Pursuant to the authority vested in the Commissioner of Health by Section 2500-g of the Public Health Law, Subpart 69-8 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivisions (g) and (h) of Section 69-8.1 are amended, and new subdivisions (i) through (q) are added, to read as follows:

(g) *Two-tier infant hearing screening* is defined as the use of otoacoustic emissions (OAE) screening or auditory brainstem response (ABR) screening followed by auditory brainstem response (ABR) screening if the patient does not pass the initial OAE or ABR screening.

(h) *Parent* means a parent by birth or adoption, legal guardian, or any other person legally authorized to consent to medical services for the infant.

[(h)] (i) *Article 28 Facility* or *Facility* shall mean a health care facility established under Article 28 of the Public Health Law.

(j) *Early Intervention Program* means the New York State Early Intervention Program for infants and toddlers with disabilities and their families, established under Title II-A of Article 25 of Public Health Law, including state-approved Program offices at the county level.

(k) *Referral to the municipal Early Intervention Program* means referral to the designated early intervention official in the municipality where the child resides, as is required of primary referral sources. Such referral shall occur within two working days of identifying an infant or toddler who is less than three years of age and suspected of having a disability or is at risk of having a disability.

(l) *Early intervention official* means the official designated by the municipality as responsible for the administration of referrals of children suspected of having or are at risk for developmental delays or disabilities.

(m) *Early Intervention Program evaluator* means an individual approved by the Early Intervention Program to evaluate children from birth to three years old with standardized assessments and criterion-referenced assessments to determine eligibility for early intervention services.

(n) *Primary referral sources* are defined as all individuals who are Early Intervention Program qualified personnel; all approved evaluators, service coordinators, and providers of early intervention services; Article 28 facility hospitals and clinics; child health care providers; day care programs; local health units; local school districts; local social service districts including public agencies and staff in the child welfare system; public health facilities; early childhood direction centers; domestic violence shelters and agencies; homeless family shelters; and, operators of any clinic approved pursuant to Article 16 of the Mental Hygiene Law, or Article 31 of the Mental Hygiene Law.

(o) An *"at risk" referral to the Early Intervention Program* means referral of an infant who has failed newborn hearing screening prior to discharge from neonatal care with no documented follow-up results reported by the birth facility at 60 days post-discharge. Upon such referral, the county Early Intervention Program shall facilitate newborn hearing screening follow-up.

(p) A *"suspected of hearing loss" referral to the Early Intervention Program* means referral of an infant who has failed a two-tier inpatient hearing screening and any follow-up out-patient re-screening. Upon such referral, the Early Intervention Program evaluator may first provide a

confirmatory audiological evaluation to determine whether a hearing loss exists, pursuant to section 69-4.8 of this Part.

(q) A *prescription* shall mean a written order issued by the facility for an infant to obtain a follow-up screening or diagnostic audiological evaluation, as appropriate, from an article 28 licensed facility or a provider authorized to perform audiological evaluations under title eight of the education law.

Subdivisions (b) and (c) of Section 69-8.2 are amended to read as follows:

(b) General requirements of an infant hearing screening program are:

(1) T[t]he conduct of a two-tier inpatient infant hearing screening prior to discharge from [the facility;] neonatal care for infants in the normal newborn nursery. Two-tier infant hearing screening consists of initial screening with OAE or ABR on both ears. Each ear must pass the OAE or ABR screening to be considered a “pass.” If the OAE or ABR screening is not passed in one or both ears, an ABR screening is performed on both ears. If the infant passes the ABR screening, the infant has "passed" the hearing screening. If one or both ears do not pass the ABR screening, the infant shall be referred for outpatient re-screening and/or diagnostic audiological evaluation.

(2) The conduct of newborn hearing screening using ABR for infants who have received care in a neonatal intensive care unit (“NICU”), for the initial and any secondary screening. Infants cared for in the NICU who do not pass the inpatient ABR screening shall be referred to a provider licensed under State Education Law and authorized to provide infant hearing screening

and diagnostic audiological evaluations for rescreening, and, if indicated, given a comprehensive audiological evaluation including diagnostic ABR.

[(2)] (3) C[c]ommunication of results of infant hearing screenings to parents by designated personnel, including provision of written materials supplied by the department[;].

[(3)] (4) T[t]he conduct of follow-up infant hearing screening or provision of referrals to obtain follow-up screening on an outpatient basis for those infants who fail or do not receive infant hearing screening prior to discharge from the facility. On an annual basis, facilities shall notify the department whether the facility will conduct follow-up infant hearing screening or provide referrals for infants to obtain such screening from another facility or provider licensed under State Education Law and authorized to provide infant hearing screening[;].

[(4)] (5) R[r]eferral of infants who are suspected of having a hearing loss as defined in this part to the Early Intervention Program for appropriate evaluation and early intervention services pursuant to section 69-4.3 of this title including, but not limited to:

* * *

[(5)] (6) T[t]he reporting of aggregate data on infant hearing screenings to the department upon department request, in a format and frequency prescribed by the commissioner[; and].

[(6)] (7) T[t]he establishment of facility quality assurance protocols as necessary pursuant to section 405.6 of this Title to determine and evaluate the effectiveness of the program in ensuring all infants are screened for hearing loss.

(8) Individual infant data must be reported or updated through the Early Hearing Detection and Intervention – Information System (EHDI-IS) or any successor system whenever new screening results are obtained.

(c) Facilities with 400 or fewer births annually, based on a three-year rolling average, may provide referrals for infants to receive hearing screening from an article 28 facility or a provider licensed under State Education Law and authorized under such law to perform infant hearing screening, or medical assistants trained and deemed capable by an infant hearing screening program manager, as defined in section 69-8.3 of this Subpart, to perform basic hearing tests which do not require exercise of clinical decision-making.

(1) Such referrals shall include a prescription issued by the facility for infants to receive hearing screening, including a request for results of the screening to be returned to that facility [,for infants to receive hearing screening from an article 28 facility or a provider licensed under State Education Law and authorized under such law to provide infant hearing screening].

* * *

Subdivision (b) of Section 69-8.3 is amended to add a new paragraph (6) to read as follows:

(b) The program manager shall be responsible for ensuring:

* * *

(6) Establishment of policies and procedures for the audiological screening of newborns, including training of all personnel, conduct of the screening, referral, follow-up and documentation procedures.

Section 69-8.4 is amended to read as follows:

(a) All infants born in the facility shall receive an initial hearing screening prior to discharge from the facility, pursuant to section 69-8.2(b) of this Subpart, except as provided in section 69-8.2(c) of this Subp[P]art.

* * *

(e) In the event that an infant is not screened for hearing loss prior to discharge from [the facility] inpatient neonatal care, the program manager shall ensure that:

* * *

(f) If the infant fails the two-tier inpatient hearing screening, [a repeat screening shall be conducted whenever possible prior to the infant's discharge from the facility to minimize the likelihood of false positive results and need for a follow-up outpatient screening] an outpatient follow-up screening and/or diagnostic audiological evaluation shall be performed to confirm the results of the inpatient screenings.

[(g) If the infant fails the inpatient screening and any repeat screening, if performed, an outpatient follow-up screening shall be performed to confirm the results of the inpatient screens.

(h)] (g) If the facility has elected to conduct follow-up hearing screening either directly or through a contractual agreement, the following procedures shall be followed:

* * *

(7) If the facility or provider under contract with the facility cannot reach the family or for any other reason cannot schedule and complete a follow-up screening within [seventy-five] sixty days from discharge, the infant shall be referred to the early intervention official in his or her county of residence as an at-risk child in accordance with section 69-4.3 of this title, unless the

parent objected to the referral at the time of the inpatient hearing screening[;]. The parent's objection to a follow-up screening must be entered into EHDI-IS or any successor system;

* * *

[(i)] (h) If the facility elects to refer infants who fail the inpatient hearing screening to other facilities or providers licensed under the State Education Law and authorized by such law to perform infant hearing screening on an outpatient basis, the following procedures shall be used:

* * *

(4) The parent shall be informed that if results of a follow-up outpatient screening are not returned to the facility within sixty days, the infant will be referred as an at-risk child to the early intervention official in their county of residence for follow-up purposes unless the parent(s) object to such a referral, in accordance with section 69-4.3 of this Part.

* * *

(7) If results of a follow-up outpatient screening are not returned to the facility within [seventy-five] sixty days, the infant shall be referred as an at-risk child to the early intervention official in his/her county of residence for follow-up purposes, in accordance with section 69-4.3 of this part, unless the parent has objected to such a referral. The parent's objection to a follow-up screening must be entered into EHDI-IS or any successor system.

Subdivision (d) of Section 69-8.5 is amended, and a new Subdivision (e) is added to read as follows:

* * *

(d) The program manager shall report all infant hearing screening results in the EHDI-IS, or any successor system, as directed by the department.

[(d)] (e) The department may seek corrective action as necessary to ensure infants are screened for hearing loss under the referral process provided for in this section.

Section 69-8.6 is amended to read as follows:

(a) In the event that an infant is transferred from one facility to another such facility, the facility discharging the infant to home shall be responsible for ensuring that infant hearing screening services are provided to the infant and reported to the department in a manner consistent with the applicable provisions set forth in this [Part] Subpart. If the infant fails [both an initial] the inpatient infant hearing screening and any follow-up outpatient infant hearing screening, the infant shall be referred for an evaluation to the early intervention official in his or her county of residence, according to the procedures set forth in Section 69-4.3 of this Part unless the parent objects. The parent's objection to a follow-up screening must be entered into EHDI-IS or any successor system.

(b) Medically unstable infants shall receive infant hearing screening prior to discharge to home and as early as development or medical stability will permit such screening. In instances where the medical condition of the infant contraindicates infant hearing screening, a decision to forgo such screening may be made and documented in the medical record and reported to the department in a manner consistent with the applicable provisions set forth in this Subpart.

A new Section 69-8.7 is added to read as follows:

Section 69-8.7 Responsibilities of Persons Performing Infant Hearing Screening.

(a) Anyone who performs an infant hearing screening and/or diagnostic audiological evaluation upon a child under six months of age shall report the results of such screening or evaluation to the department through the Early Hearing Detection and Intervention – Information System (EHDI-IS) or any successor system as directed by the department.

(b) Infant hearing screening reporting must include:

(1) the results of each newborn infant hearing screening performed and

(2) such other information or data as may be required by the department to fulfill the purposes of this section.

Regulatory Impact Statement

Statutory Authority:

Section 2500-g of the Public Health Law (PHL) provides authority for the Department of Health (Department) to oversee and regulate Statewide newborn hearing screening and follow-up.

Legislative Objectives:

The proposed regulations satisfy the objective of PHL section 2500-g to establish a Statewide program for screening newborns for hearing problems and detecting hearing problems as early as possible in an infant's life. Particularly, this statute directs the Commissioner to incorporate medical guidelines and protocols that reflect the most cost-effective methods for early detection of newborn hearing problems. Consistent with this objective, the regulations will align with National Joint Committee on Infant Hearing (JCIH) evidence-based practices for newborn hearing screening to ensure early detection and referral for infants identified as having hearing difficulties, while also reducing the number of infants requiring follow-up hearing screening following discharge from neonatal care, which can result in cost savings.

Needs and Benefits:

The proposed rule is necessary to establish procedures for a two-tier inpatient newborn hearing screening protocol for infants in the well-born nursery, which will align with National Joint Committee on Infant Hearing (JCIH) evidence-based practices and reduce the number of infants requiring follow-up hearing screening following discharge from neonatal care. Implementation of two-tier inpatient newborn hearing screening benefits families with newborns by decreasing the number of infants who do not pass their hearing screening prior to discharge (reduces the

number of infants who receive false positive results) and benefits perinatal facilities by reducing the number of infants that require tracking to report outpatient hearing screening results. This method will increase the accuracy of the newborn hearing screening program. In addition, the proposed rule changes are necessary to update the requirement to report hearing screenings to the Department, to ensure effective Statewide monitoring and clarify the responsibilities of health care professionals with respect to reporting newborn hearing screening data.

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

Some Article 28 facilities that do not have both otoacoustic emissions (OAE) and auditory brainstem response (ABR) technology available will need to acquire new equipment to comply with the updated newborn hearing screening requirements. Based on 2021 data, approximately 76 Article 28 facilities statewide have both OAE and ABR equipment for newborn hearing screening. Approximately 56 facilities have ABR only and can opt to continue utilizing this technology for their newborn hearing screening programs. A significantly smaller number of birth facilities (an estimated two facilities) will need to acquire ABR equipment, an expenditure of approximately $15,000 for either ABR alone or combination ABR/OAE screening equipment. Initial costs would be offset by revenue (global fee for inpatient stay).

Costs to the Agency, the State and Local Governments for the Implementation of and Continuing Compliance with the Rule:

The proposed rules will result in no additional costs for the Department or State and local governments.

Local Government Mandates:

The proposed rule does not impose any new duty upon any county, city, town, village, school district, fire district, or other special district, as all existing EIP requirements on localities that administer the EIP at the local level will remain unchanged by the amended regulations.

Paperwork:

The proposed rules do not impose any new paperwork requirements upon any state or local governments.

Duplication:

The proposed rules do not duplicate, overlap, or conflict with relevant rules and other legal requirements of the state and federal government.

Alternatives:

Alternatives to the proposed rules include amendments or additions to the following;

- Subdivision (g) of Section 69-8.1: Includes the addition of auditory brainstem response (ABR) screening as a Two-tier infant hearing screening option,

- Subdivision (b) of Section 69-8.2: Requires that infants cared for in the NICU who do not pass the inpatient ABR screening are referred to a licensed provider to perform a comprehensive audiological evaluation, follow up screenings/referrals are obtained prior to discharge from the facility, hearing screening data is reported to the Department upon request and in a format and frequency prescribed by the commissioner, and the establishment of facility quality assurance protocols pursuant to Section 405.6.

Not adopting these rules is not a viable option, as amendment is necessary to align Department regulations with the Joint Committee on Infant Hearing recommendations, thereby satisfying the directive in PHL section 2500-g to regulate newborn hearing screening in a manner that incorporates consensus medical guidelines and protocols that reflect the most cost-effective methods for detecting hearing problems as early as possible in an infant's life.

The Department presented the proposed regulations to the Early Hearing Detection and Intervention (EHDI) Advisory Group meeting on June 17, 2021. The EHDI Advisory Group was supportive of the proposed changes; no specific alternative proposals were recommended by the EHDI Advisory Group.

Federal Standards:

There are no applicable federal standards.

Compliance Schedule:

The proposed rules will be effective immediately upon adoption. These proposed rules conform current regulation to existing requirements in state statutes.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

Statement in Lieu of Regulatory Flexibility Analysis

No Regulatory Flexibility Analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping, or other compliance requirements on small businesses or local governments.

Statement in Lieu of Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping, or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

Statement in Lieu of Job Impact Statement

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

Public comments were received from fourteen (14) various stakeholders including but not limited to birth facilities (5), three professional organizations, three non-facility providers of newborn hearing screening services, two companies that furnish newborn hearing screening equipment and services, and an advocate of American Sign Language. The Department provided updates on proposed regulations to stakeholders at bimonthly meetings of its Early Hearing Detection and Intervention (EHDI) Advisory Group, and shared general updates at quarterly Early Intervention Coordinating Council (EICC) meetings. Additionally, the New York State Department of Health (Department) convened a public hearing. An in-person public hearing was held at the New York State (NYS) Convention Center, Meeting Room 1, Empire State Plaza in Albany, New York on April 13, 2023 11:00 AM to 1:00 PM. One individual attended the public hearing: no members of the public presented comments on April 13, 2023.

Section 69-8.2(b)1

Subject: Type of technology and screening protocols for infant hearing screening for well-born nursery (WBN) and for neonatal intensive care unit (NICU)

COMMENT: Eight commenters recommended that a distinction be included in the regulation regarding the screening protocols and equipment used for infant hearing screening depending on whether the infant was in the well-born nursery (WBN) or received care in a neonatal intensive care unit ("NICU"). Specifically, these commenters recommended the sole use of (automated) auditory brainstem response (ABR) screening for infants who have received care in the neonatal intensive care unit (NICU) to conform with the Joint Committee on Infant Hearing 2019 recommendations.

RESPONSE: The Department incorporated the recommended modification in section 69-8.2(b)(1) of the proposed regulation.

COMMENT: Several commenters recommended limiting the two-tier screening protocol to the well-born nursery (WBN) and further recommended allowing the use of either AABR or OAE for the initial screening in the WBN.

RESPONSE: The Department modified the proposed rule to specify the use of a two-tier screening protocol for newborn hearing screening in the well-born nursery (WBN). Additionally, either AABR or OAE may be used for the initial screening; if the initial hearing screening is failed in one or both ears, the infant must receive a re-screening with AABR in both ears prior to discharge.

COMMENT: Two commenters recommended broadening the regulations to allow the use of either a two-tiered screening system or a single-tier AABR-only screening system in the well-born nursery (WBN).

RESPONSE: The two-tier hearing screening protocol for inpatient screening in the well-born nursery will assist in identifying infants suspected of hearing loss earlier and will be of benefit in efforts to identify infants with potential congenital cytomegalovirus (cCMV) as early as possible. The two-tier screening requirement – a secondary newborn hearing screening using AABR

before discharge from the birth facility for infants in the well-born nursery who fail the initial newborn hearing screening – is retained.

Subject: Follow-up protocol for infants who received NICU care and fail AABR

COMMENT: Four commenters recommended including a specific follow-up protocol, in accordance with the JCIH 2019 Position Statement (page 9), for infants cared for in the NICU who do not pass the AABR, indicating they should be referred directly to an audiologist for rescreening, and if indicated, given a comprehensive audiological evaluation including diagnostic ABR.[1]

RESPONSE: The Department incorporated this recommendation.

COMMENT: One commenter recommended adding a requirement that birth facilities be required to achieve standard quality benchmark rates via appropriate application of screening protocols.

RESPONSE: The Department will take this comment under advisement.

Subject – Expense of newborn hearing screening equipment

COMMENT: One commenter stated that some hospitals do not have the ability to do ABR testing and thus do only OAE testing, and further noted that the cost of ABR can be expensive. Another commenter expressed concerns about the potential difficulty for programs using AABR

[1] Joint Committee on Infant Hearing (2019). Year 2019 position statement: Principles and guidelines for Early Hearing Detection and Intervention Programs. *Journal of Early Hearing Detection and Intervention, 4*(2): 1-44.

only to add OAE screening and train personnel to use OAE effectively, which, they assert, could potentially increase refer rates.

RESPONSE: One goal of the current amendments to statewide newborn hearing screening regulations is to reduce loss to follow up/loss to documentation for those infants who fail inpatient newborn hearing screening. A two-tier protocol consisting of initial OAE or AABR screening followed by AABR for infants who fail the initial screening can decrease the fail rate at hospital discharge, thereby reducing the need for outpatient follow up, according to the Joint Committee on Infant Hearing (JCIH) 2019 Position Statement.

In response to public comments, the Department modified the two-tier inpatient newborn hearing screening protocol. Specifically, birth facilities will be required to implement a two-tier screening protocol for those infants in the WBN who fail initial OAE or AABR. The secondary screening, for infants who fail the initial screening, will be conducted using AABR. Further, infants who have received NICU care will be screened using AABR equipment for the initial hearing screening and for any secondary screen. Data from 2021 data show that two birth facilities have only otoacoustic emission (OAE) screening capability, while 76 have both OAE and AABR and 56 utilize AABR only.

Subject – Administrative questions

COMMENT: Two commenters requested additional information regarding the logistics of the Public Hearing on the proposed newborn hearing screening regulations, which was held on April 13, 2023, in Albany, NY.

RESPONSE: The Department provided responses to these inquiries in advance of the Public Hearing, which was included with the proposed rulemaking in the March 22, 2023 publication of the NY State Register.

Subject – Clarification of content of public hearing

COMMENT: One commenter requested clarification on whether open discussion or learning tools about the hearing screening process would be part of the public hearing.

RESPONSE: The Department clarified the process in a written response, which indicated that the public hearing would be conducted in person and include an overview of the proposed regulations (presented orally and visually) and an opportunity for community members to provide comments to the Department.

Subject – American Sign Language

COMMENT: One commenter expressed concern that the proposed regulations on newborn hearing screening do not mention American Sign Language (ASL) and expressed an interest in ensuring that EHDI Program is inclusive of ASL and the needs of the deaf and hard-of-hearing community.

RESPONSE: This comment is noted. The Department recognizes that families of young children who are deaf or hard-of-hearing can benefit from information on the continuum of communication options available to them. The Department's Early Intervention Program developed a clinical practice guideline on hearing loss titled *Hearing Loss: Assessment and Intervention for Young Children (Age 0-3 Years),* which includes American Sign Language and other communication approaches for families to consider when exploring options for their child

and family. Additional information is available at https://www.health.ny.gov/community/infants_children/early_intervention/docs/guidelines_hearing_loss_recommendations.pdf

Subject – General support/follow-up rates

COMMENT: One commenter generally agreed with most of the changes to the newborn hearing screening regulations, including advantages to a two-tier screening program. The commenter expressed concerns including the poor follow-up rates across New York State.

RESPONSE: The Department recognizes that infants are lost to follow up and/or lost to documentation after discharge from birthing facilities, resulting in poor follow-up rates. The proposed regulations are intended to improve the inpatient newborn hearing screening process, which is one step in improving statewide performance. Additionally, the updated screening protocol for inpatient screening will assist in identifying infants suspected of hearing loss earlier, which will be of benefit in efforts to identify infants with potential congenital cytomegalovirus (cCMV) as early as possible. To address loss to documentation, the proposed regulations also require those conducting outpatient follow-up hearing screening on infants under six months of age to report date to the Department's Early Hearing Detection and Intervention Information System (EHDI-IS).

Subject – General support/technical assistance questions

COMMENT: One commenter indicated appreciation for the proposed modifications to the current regulations and submitted several technical assistance questions for the Department's review.

RESPONSE: The comment is noted. The Department is reviewing the technical assistance questions and will issue responses once the proposed regulations are finalized.

Subject – Follow-up rates

COMMENT: A commenter also suggested potential ways to improve follow-up rates, including targeted technical assistance to underperforming facilities and networking in regions of the State.

RESPONSE: The Department agrees that technical assistance is an important component of the EHDI Program and provides regular technical assistance to birth facilities in response to inquiries and based on review of data.

Subject – Rescreening (multiple)

COMMENT: One commenter suggested encouraging facilities to rescreen an infant multiple times (2-3 times) prior to discharge as feasible instead of implementing a two-tier newborn hearing screening protocol.

RESPONSE: The proposed regulations strengthen inpatient protocols by requiring the use of a two-tier approach to newborn hearing screening prior to discharge for infants in the well-born nursery. Birth facilities retain the option to conduct repeat AABR screening for infants who have received NICU care. The JCIH 2019 Position Statement (page 8) recommends providing a single repeat screen prior to discharge, as close to discharge as practicable, if the infant does not pass the first hearing screen, and notes that the second screen, if required, should not be performed immediately following the first screen, but should occur at least several hours later.[2] The

[2] I Joint Committee on Infant Hearing (2019). Year 2019 position statement: Principles and guidelines for Early Hearing Detection and Intervention Programs. *Journal of Early Hearing Detection and Intervention, 4*(2): 1-44.

proposed amendments are intended to ensure a consistent, reliable approach in the EHDI Program across the State and facilitate early identification of infants suspected of hearing loss.

Subject – Birth facility reporting responsibilities

COMMENT: One commenter notes some birthing facilities have requested not to receive hearing screening outpatient results.

RESPONSE: Birth facilities are required to report data on infant hearing screenings to the Department. Outpatient providers should be notifying the birth facility of outcomes on hearing rescreening conducted post-discharge to assist the facility with Early Hearing Detection and Intervention (EHDI) Program management, including reporting requirements and quality improvement efforts.

Subject – Bilateral rescreening

COMMENT: A commenter asserted that if OAE screening is not passed in only one ear, only that ear must be rescreened to save time and money.

RESPONSE: If a baby fails a screening in one ear, the rescreening must still be done on both ears. The JCIH 2019 Position Statement indicates that "a pass outcome implies that the infant passes both ears simultaneously (in the same screening session). Specifically, an infant who does not pass both ears in the same screening session, even if each ear has separately passed a

screening, does not constitute a pass outcome" (page 7).[3] The JCIH 2019 Position Statement further notes that outpatient rescreening should always include the testing of both ears, even if only one ear did not pass the inpatient screening (page 10).

[3] Joint Committee on Infant Hearing (2019). Year 2019 position statement: Principles and guidelines for Early Hearing Detection and Intervention Programs. *Journal of Early Hearing Detection and Intervention, 4*(2): 1-44.