce or eliminate these costs, any financial benefits.

- C: The proposed rules largely codify current processes for the hearing portion of the newborn screening program. The majority of changes are clarifying and updates to align with the current statute and the current operation of the Colorado Newborn Hearing Screening Program. A designated health professional at each birthing facility or other birthing location must fill out the hearing screening results on the Electronic Birth Certificate. Electronic reporting to the Vital Records Department occurs for the vast majority of results. Hearing rescreens will be reported via the health information data system, which will be a free web-based tool. The only cost expected to access this data system is the cost of internet access.
- S: NA
- B: The parent or guardian out-of-pocket expense is unknown.

Section 25-4-1004.7(11), C.R.S., states that a parent or guardian may be assessed a reasonable fee to cover the costs of providing services. The fee for the newborn hearing screen may be bundled in with other fees. If the newborn is screened in the hospital at the time of birth, insurance often will cover the cost of the screening in the fees for the delivery. If the parent refuses the initial hearing screening at birth and then goes back for a screening later, their health insurance may bill them for the cost of the screening. Parents may receive a bill for a hearing rescreen, since insurance may not cover it if it is outside the date span for delivery hospital admission.

Early screening and consistent follow-up, which may include comprehensive audiological evaluation and referral to early intervention, improves long term childhood language outcomes. Early support reduces medical and educational costs to both the child's family and the state as it allows for the timely development of language skills.

Non-economic outcomes

Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

Timely screening and follow-up services that bridge the birth to pediatric services benefit the medical providers involved. Pediatricians benefit directly from the follow-up services covered by the newborn hearing screening program, as these services provide immediate access to audiologists and expert medical advice. Early identification will lead to early intervention.

Early intervention is important; this work is performed by the health care community and is not part of the Department's newborn hearing screening program.

- C: Early screening and audiological evaluation may lead to early intervention which allows providers to get newborns into care early.
- S: NA
- B: Newborns who receive newborn hearing screening, audiological evaluation and early intervention for hearing loss typically achieve better outcomes in their language development, which will influence their overall academic performance when they enter school.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

The fee for newborn hearing screening is established by the Department and supports the newborn hearing screening program. The fee covers the direct and indirect costs of the program. The health information data system is being built with these funds. The Newborn Hearing Screening Coordinator and Data Manager positions are also funded with these fees. The Coordinator will work with providers and facilities and contact families concerning follow-up services and missed screenings.

The fiscal note for HB 18-1006 identified the following costs:

Type of Expenditure	FY 2018-2019	FY2019-20	FY2020-21
Personal Services	\$78,866	\$157,731	\$157,731
Operating Expenses and Capital Outlay Costs	\$10,356	\$1,900	\$1,900
Information Technology Costs	\$700,000	-	\$140,000
Centrally Appropriated Costs	\$37,936	\$71,077	\$106,777
FTE - Personnel Services	1.0 FTE	2.0 FTE	2.0 FTE
Total	\$827,158	\$230,708	\$406,408

Anticipated CDPHE Revenues:

\$4.00 Newborn Hearing Screening Fee billed to hospitals from the Vital Records program funds the administration of this program. The fee began to accrue after the passage of HB 18-1006.

- B. Anticipated personal services, operating costs or other expenditures by another state agency:
NA

Anticipated Revenues for another state agency:

NA

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Along with the costs and benefits discussed above, the proposed revisions:

- Comply with a statutory mandate to promulgate rules.
- Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
- Maintain alignment with other states or national standards.
- Implement a Regulatory Efficiency Review (rule review) result
- Improve public and environmental health practice.
- Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

- | |
|---|
| <p>1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO₂e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO₂e per year by June 30, 2020 and to 113.144 million metric tons of CO₂e by June 30, 2023.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Contributes to the blueprint for pollution reduction <input type="checkbox"/> Reduces carbon dioxide from transportation <input type="checkbox"/> Reduces methane emissions from oil and gas industry <input type="checkbox"/> Reduces carbon dioxide emissions from electricity sector |
| <p>2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Reduces volatile organic compounds (VOC) and oxides of nitrogen (NO_x) from the oil and gas industry. <input type="checkbox"/> Supports local agencies and COGCC in oil and gas regulations. <input type="checkbox"/> Reduces VOC and NO_x emissions from non-oil and gas contributors |
| <p>3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. <input type="checkbox"/> Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. <input type="checkbox"/> Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing. |

<p>4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023.</p> <p>___ Ensures access to breastfeeding-friendly environments.</p>
<p>5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.</p> <p>___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.</p> <p>___ Performs targeted programming to increase immunization rates.</p> <p>___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).</p>
<p>6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.</p> <p>___ Creates a roadmap to address suicide in Colorado.</p> <p>___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.</p> <p>___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.</p> <p>___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.</p>
<p>7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.</p> <p>___ Conducts a gap assessment.</p> <p>___ Updates existing plans to address identified gaps.</p> <p>___ Develops and conducts various exercises to close gaps.</p>
<p>8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.</p> <p>___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.</p> <p>___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.</p> <p>___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.</p>

<p>9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.</p> <p><input type="checkbox"/> Implements the CDPHE Digital Transformation Plan.</p> <p><input type="checkbox"/> Optimizes processes prior to digitizing them.</p> <p><input type="checkbox"/> Improves data dissemination and interoperability methods and timeliness.</p>
<p>10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.</p> <p><input type="checkbox"/> Reduces emissions from employee commuting</p> <p><input type="checkbox"/> Reduces emissions from CDPHE operations</p>
<p>11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.</p> <p><input type="checkbox"/> Used a budget equity assessment</p>

Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

NA- the rule largely codifies current practice.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific rules proposed in this rulemaking largely codify current practice.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

See response #4 and 5.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

NA

STAKEHOLDER ENGAGEMENT
for New Rule
6 CCR 1009-6, Newborn Hearing Screening

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:

The Department emailed the 120 stakeholders on its stakeholder list and posted the draft documents on the Department's newborn hearing website for comment. Stakeholders were invited to forward the rulemaking to interested parties. The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Organization	Representative and Title
American Academy of Pediatrics	Ted Maynard, MD, FAAP, Vice President of Colorado Chapter
Arkansas Valley Regional Medical Center	Mary Osborn, Newborn Hearing Screening Program Coordinator (NBH Coordinator)
Aspen Valley Hospital	Valerie Hincy, OB dept./Newborn Hearing contact
Avista Adventist Hospital	Justine Taudien, NBH Coordinator
Banner Ft. Collins Medical Center	Michelle Shaffer, Women & Infant Services RN Senior Manager and Newborn Hearing contact
Birth Center of Boulder	Elizabeth Simmons, Midwife
	Jenifer James, Midwife
Boulder Community Hospital	Glenda Diggins, Birth Registrar
Castle Rock Adventist/Sky Ridge	Aubrey Murray, NBH Coordinator
Children's Hospital Colorado	Deborah Hayes, Infant Hearing/ Professor of Pediatrics and Physical Medicine
	Ellen Stern, Senior Policy Coordinator, Government Affairs
	Kristina Kocsis, Certified Genetic Counselor
	Kristin Uhler, Ph.D., MA, Audiologist, Chair for Audiology, Speech Pathology, and Learning Services
	Maureen Cunningham, MD, MPH, FAAP, Assistant Professor, Pediatrics-Pediatric Hospital Medicine

	Peggy Kelley, MD/ENT
	Renee Johnson
	Stephanie Olson, Family Consultant
	Rebecca Awad, Au.D., CCC-A, NBH Coordinator
Colorado Academy of Audiology	Cory Portnuff, Au.D., PhD, President of Colorado Academy of Audiology
Consultant	Charlie Hebel
Private Practicing Audiologist	Beth O'Brien, Au.D.
Colorado Association of the Deaf	Vance Youngs, President of the Board
	Amanda Sortwell, Vice President
Colorado Commission for the Deaf, Hard of Hearing and Deafblind	Cliff Moers, Director
	Timothy Chevalier, Outreach Consultant
Colorado Department of Health Care Policy and Financing	Alex Weichselbaum, Rehabilitative and Behavioral Policy Specialist
	Matthew Colussi, Health Program Office, Section Manager, Benefits Management
Colorado Early Childhood Leadership Commission Early Learning and Developmental Guidelines Advisory Board	Lenita Hartman, Advisory Board Member
CO-Hears/Colorado School for the Deaf and the Blind	Annette Landes, M.A., CCC-SLP, CO-Hear
	Ashley Renslow, M.A., CCC-SLP, Early Education Consultant, CHIP Program Lead
	Dale Wolf, Program Support/Administrative Assistant
	Dee Shuler-Woodard, M.A., CCC- SLP, CO-Hear
	Dinah Beams, retired CO-Hear
	Emily Wojahn, teacher of the deaf, CO-Hear
	Erin Slone, teacher of the deaf, CO- Hear
	Karen Carpenter, Au.D., Unilateral Hearing Loss Coordinator
	Kelly Doolittle, teacher of the deaf, CO-Hear
	Kirsten Gardzelewski, CO-Hear

	Laura Douglas, Interim Director of Outreach
	Lynn Wismann, teacher of the deaf, CO-Hear
	Mary Cuccaro, Program Support/Administrative Assistant
	Michelle Brady, Program Support/Administrative Assistant
	Robin Getz, teacher of the deaf, CO-Hear
	Terry Wayt, teacher of the deaf, CO-Hear
Colorado Infant Hearing Advisory Committee (An advisory board within CDPHE)	Members include: Alex Weichselbaum, Ashley Renslow, Linda Herzberger-Kimball, Maureen Cunningham, Rebecca Awad, Samuel Gubbels, Stacy Claycomb, Karina Mays-Briscoe, and Sara Kennedy (see rest of list for details)
Colorado Hands & Voices	Sara Kennedy, Director
	Liesel Thomas, Assistant Director
Hands & Voices	Janet DesGeorges, Executive Director
Parent of child affected	Karina Mays-Briscoe
	Mah-rya Proper (Colorado Hands & Voices)
	Megan Nix
	Stacey Geisel
Colorado Plains Medical Center	Debra Tolson, RN, BSN, Childbirth Education Coordinator & Lactation Consultant
Community Hospital	Lisa Hill
Delta County Memorial Hospital	L. Spencer
Denver Center for Birth	Karen Loughlin, Midwife
Denver Health Medical Center	Tracey Yokley, former assistant newborn hearing coordinator
Denver Health Medical Center/Swedish Medical Center	Trudy Frederics, Au.D., CCC-A, Clinical Audiologist Supervisor and NBH Coordinator
Denver Public Schools	Lisa Cannon, Au.D., Educational Audiologist/Audiology Coordinator
Early Periodic Screening, Diagnostic, and Treatment	Gina Robinson, EPSDT Program Contact

East Morgan County Hospital	Amanda Boshell, Senior RN Manager and newborn hearing contact
Estes Park Health	Dianna Cordsen, Newborn hearing HIM data entry
Evans Army Community Hospital	JoAnn Madorran, NBH Coordinator
Good Samaritan Med Ctr/St. Joseph Hospital	Emily Stratton, M.A., Clinical Audiologist, NBH Coordinator
Gunnison Valley Hospital	Vallerie Funk, RN, NBH Coordinator
Heart of the Rockies Regional Medical Center	Judy Smith, NBH Coordinator (until mid-June of 2019)
Homebirth Midwifery Services	Jan Lapetino, midwife
Kaiser Permanente	Linda Herzberger-Kimball, M.S., Au.D., Audiologist
Kit Carson County Memorial Hospital	Heather Morris, NBH Coordinator
Longs Peak Hospital	Kathryn Dobler, RN
	Heidi Bradley, MSN/RN and NBH Coordinator
Marion Downs Center	Sandra Gabbard, Audiologist
McKee Medical Center	Julie Shuck, Newborn Hearing contact
Memorial Hospital Children's NICU	Wendy Vance, Newborn Hearing contact
Memorial Hospital North/Central	Julie Miller, Audiologist
	Meghin Purdy, PT, DPT, NCS, Newborn Hearing contact
	Nicolette Amos, Memorial Hospital Rehab Coordinator
Medical Center of the Rockies	Jenna Duetsch, MSN, RN-C OB, Nurse Manager and NBH Coordinator
Mercy Medical Center	Jennifer Hyson, RN, BSN, and NBH Coordinator
Montrose Memorial Hospital	Courtney Cryer, BSN Director of family center/Newborn hearing Contact
Mountain Midwifery	Joel Ryan, CEO of Mountain Midwifery
Parker Adventist Hospital	Holly James
Parkview Episcopal Medical Center	Sara Breckenridge, Newborn Hearing contact
	Tami Gavin
Pediatrix	Jeryl Barganski, Regional Manager
	Linda Trigg, Regional Coordinator

Platte Valley Medical Center	Delilah Botello, NBH Coordinator
	Elizabeth Rodriguez, NBH Coordinator
	Raquel Ochoa, MA/CAN, NBH Coordinator
Poudre Valley Hospital	Julie Brain, Newborn Hearing Contact
	Maggie Lujan
Prowers Medical Center	Angela Hoffman, NBH Coordinator
	Julie Hobden, NBH Coordinator
Rocky Mountain Deaf School	Amy Novotny, Director
San Luis Valley Regional Medical Center	Sarah Herrera, Supervisor
Sedgwick County Memorial Hospital	Machelle Newth, NBH Coordinator
Southwest Memorial Hospital	Nicole Loyd, Newborn Hearing contact
St. Anthony Hospital North	Karen Musselman, Newborn Hearing contact
St. Anthony Summit Medical Center	Julie Cox, Newborn Hearing contact
St. Mary Corwin Regional Medical Center	Susan Wilczynski, Newborn Hearing contact
St. Mary's Hospital and Med Center	Charlotte Balerio, Childbirth Coordinator and NBH Coordinator
St. Thomas More Hospital	Brooke Lee, NBH Coordinator
	Sabrina Fluharty, NBH Coordinator
The Memorial Hospital	Aimee Haskins, NBH Coordinator
University of Colorado at Boulder	Allison Sedey, CO-Hear Advisor/Consultant
	Christine Yoshinaga-Itano, Ph.D., Research Professor & Professor Emeritus
University of Colorado at Denver	Stephen Cass, ENT - Otolaryngologist
	Vickie Thomson, Principal Investigator, Early Hearing Detection & Intervention (EHDI) grant thru HRSA
University of Colorado School of Medicine	Samuel Gubbels, MD, FACS, Associate Professor
	Stacy Claycomb, Au.D., Clinical Audiologist
Vail Valley Medical Center	Shama Sambergerova, NBH Coordinator
Valley View Hospital	Laura Cross, NBH Coordinator

Wray Community Hospital	Cathy Bard, NBH Coordinator
	Jennifer Kramer, NBH Coordinator
Yampa Valley Medical Center	Pauline Kopsa, Newborn Hearing contact/Lactation Consultant
Other Stakeholders	Gretchen Boling
	Heather Edwards
	jolene@jolenethemidwife.com
	Nunez.af87@gmail.com
	plannerps@yahoo.com
	Tina Jordan
	Veronica Gutierrez

Copies of the rulemaking were also posted to the Department's Facebook and Twitter pages for the CDPHE: Colorado Health Service Corps by the Health Access Branch/Primary Care office. On the Facebook page, which has 308 followers, 52 people were reached with 1 like and 3 engagements for the first draft of the rulemaking. On the Twitter page, which has 382 followers, there were 406 impressions, 4 engagements, 1 like and 1 retweet, for the first draft of the rulemaking. When the second rulemaking draft was posted to these pages, there were 49 people reached on the Facebook page with 2 likes and 2 engagements, and there were 49 impressions on the Twitter page. At the time of the second draft of the rulemaking, the Facebook page had 309 followers and the Twitter pages had 385 followers. There were no comments received from these social media pages for either of the first two rulemaking drafts.

A variety of early stakeholder engagements were conducted through the quarterly CIHAC meetings. These events included updates to the committee on HB 18-1006, and the Department's plans to update the program based on statute.

On June 28, 2019, the Department hosted a stakeholder meeting in order to address stakeholders' concerns on the rulemaking. Prior to the meeting, a third draft was sent out for stakeholder review. During the meeting, stakeholders expressed the desire to postpone the request for rulemaking to further develop the proposal. The following individuals provided comments on this draft before sending it back to the Department: Rebecca Awad, Maureen Cunningham, Charlie Hebel, Sara Kennedy, Ashley Renslow, Ellen Stern, and Vickie Thomson. The Department reviewed stakeholder feedback and was able to incorporate some of the stakeholder feedback; some feedback was not incorporated after consultation within the Department, and including the Office of the Attorney General. The packet was revised to further explain why not all suggestions were incorporated.

A follow-up meeting with stakeholders was convened on September 9, 2019, to discuss what feedback was incorporated and clarify the difference between rule and statute.

After this stakeholder meeting, further edits were made to the rule to delineate the timeline for reporting data in extenuating circumstances, clarify what information will be submitted through the Electronic Birth Certificate and the health information data system, clarify and expand the follow-up services section to describe in detail what statistical information the Department shall monitor and to clarify the Department's role in

connecting individuals to services, and include a description of key statistical information or de-identified, aggregate data the Department would provide the CIHAC, the CDC and Colorado's newborn hearing screening community. Edits also described what data would be reported to public entities, as well as describe what quality control measures would be put in place. This draft was sent out to stakeholders on September 13, 2019.

Comments were due on September 23, 2019. The department extended the comment period to October 1, 2019, provided reminder emails and ensured stakeholders understood that the Department needed feedback to determine if the community was ready for the Department to request rulemaking. The Department received 5 comments of support on the draft. Two communications included substantive feedback on behalf of individuals that participated in the September 9, 2019 stakeholder meeting. Both commenters indicated that the latest edits were appreciated. Both offered further suggestions to improve the draft. These edits were specific and generally clarifying. Many were incorporated into this packet.

The Department received a total of 44 email responses from 32 individuals representing themselves or a stakeholder organization. Many comments offered technical and clarifying edits or asked for more detail on definitions of terms used in the rulemaking. Little to no substantive feedback was received from stakeholders responsible for implementing the rule (health professionals and birthing facilities). Operationally, the rule codifies current practice. While there is always an opportunity for continuous process improvement, no major gaps in the work performed by those responsible for performing the daily screening, reporting and linkage to care activities, have been identified. A number of edits were made to Section 4, the section on follow-up services to clarify current practices and the Department's role in connection to care. Also, a few stakeholders requested more information regarding how the health information data system would be set up to provide data quality assurance. These comments were incorporated.

For those that apply the proposed rule- named submitters and those providing follow-up services, the rule delineates clear reporting, communication and coordination standards. The standards are feasible while ensuring newborns are timely connected to early intervention services. The feedback suggests consensus on what is included in the rule. The Department appreciates that a subset of stakeholders would like the Department to pursue being an EHDI site and CDC grant funds. By doing this, the Department would perform additional monitoring of early intervention services. For the reasons described in the Statement of Basis and Purpose and below, the Department has not expanded its follow-up services responsibilities in this manner. Though the Department was unwilling to expand the newborn hearing screening program to monitor delivery of early intervention services, the rule language is based upon and aligns with CDC standards, EHDI site standards to the extent they are within the scope of the program, and CIHAC recommendations. The Department has also agreed to provide de-identified data and statistical information to the CDC. Section 5.2.B was added to the rule to acknowledge that the CDC will receive reports of de-identified aggregate data to help compare the outcomes of Colorado's newborn screening program to national standards and outcomes.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

- Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.
- Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

Topics that were studied but ultimately not fully incorporated are:

Cultural Competence

One set of comments was regarding culturally-competent wording, and these were incorporated to the greatest extent possible. For example, "intervention" rather than "treatment" is used throughout the document. The Department received a request to change the term "hearing loss" to "decreased hearing acuity." While the Department appreciates that negative labels such as the term "loss" can result in lower aspirations of these newborns as they grow older, the term is used in statute and the term "hearing loss" is in plain language. Similarly, the Department received stakeholder input asking that we replace "fail" or "failed screen" with "results warrant referral." The Department studied this at length. Language was added to the rulemaking packet to explain that this is a screening result and is not a reflection on the quality of life for the newborn. The terms "pass" and "fail" are the terms on the State of Colorado Birth Certificate Worksheet which is based on the National Vital Statistics Registry Forms used to report birth anomalies nationally. To change this term in the rule could create confusion for those charged with entering important data. Also, a few stakeholders explicitly stated in their feedback that they wanted to make sure "failed screen" results are reported to the Department so follow-up services can be initiated. The Department will continue to monitor this. We appreciate not wanting the rule to give rise to stigma. In the new data system for newborn hearing screening, results for hearing screenings have already been changed to be reported as "did not pass/referred" for cultural competency. The Program will be mindful of these terms in future communications with stakeholders, parents, guardians, legal guardians, and when providing statistical reports to the public.

Redefining Initial Hearing Screen and the Hearing Rescreen

Some stakeholders sought the terms "Initial Hearing Screen" and "Hearing Rescreen". Two stakeholders offered "inpatient screen" and "outpatient screen." The terms "initial hearing screen" and "hearing rescreen" were retained because some births occur outside a birthing facility and thus, the terms inpatient and outpatient were not accurate.

Collect information from families

Stakeholder requested that the rule go beyond providing parents information to having the Department collect information from families. This allows for more complete information. The statute does not mandate parent reporting. While the Department appreciates the benefit of having complete data, this could be a burden to families and have a workload impact to the program. The rule focuses on health professional, birthing facility reporting as delineated in

statute; however, the rule authorizes the Department to intervene and enter information into the database so if circumstances require a correction or entry, the rule has a mechanism to allow for this while not imposing a requirement.

Expansion of the Colorado Infant Hearing Advisory Committee (CIHAC)

The CIHAC develops recommendations for newborn hearing screening and reporting to birthing facilities, other health care institutions, the Department and the public," Section 25-4-1004.7, C.R.S. The recommendations are critical feedback that inform the Department's newborn hearing screening program and these rules; however, the recommendations are not rules. These rules acknowledge the authority of the CIHAC as an advisory body to the Department and the statutory duties of the CIHAC. The proposed rule language aligns with CIHAC recommendations.

Some of the suggestions from stakeholders exceed the rulemaking authorization. For example, the composition of the CIHAC is delineated in statute. There is no authority for the composition to be expanded through rulemaking. Similarly, the statute does not assign the CIHAC a role in rulemaking. Though not engaged as an advisory board, individual members of the CIHAC were included in the stakeholder process.

Cytomegalovirus (CMV)

Some comments sought rules related to CMV testing. Though there is a nexus to newborn hearing screening, there is no rulemaking authority related to CMV testing. Section 25-4-1004.7(10)(a), C.R.S., states, "The Department shall develop and publish materials on its website for use in educating and training on cytomegalovirus." The statute specifies what information is to be included. Section 25-4-1004.7(10)(b), C.R.S., states, that the Department will provide technical assistance and training to health facilities and providers upon their request; however, this requirement is contingent upon the Department receiving appropriations.

The statute has been implemented. A list of CMV resource materials has already been published on the Department's newborn hearing website. The Department will continue to work with stakeholders to review additional CMV materials and publish them on the Department's website as appropriate. The Department provides technical assistance upon request. No appropriation has been received and thus, no training has been developed or delivered.

Expanding the scope of the newborn hearing screening program

Some comments asked for the Department to: modify the wording in the rulemaking to use "children" instead of "newborn" or to monitor newborns with hearing loss until they turn age 7; track referrals to parent-to-parent support organizations, and deaf or hard-of-hearing mentors; track the delivery of early intervention services; serve as a EHDI site, and; seek CDC grant funds.

The purpose of the Department's newborn screening program is to connect newborns to the larger systems of health care and early childhood services. The proposed rule uses the term "newborn" as this is consistent with HB 18-1006. The Department ended follow-up services as confirming the connection to early intervention services for a number of reasons:

- 1) The Department's role is identification and prevention. The Department gathers data only to the extent necessary to support the public health interest.
- 2) Early development and early intervention services are available through other

agencies. The program does not manage provider intervention services. The newborn hearing screening program is not a long-term medical management program that oversees the delivery of early intervention, early development and health care services. These responsibilities reside with the provider community and the other federal and state agencies involved in early development and early intervention services. In addition, the Department does not license the oversight of the professionals performing screening, diagnosis and intervention services. These professionals are regulated by the Department of Regulatory Agencies (DORA) to ensure their actions comport with the standard of care. Department monitoring encroaches upon and create redundancy with other federal, state and local program including programs administered by the Colorado Department of Health Care Policy and Financing, and schools.

- 3) While CDC grant funds are available; the Department has previously evaluated this and found CDC funds insufficient to cover the minimum programmatic and grant program costs.
- 4) The Department gave careful consideration to this feedback as asking the Department to do more downstream in the service delivery also suggests those working in service delivery consider expanding their work upstream. The benefit of the Department housing the program is that the screening data is easily accessible. To move the program to an agency that performs early intervention services and asking them to assume the screening function is challenging because they would not have the electronic birth certificate data and public health authority; thus, they would need to enter into agreements with multiple birthing facilities and health professionals to obtain this data.
- 5) Each year the CIHAC, provider community and Department serve approximately 200 children that need additional hearing screening or follow-up services. When looking at the outcomes the community achieves under the current model, the Department finds that the newborn hearing screening program is achieving its statutory purpose within the minimum standards proposed and the current resource allocation. That said, the Department appreciates those committed to newborn hearing screening and their advocating for the best for newborns. The Department also appreciates the experience felt by any parent and child when a newborn at risk for hearing loss doesn't timely benefit from early intervention services. We agree that the data should identify system challenges and if it does, we will then work with the community to develop a solution.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

This rulemaking and the education and outreach the Program will perform will ensure named submitters and birthing facilities are informed of the regulatory requirements and resources to ensure timely newborn hearing screening. The health information data system will enable health professionals to equally track all newborns at risk for hearing loss, especially those populations less likely to receive a newborn hearing screen or at-risk for hearing loss, including but not limited to babies hospitalized in the NICU for more than five days, babies exposed to *in utero* infections, babies with family history of permanent childhood hearing loss, and babies born at home. The rulemaking will also enable health professionals to track whether newborns at risk of hearing loss have been connected to the system through follow-up services. Follow-up services link families to care and bridge the birth to short-term and long-term services and supports.

Excerpt from HB 18-1006 that pertains to newborn hearing screening.

SECTION 6. In Colorado Revised Statutes, 25-4-1004.7, **amend** (2)(a)(I) introductory portion, (2)(a)(I)(A), (2)(a)(I)(C), (2)(a)(II), (3)(a), and (5); **repeal** (1), (2)(a)(I)(B), (3)(b), and (4)(a); and **add** (7), (8), (9), (10), and (11) as follows:

25-4-1004.7. Newborn hearing screening - advisory committee - report - rules. (1) (a) ~~The general assembly finds, determines, and declares:~~

~~(I) That hearing loss occurs in newborn infants more frequently than any other health condition for which newborn infant screening is required;~~

~~(II) That eighty percent of the language ability of a child is established by the time the child is eighteen months of age and that hearing is vitally important to the healthy development of such language skills;~~

~~(III) That early detection of hearing loss in a child and early~~

~~intervention and treatment has been demonstrated to be highly effective in facilitating a child's healthy development in a manner consistent with the child's age and cognitive ability;~~

~~(IV) That children with hearing loss who do not receive such early intervention and treatment frequently require special educational services and that such services are publicly funded for the vast majority of children with hearing needs in the state;~~

~~(V) That appropriate testing and identification of newborn infants with hearing loss will facilitate early intervention and treatment and may therefore serve the public purposes of promoting the healthy development of children and reducing public expenditure; and~~

~~(VI) That consumers should be entitled to know whether the hospital at which they choose to deliver their infant provides newborn hearing screening.~~

~~(b) For these reasons the general assembly hereby determines that it would be beneficial and in the best interests of the development of the children of the state of Colorado that newborn infants' hearing be screened.~~

~~(2) (a) (I) There is hereby established an advisory committee on hearing in newborn infants for the purpose of collecting the informational data specified in paragraph (b) of subsection (3) of this section; and for the purpose of REVIEWING INFORMATION AND STATISTICS GATHERED DURING THE NEWBORN HEARING SCREENING PROGRAM AND providing recommendations to hospitals BIRTHING FACILITIES, other health care institutions, the department, of public health and environment; and the public concerning, but not necessarily limited to: the following:~~

~~(A) Appropriate methodologies to be implemented BEST PRACTICES for hearing screening of newborn infants, which methodologies shall PRACTICES MUST be objective and physiologically based and which shall MUST not include a requirement that the initial newborn hearing screening be performed by an audiologist; AND~~

~~(B) The number of births sufficient to qualify a hospital or health institution to arrange otherwise for hearing screenings; and~~

(C) Guidelines AND BEST PRACTICES for reporting and the means to assure that identified children receive referral for appropriate follow-up services.

(II) The advisory committee on hearing in newborn infants ~~shall~~ MUST consist of at least ~~seven~~ NINE members. ~~who shall be appointed by~~ The executive director of the department of public health and environment SHALL APPOINT MEMBERS TO THE ADVISORY COMMITTEE. Members appointed to the committee ~~shall~~ MUST have training, experience, or interest in the area of hearing ~~conditions~~ LOSS in children AND SHOULD INCLUDE REPRESENTATIVES FROM RURAL AND URBAN AREAS OF THE STATE, A PARENT WHO HAS A CHILD WITH HEARING LOSS, A REPRESENTATIVE OF A PATIENT AND FAMILY SUPPORT ORGANIZATION, A REPRESENTATIVE OF A HOSPITAL, A REPRESENTATIVE FROM AN ORGANIZATION REPRESENTING CULTURALLY DEAF PERSONS, AN AMERICAN SIGN LANGUAGE EXPERT WHO HAS EXPERIENCE IN EVALUATION AND INTERVENTION OF INFANTS AND YOUNG CHILDREN, AND PHYSICIANS AND AUDIOLOGISTS WITH SPECIFIC EXPERTISE IN HEARING LOSS IN INFANTS.

(3) (a) It is the intent of the general assembly that ~~newborn hearing screening be conducted on no fewer than ninety-five percent of the infants born in hospitals~~ INFANTS BORN IN THE STATE BE SCREENED FOR HEARING LOSS using procedures recommended by the advisory committee on hearing in newborn infants, created in subsection (2) of this section. Toward that end, every licensed or certified ~~hospital~~ BIRTHING FACILITY shall educate the parents of infants born in such ~~hospitals~~ BIRTHING FACILITIES of the importance of screening the hearing of newborn infants and follow-up care. Education ~~shall not be~~ IS NOT considered a substitute for the hearing screening described in this section. ~~Every licensed or certified hospital shall report annually to the advisory committee concerning the following:~~ SCREENING FOR HEARING LOSS UNDER THIS SUBSECTION (3)(a) IS NOT REQUIRED IF THE PARENT OR LEGAL GUARDIAN OBJECTS.

~~(I) The number of infants born in the hospital;~~

~~(II) The number of infants screened;~~

~~(III) The number of infants who passed the screening, if administered; and~~

~~(IV) The number of infants who did not pass the screening, if administered:~~

~~(b) The advisory committee on hearing in newborn infants shall determine which hospitals or other health care institutions in the state of Colorado are administering hearing screening to newborn infants on a voluntary basis and the number of infants screened:~~

~~(I) to (IV) Repealed:~~

~~(4) (a) If the number of infants screened falls below eighty-five percent, the board of health shall promulgate rules requiring hearing screening of newborn infants pursuant to section 24-4-103, C.R.S., of the "State Administrative Procedure Act":~~

(5) A physician, nurse, midwife, or other health professional attending a birth outside a hospital or institution shall MAKE EVERY PROFESSIONAL EFFORT, AS DEFINED BY THE BOARD, INCLUDING FOLLOWING UP AT SCHEDULED POSTPARTUM APPOINTMENTS, TO ENSURE THAT THE HEARING SCREENING IS PERFORMED WITHIN THIRTY DAYS OF THE BIRTH AND SHALL provide information, as established by RULE OF the department, to parents regarding places where the parents may have their infants' hearing screened and the importance of such THE screening. THE PHYSICIAN, NURSE, MIDWIFE, OR OTHER HEALTH PROFESSIONAL WHO PERFORMS THE SCREENING SHALL PROVIDE A REPORT OF ANY SCREENING TO THE PARENT OR GUARDIAN OF THE INFANT, THE PRIMARY CARE PROVIDER OF THE INFANT, AND THE DEPARTMENT. SCREENING FOR HEARING LOSS UNDER THIS SUBSECTION (5) IS NOT REQUIRED IF THE PARENT OR LEGAL GUARDIAN OBJECTS.

(7) UPON RECEIPT OF SUFFICIENT FINANCIAL RESOURCES IN THE NEWBORN HEARING SCREENING CASH FUND, AS DETERMINED BY THE DEPARTMENT, TO SUPPORT A NEW INFORMATION TECHNOLOGY SYSTEM FOR THE PURPOSE OF MANAGING THE NEWBORN HEARING SCREENING PROGRAM, THE DEPARTMENT SHALL PROCURE AN INFORMATION TECHNOLOGY SYSTEM AND PROMULGATE RULES IN ORDER TO IMPLEMENT THE SYSTEM.

(8) (a) THE STATE BOARD OF HEALTH SHALL PROMULGATE RULES THAT REQUIRE EACH OF THE FOLLOWING WITH INFORMATION PERTINENT TO THIS SECTION TO REPORT THE RESULTS OF INDIVIDUAL SCREENING TO THE DEPARTMENT:

(I) A BIRTHING FACILITY; OR

(II) ANOTHER FACILITY OR PROVIDER.

(b) THE RULES MUST INCLUDE A REQUIREMENT THAT THE BIRTHING FACILITY INCLUDE THE RESULTS OF THE HEARING SCREENING IN THE ELECTRONIC MEDICAL RECORD OF THE NEWBORN. THE INFORMATION SYSTEM REQUIRED IN SUBSECTION (7) OF THIS SECTION MUST ALLOW THE RESULTS OF OUTPATIENT RESCREENINGS TO BE REPORTED TO THE DEPARTMENT AND TO THE PARENT OR GUARDIAN OF THE NEWBORN.

(9) (a) THE STATE BOARD OF HEALTH SHALL PROMULGATE RULES TO ESTABLISH AND MAINTAIN APPROPRIATE FOLLOW-UP SERVICES FOR NEWBORNS AT RISK OF HEARING LOSS. THE FOLLOW-UP SERVICES MUST INCLUDE IDENTIFICATION OF NEWBORNS AT RISK FOR HEARING LOSS, COORDINATION AMONG MEDICAL AND AUDIOLOGY PROVIDERS AND FAMILIES, CONNECTING NEWBORNS TO TIMELY INTERVENTION, APPROPRIATE REFERRALS TO SPECIALISTS FOR FOLLOW-UP AND DIAGNOSTIC TESTING, AND ADDITIONAL DUTIES AS DETERMINED BY THE DEPARTMENT.

(b) THE FOLLOW-UP SERVICES MUST PROVIDE THE PARENTS WITH INFORMATION AND RESOURCES SO THAT THE PARENTS CAN, IN A TIMELY MANNER, LOCATE APPROPRIATE DIAGNOSTIC AND TREATMENT SERVICES FOR THE NEWBORN.

(c) THE DEPARTMENT SHALL ALSO PROVIDE APPROPRIATE TRAINING, ON A PERIODIC BASIS, TO BIRTHING FACILITIES AND MIDWIVES ON THE DEPARTMENT'S SCREENING PROGRAM.

(d) THE INFORMATION GATHERED BY THE DEPARTMENT, OTHER THAN STATISTICAL INFORMATION AND INFORMATION THAT THE PARENT OR GUARDIAN OF A NEWBORN ALLOWS TO BE RELEASED THROUGH THE PARENT'S OR GUARDIAN'S INFORMED CONSENT, IS CONFIDENTIAL. PUBLIC ACCESS TO NEWBORN PATIENT DATA IS LIMITED TO DATA COMPILED WITHOUT THE NEWBORN'S NAME. AUDIOLOGISTS AND OTHER HEALTH PROFESSIONALS PROVIDING DIAGNOSTIC SERVICES TO NEWBORNS AND THEIR FAMILIES MAY ACCESS THE INFORMATION, ON A NEWBORN-SPECIFIC BASIS, FOR THE PURPOSE OF ENTERING FOLLOW-UP INFORMATION. THE INFORMATION GATHERED IN ACCORDANCE WITH THIS SUBSECTION (9)(d) DOES NOT RESTRICT THE DEPARTMENT FROM PERFORMING FOLLOW-UP SERVICES WITH

NEWBORNS, THEIR PARENTS OR GUARDIANS, AND HEALTH CARE PROVIDERS.

(10)(a) THE DEPARTMENT SHALL DEVELOP AND PUBLISH MATERIALS ON ITS WEBSITE FOR USE IN EDUCATING AND TRAINING ON CYTOMEGALOVIRUS, REFERRED TO AS "CMV", THAT INCLUDE THE FOLLOWING:

(I) THE ESTIMATED INCIDENCE OF CMV;

(II) THE TRANSMISSION OF CMV TO PREGNANT WOMEN OR WOMEN WHO MAY BECOME PREGNANT;

(III) BIRTH DEFECTS CAUSED BY CONGENITAL CMV;

(IV) METHODS OF DIAGNOSING CONGENITAL CMV;

(V) AVAILABLE PREVENTIVE MEASURES TO AVOID THE INFECTION IN WOMEN WHO ARE PREGNANT OR MAY BECOME PREGNANT;

(VI) RESOURCES AND EVIDENCE-BASED TREATMENT AS THEY BECOME AVAILABLE FOR FAMILIES OF CHILDREN BORN WITH CMV; AND

(VII) ANY FEDERAL OR STATE REQUIREMENTS REGARDING TESTING FOR CMV.

(b) SUBJECT TO AVAILABLE APPROPRIATIONS, THE DEPARTMENT SHALL PROVIDE TECHNICAL ASSISTANCE AND TRAINING REGARDING CMV TO HEALTH CARE FACILITIES AND HEALTH CARE PROVIDERS UPON REQUEST.

(11) THE EXECUTIVE DIRECTOR OF THE DEPARTMENT MAY ASSESS A FEE THAT IS SUFFICIENT TO COVER THE ONGOING DIRECT AND INDIRECT COSTS OF ALL INITIAL NEWBORN HEARING SCREENING AND FOLLOW-UP SERVICES AND TO ACCOMPLISH THE OTHER PURPOSES OF THIS SECTION, WHICH FEE SHALL BE DEPOSITED INTO THE NEWBORN HEARING SCREENING CASH FUND CREATED IN SECTION 25-4-1006 (3). BIRTHING FACILITIES MAY ASSESS A REASONABLE FEE TO BE CHARGED THE PARENT OR GUARDIAN OF THE NEWBORN TO COVER THE COSTS OF PROVIDING SERVICES NECESSARY TO IMPLEMENT THE PURPOSES OF THIS SECTION.

SECTION 7. In Colorado Revised Statutes, amend 25-4-1005 as

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Center for Health and Environmental Data

3
4 6 CCR 1009-6, Newborn Hearing Screening

5
6 Adopted by the Board of Health _____; effective _____.

7
8 SECTION 1: AUTHORITY AND DEFINITIONS

9
10 1.1 These rules and regulations are established under the authority § 25-4-1004.7, C.R.S.

11
12 1.2 Definitions

13
14 The following terms, whenever used in or referred to in these regulations, shall have the following
15 respective meanings, unless a different meaning clearly appears from the context:

16
17 “Attending a birth” means delivery of a newborn and postpartum medical services provided to the
18 newborn until the date of discharge, or for births occurring outside a birthing facility, until the health
19 professional’s services have concluded.

20
21 “Audiological intervention” means any management of hearing loss performed by an audiologist,
22 including but not limited to fitting for any amplification device designed to compensate for hearing loss,
23 such as hearing aids or cochlear implants, as well as auditory training to aid in recognition of speech
24 sounds once an amplification device is in place.

25
26 “Audiologist” means a person licensed pursuant to Article 29.9 of Title 12, of the Colorado
27 Revised Statutes, who has specialized training in hearing testing and intervention for newborns. These
28 professionals may perform initial hearing screens or rescreens on newborns, but their role is primarily
29 focused on audiological evaluation, diagnosis and audiological intervention for newborns with
30 suspected or confirmed hearing loss. Audiologists may establish standards of care and provide
31 consultation and supervision for hearing screening programs in birthing facilities.

32
33 “Auditory Brainstem Response” means a hearing test in which electrodes are placed strategically on
34 the baby’s head and record brain wave activity in response to sounds heard through an earphone.

35
36 “Birthing Facility” means a general hospital or birthing center licensed or certified pursuant to §25-1.5-
37 103, C.R.S.

38
39 “Department” means the Colorado Department of Public Health and Environment.

40
41 “Early Intervention” for purposes of this rule, means the services, education and support to children
42 who are deemed to have a hearing loss, or who are evaluated and deemed to have a diagnosed
43 physical or mental condition with a high probability of resulting in a developmental delay.

44
45 “Failed Screen” means any result from a completed hearing screening test or a rescreening test that is
46 not “pass.”

47
48 “Follow-up services” for purposes of the newborn hearing screening program means, 1) identification
49 of newborns at risk for hearing loss through the screening process; 2) coordination among medical and
50 audiology providers, and families (the newborn’s parent(s) or legal guardian(s)); 3) providing
51 information and timely referral for audiological evaluation; 4) providing information and timely referral
52 for early intervention services; 5) confirming the connection to early intervention services; and; 6)

53 monitoring screening for a missed screen, rescreening, and audiological evaluation and early
54 intervention connection. Follow-up services facilitate rapid connection of newborns to early
55 intervention, but are not intended to serve as clinical case management services. Follow-up services
56 does not include the delivery of early intervention services except as described in Section 4.

57
58 “Health professional” means a physician, nurse, midwife, or other health professional attending the
59 birth. The definition of health professional also includes other health professionals providing medical
60 services to the newborn prior to discharge, including professionals that perform newborn hearing
61 screening, serve as newborn hearing hospital coordinators, connect infants to hearing evaluation and
62 early intervention resources, perform or report the date of the first CO-Hear’s Home Visit, and develop
63 or report the date of initial Individualized Family Services Plan.

64
65 “Hearing rescreen” means a hearing screening performed on a newborn who received a failed screen
66 result for an initial hearing screen.

67
68 “Initial hearing screen” means an otoacoustic emissions or auditory brainstem response screen
69 performed on a newborn who has not previously received a screen.

70
71 “Missed Screen” means that the newborn missed receiving their initial hearing screen, and an initial
72 hearing screen is pending.

73
74 “Named Submitter” means the entity or individual who submits initial hearing screen or hearing
75 rescreen reports to the Department electronically. This can include, but is not limited to hospitals,
76 birthing facilities, audiologists, health professionals or providers trained to perform a newborn hearing
77 screening.

78
79 “Newborn” means an infant between 0 and 1 year of life.

80
81 “Otoacoustic Emissions” means a hearing test in which a small earphone emits sounds into the ear
82 and measures the sounds that are produced by the vibration of hair cells in the inner ear in response
83 to that sound.

84
85 “Passed Screen” means that the newborn passed a hearing screening and no further testing is
86 currently required for purposes of the newborn hearing screening program.

87
88 SECTION 2: REQUIREMENTS FOR HEALTH PROFESSIONALS ATTENDING A BIRTH IN A SETTING
89 OTHER THAN A BIRTHING FACILITY

90
91 2.1 A. For health professionals attending a birth in a setting other than a birthing facility who perform
92 the initial hearing screen and hearing rescreen “professional effort” means:

- 93
94 1. Providing the parent or guardian with information about the importance of performing
95 a newborn hearing screening in a timely manner within 30 days of the newborn’s birth.
96 The information provided must explain that appropriate testing and identification of
97 newborn at risk for hearing loss facilitates early intervention and supports the linguistic
98 and cognitive development of children, including the value of a hearing screen later in
99 life if there is a concern with a newborn’s hearing, speech or language development.
100 The information provided must also explain how often a failed screen occurs and next
101 steps for a parent or guardian when rescreening and follow-up services are
102 necessary. The health professional may distribute information that has been
103 developed by the Department to comply with this requirement;
104
105 2. Performing the initial hearing screen in a manner that comports with the health

- 106 professional's scope of practice or newborn hearing screening training to ensure
107 accurate test results. The initial hearing screen will occur no sooner than 12 hours
108 after birth and prior to the health professional terminating care of the newborn. If the
109 newborn is unavailable for screening due to serious health problems that prevent
110 hearing screening, hearing screening will be performed prior to discharge from
111 services;
- 112
- 113 3. Performing a hearing rescreen for a "failed screen" result on the initial hearing
114 screening. The hearing rescreen will be performed in a manner that comports with the
115 health professional's scope of practice or newborn hearing screening training to
116 ensure accurate test results. The hearing rescreen will occur within 30 days of birth;
117
- 118 4. Reporting the initial hearing screen and if applicable, the hearing rescreen result to the
119 newborn's parent or guardian at the time of the screening;
120
- 121 5. Reporting the initial hearing screen and, if applicable, the hearing rescreen result to
122 the newborn's primary care provider within 30 days of birth, and;
123
- 124 6. Reporting any missed screen or hearing rescreen failed screen result to the
125 Department pursuant to Section 3 of this rule;
126
- 127 7. Referring the parent or legal guardian for further diagnostic testing as appropriate
128 based on screen results and risk factors for hearing loss.
129
- 130 B. For health professionals attending a birth in a setting other than a birthing facility who do not
131 perform the initial hearing screen or hearing rescreen, the health professional does not
132 constitute a named submitter and "professional effort" shall mean:
133
- 134 1. Providing the parent or guardian with information about the importance of performing
135 a newborn hearing screening within 30 days of the newborn's birth. The information
136 provided must explain that appropriate testing and identification of newborns at risk for
137 hearing loss facilitates early intervention and supports the appropriate language and
138 cognitive development of children, including the value of hearing screen later in life if
139 there is a concern with a child's hearing, speech or language development. The
140 information provided must also explain how often a failed screen occurs and next
141 steps for a parent or guardian when rescreening and follow-up services are necessary.
142 The health professional may distribute information that has been developed by the
143 Department to comply with this requirement;
144
- 145 2. Providing the newborn's parent or legal guardian with a list of providers that can
146 perform the initial hearing screen and hearing rescreen. The list will include providers
147 that have newborn hearing screening within their scope of practice or providers known
148 to the health professional to have received training to perform newborn hearing
149 screening. To the extent practicable, the list will identify providers that are within a
150 reasonable travel distance of the newborn's parent or legal guardian;
151
- 152 3. Asking the newborn's parent or guardian at a postpartum appointment whether the
153 newborn received an initial hearing screen, and if the parent or legal guardian
154 indicates the initial screening has not occurred, discussing the importance of
155 screening at the postpartum appointment and notifying the newborn's primary care
156 provider, within 14 to 30 days after the postpartum appointment, that screening needs
157 to be scheduled.
158

159 C. Nothing in this definition or the rule should be construed to require that screening services be
160 performed if the parent or legal guardian objects, as the statute directs that screening for
161 hearing loss is not required if the parent or legal guardian objects. If a parent or legal
162 guardian objects, the health professional should document this in newborn's medical record.
163

164 SECTION 3. REPORTING INITIAL HEARING SCREENING AND HEARING RESCREEN RESULTS TO
165 THE DEPARTMENT
166

167 3.1 Results that are included in the approved data system(s) include:
168

169 A. Initial hearing screen reported in the Electronic Birth Certificate: Passed screen results. These
170 results are available to the newborn hearing screening program when the Department
171 determines the pass result needs to be confirmed or reviewed;
172

173 B. Initial hearing screen: Failed screen results;
174

175 C. Initial hearing screen: Missed screen results;
176

177 D. Initial hearing screen reported to the health information data system rather than the Electronic
178 Birth Certificate as described in section 3.2.A.1.b. This entry resolves a missed screen result.
179

180 E. Hearing rescreen: Failed screen results, and
181

182 F. Hearing rescreen: Passed screen results.
183

184 3.2 The result will be reported electronically to the approved data system(s).
185

186 A. 1. a. Named submitters attending a birth in a birthing facility will submit all initial
187 hearing screening results electronically through the Electronic Birth Certificate.
188 Initial hearing screening results submitted through the Electronic Birth
189 Certificate will include passed, missed, and failed screen results.
190

191 b. The initial screening result will be submitted to the Department prior to the
192 newborn's discharge from the birthing facility, unless extenuating
193 circumstances are present.
194

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

201
202 2. a. All other named submitters who perform the initial newborn screening will
203 submit initial hearing results electronically through the Electronic Birth
204 Certificate or through the Department approved health information data
205 system.
206

207 b. Reports will be submitted in a timely manner, no later than 30 days after the
208 newborn's birth, unless extenuating circumstances are present.
209

210 When there are extenuating circumstances, the initial screening result will be

211 submitted by the health professional at such a time as is deemed safe and
212 practicable for the infant to receive the screening.

- 213
214 B. Named submitters may enter newborn information and newborn hearing results for newborns
215 that moved to Colorado after their birth to support the provision of follow-up services. This
216 information is submitted to the health information data system. It is not part of the Electronic
217 Birth Certificate.
218
219 C. Named submitters who perform hearing rescreening will provide hearing rescreen results
220 electronically through the Department approved data system. Results will be submitted in a
221 timely manner. Unless there are unusual extenuating circumstances, rescreening results will
222 be provided within 30 days of the newborn's birth. When there are extenuating circumstances,
223 the rescreen result will be submitted by the health professional at such a time as is deemed
224 safe and practicable for the infant to receive the screening.
225

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

- 227
228 4.1 A. Screening to resolve a missed screen, rescreening, audiological evaluation and similar
229 diagnostic testing services are not provided by the Department's newborn hearing screening
230 program. These services are provided through other government agencies, community
231 partners and private entities. Any costs incurred for these services is the responsibility of the
232 parent or service provider.
233
234 The Department's newborn hearing screening program only monitors the result of these
235 services for the limited purpose of rapidly connecting newborns and their families to early
236 intervention services, and for the purposes of program evaluation and quality improvement.
237
238 B. A parent or legal guardian, and their newborn's participation in the follow-up services is
239 voluntary.
240
241 4.2 A. The Department monitors reporting pursuant to Section 3. For screen missed and screen fail
242 results, the Department will send the parent or legal guardian information about the
243 importance of screening and screening services. This information is sent when or soon after
244 the 30 day reporting requirements have passed.
245
246 B. For newborns that are screened to address a missed screen:
247
248 1. A health professional resolves a missed screen by performing a hearing screen and
249 reporting the result as required by Section 3 of these rules.
250
251 2. a. If the result is screen pass, no further action is required but health
252 professionals are encouraged to provide information about value of hearing
253 screen later in life if there is a concern with a child's hearing, speech or
254 language development.
255
256 b. If the result is screen fail, a hearing rescreen or more comprehensive hearing
257 evaluation as deemed necessary by the health provider, is required.
258
259 The health professional who performed the hearing screen will provide the
260 parent or legal guardian with the screening result, information about the
261 importance of newborn hearing screening and will perform the rescreen or
262 provide information about which providers can perform hearing rescreening.

- 263 To extent practicable, the list will identify providers that are within a
264 reasonable travel distance of the newborn's parent or legal guardian.
265
- 266 C. For newborns that are rescreened to confirm the initial screening result:
267
- 268 1. A health professional performs the hearing rescreen and reporting the result as
269 required by Section 3 of these rules.
270
- 271 2. a. If the rescreen result is screen pass, no further action is needed.
272
- 273 b. If the rescreen result is screen fail, the health professional that performed the
274 hearing rescreen will refer the newborn for a comprehensive audiological
275 evaluation. To the extent practicable, the list will identify providers that are
276 within a reasonable travel distance of the newborn's parent or legal guardian.
277
- 278 D. An audiologist will provide a comprehensive hearing evaluation or diagnostic service within the
279 first three months of life or, for newborns that experience delays in screening or follow-up services, as
280 soon the need for audiological services becomes known to the audiologist. After the evaluation is
281 completed, the audiologist should communicate the results of the evaluation and any
282 recommendations to the parent or legal guardian, and other health professionals as
283 authorized by the parent or legal guardian, and the Department, and; refer the newborn to
284 early intervention services. When the audiologist confirms that the newborn has a permanent
285 hearing loss, the referral for early intervention services will occur within 48 hours. To the extent
286 practicable, the referral will identify early intervention service providers that are within a
287 reasonable travel distance of the newborn's parent or legal guardian.
288
- 289 E. Early intervention service providers will submit the date of the newborn's first CO-Hear Home
290 Visit and the date of the initial Individualized Family Service Plan.
291
- 292 4.3 In addition to coordination through the referral process, coordination among medical and audiology
293 providers, and families (the newborn's parent(s) or legal guardian(s) occurs when:
294
- 295 A. A health professional attending a birth in a setting other than a hospital facility provides the
296 screen result to the newborn's primary care provider, and;
297
- 298 B. Individuals granted access to the health information data system enter or review screening
299 results, rescreening results and audiological evaluation results as authorized in Section 5.
300
- 301 4.4 The Department shall monitor:
302
- 303 A. 1. The number of newborns with screen pass results reported in the Electronic Birth
304 Certificate.
305
- 306 2. To the extent it can be assessed, the number of pass results that were entered
307 incorrectly and subsequently corrected, and the number of days it took for the initial
308 screen result correction to be entered. This analysis only concerns the accuracy of
309 initial screen results data entry.
310
- 311 B. The number of newborns with missed screen results, failed initial screen results, hearing
312 rescreen fail results and hearing rescreen pass results;
313
- 314 C. The number of newborns that receive any follow-up services;

- 315
316 D. The number of newborns who are eligible but opt to not participate in follow-up services;
317
318 E. The length of time between the last failed screening and the first audiological evaluation;
319
320 F. The number of newborns that receive an early intervention described in Section 4.2(E), and;
321
322 G. The length of time between the audiological evaluation and the early intervention described in
323 Sections 4.2(D) and 4.2(E).
324
325 H. Such other monitoring the Department deems appropriate to monitor the effectiveness of
326 newborn hearing screening program and support the statutory duties of the Colorado Infant
327 Hearing Advisory Committee (CIHAC) as defined in § 25-4-1004.7(2)(a)(I), C.R.S.
328

- 329 4.5 The Department may provide educational material or materials developed by the CIHAC pursuant to
330 § 25-4-1004.7(2)(a)(I), C.R.S., on the Department website to assist parents, legal guardians, and
331 newborn hearing screening providers, coordinators and partners.
332

333 The Department may assist a health professional, parent or guardian seeking a referral for screening,
334 audiological evaluation or early intervention; however, the Department cannot endorse any service
335 provider. The Department may provide a health professional, parent or legal guardian with the contact
336 information for the applicable licensing board when the individual seeks to file a complaint.
337

338 SECTION 5: HEALTH INFORMATION DATA SYSTEM STANDARDS

- 339
340 5.1 A. Only reports of initial hearing screens, hearing rescreens, and follow up services for newborns
341 at risk of hearing loss as described in Section 3.1 and 4.1 of these rules will be maintained in
342 the Department's health information data system.
343
344 B. The Department will limit the reported data to the minimum information necessary for a health
345 professional attending the birth or providing follow-up services for newborns at risk of hearing
346 loss to execute their obligations under the statute and this rule. A health professional will only
347 be able to input and view records for patients from their own facility.
348
349 C. The Department approves all access to its health information data system. To receive access,
350 the health professional attending the birth or providing follow-up services for newborns at risk
351 of hearing loss will sign the Department's confidentiality agreement. A health professional
352 attending the birth or providing follow-up services for newborns at risk of hearing loss may
353 access the Department health information data system to input or retrieve their patient care
354 data. A primary care provider of a newborn receiving follow-up services may access the
355 system for the purpose of coordinating care regardless of whether the primary care provider is
356 performing follow up services. The Department will log and monitor health information data
357 system use. The only authorized use of the data is to connect newborns at risk for hearing
358 loss to appropriate follow-up services, pursuant to § 25-4-1004.7(5) and § 25-4-1004.7(8),
359 C.R.S., and these rules.
360
361 The Department may revoke access to the health information data system at any time,
362 including when the patient is no longer under the health professional's care, follow-up services
363 have concluded, the individual has violated the terms of the signed confidentiality agreement,
364 or the data are being used for a purpose that is outside the statutory and regulatory
365 authorization.
366
367 D. Entities, including but not limited to the Department and the Colorado School for the Deaf and

- 368 the Blind, Article 80, Title 22, C.R.S., CO-Hears Program may access and input data into the
369 health information data system to coordinate care, provide referrals and similar follow-up
370 services.
371
- 372 E. Entities and individuals granted access have the ability to run facility-level reports for the
373 purpose of improving the facility or individual's newborn hearing screening practices and
374 service delivery.
375
- 376 F. The Department may access the health information data system to identify an appropriate
377 follow-up services provider for a child with a failed screen result when:
378
- 379 1. Requested by the parent, named submitter, newborn's primary care provider or follow-
380 up service provider and the relationship with the newborn has been confirmed.
381
 - 382 2. The Department communicates to the requestor that identifying a potential provider is
383 not an endorsement for the provider or their services.
384
- 385 5.2 Except as authorized in Section 5.1, newborn hearing screening program data, whether recorded on
386 paper or electronically, shall be strictly confidential and shall not be released. § 25-4-1004.7(9)(d),
387 C.R.S., allows the Department to provide statistical reports with aggregate data; such reports will not
388 include the name or any other patient specific data that could reasonably lead to identification of the
389 patient. To ensure accurate assessment of prevalence, statistical reports will be comprised of data for
390 newborns born in Colorado.
391
- 392 A. The Department will provide statistical reports to the CIHAC to support the CIHAC's execution
393 of its statutorily assigned duties in § 25-4-1004.7(2)(a)(I), C.R.S.
394
 - 395 B. The Department will submit de-identified, aggregate data to entities such as Centers for
396 Disease Control and Prevention for comparison to national standards and outcomes. When
397 appropriate, de-identified, aggregate data may also be used for the purpose of improving
398 newborn hearing screening, evaluation, and connection to follow-up services.
399
 - 400 C. The statistical reports and de-identified, aggregate data identified in Section 5.2.A and 5.2.B
401 can be made available to named submitters, entities with access to the health information data
402 system and other interested persons for the purpose of comparing an entity or individual's
403 services to state outcomes and national standards, or improving practice.
404
- 405 5.3 Quality Control
406
- 407 The Department will ensure quality newborn hearing screening data by:
408
- 409 A. Training individuals granted access to the system to report screening results pursuant to
410 Section 3 and follow-up services pursuant to Section 4. Training will be provided annually and
411 more often as determined by the Department to be appropriate. Such training may be offered
412 in conjunction with the periodic training required by § 25-4-1004.7(9)(c), C.R.S.
413
 - 414 B. Training individuals entering hearing screening data in the electronic birth certificate.
415 Such training can be offered in conjunction with other Department training related to
416 completing the electronic birth certificate.
417
 - 418 C. Utilizing the data identified in Rule 4.4(H) to implement quality improvement activities.
419
- 420 Nothing in this subsection should be read to limit the CIHAC's ability to recommend best

421 practices and guidelines as delineated in § 25-4-1004.7(2)(a)(I), C.R.S. as those activities may
422 also concern quality improvement.