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 followed by auditory brainstem response (ABR) screening if the patient does not pass the OAE 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) The conduct of a two-tier inpatient infant hearing screening prior to discharge from [the facility;] neonatal care. Two-tier infant hearing screening consists of initial screening with OAE on both ears. Each ear must pass the OAE screening to be considered a “pass.” If the OAE 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.

* * *

(7) 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 persons or entities contracted therewith.

(1) Such referrals shall include a prescription issued by the facility, 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, or persons or entities contracted therewith.

* * *

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, 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. Approximately 60 Article 28 facilities statewide have the necessary newborn hearing screening equipment (OAE and ABR). Approximately 57 facilities with ABR only will need to acquire OAE technology, with an associated expenditure in the range of $6,000 to $7,500 per OAE device. A smaller number of birth facilities (an estimated seven 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:**

There are no alternatives to the proposed rules. 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.

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## 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.