Pursuant to the authority vested in the New York State Department of Health by Section 2500-g of the Public Health Law and Chapter 585 of the Laws of 1999, Part 69 of Subchapter H of Chapter II of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by the addition of a new Subpart 69-8 to be effective upon filing with the Secretary of State and publication in the State Register.

Part 69

Testing for Phenylketonuria and Other Diseases and Conditions/Early Intervention Program/Newborn Hearing Screening

A new Subpart 69-8 is added as follows:

Subpart 69-8

Newborn Hearing Screening

(Statutory authority: Public Health Law Section 2500-g)

Section 69-8.1 *Definitions*

(a) Administrative officer means the chief executive officer of the hospital, as defined in section 405.3 of this title.

(b) Audiologic evaluation means the use of physiologic and behavioral procedures to evaluate and diagnose hearing loss.

(c) Hearing problems (hearing loss) shall mean a permanent unilateral or bilateral hearing loss of mild (30 to 40 dB HL) or greater degree in the frequency region (500-4000 Hz) important for speech recognition and comprehension.

(d) Institution caring for infants (facility) means all general hospitals having maternity and infant services or premature infant services as defined in section 405.21 of this title and primary care hospitals and critical access hospitals as defined in section 407.1 of this title and birthing centers as defined in section 754.1 of this title.

(e) Newborn infant (infant) means a minor child who is less than ninety days of age.

(f) Newborn infant hearing screening (infant hearing screening) means the use of an objective electrophysiologic or otoacoustic measurement of the auditory system using equipment approved by the United States Department of Health and Human Services, Food and Drug Administration (FDA), to identify infants at risk for hearing loss.

(g) 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) Article 28 facility shall mean a health care facility established under article 28 of the Public Health Law.

Section 69-8.2 General Requirements for Infant Hearing Screening Programs and Responsibilities of the Administrative Officers or Designees of Facilities

(a) Each facility shall administer an infant hearing screening program, directly or by contract pursuant to section 400.4 of this title, as required by this part and as generally described in subdivision (b) of this section, except for those facilities identified in subdivision (c) of this section.

(1) Facilities that establish a contract(s) with providers of infant hearing screening shall designate a staff member responsible for contract management and general oversight of the program.

(2) Contracts may be established for the conduct of inpatient and/or outpatient infant hearing screening.

(3) Contractors must be article 28 facilities or health care providers licensed under state education law and authorized under such law to perform infant hearing screening.

(4) Contractors shall have the capacity to meet general requirements for infant hearing screening programs as set forth in subdivision (b) of this section.

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

(1) The conduct of inpatient infant hearing screening prior to discharge from the facility.

(2) Communication of results of infant hearing screenings to parents by designated personnel, including provision of written materials supplied by the Department.

(3) The 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) Referral 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:

(i) providing a general explanation of the Early Intervention Program and the purpose of referral and the parents' right to object to the referral;

(ii) ensuring confidentiality of referral information transmitted; and

(iii) transmitting of personally identifying information as necessary to ensure follow-up.

(5) The reporting of aggregate data on infant hearing screenings to the Department upon Department request, in a format and frequency prescribed by the commissioner.

(6) The 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.

(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.

(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.

(2) Such facilities shall submit screening results returned to the facility by the outpatient provider as required by the Department to determine the effectiveness of referral procedures in ensuring infants are screened for hearing loss.

Section 69-8.3 General Requirements for Administration of the Infant Hearing Screening Program

(a) The administrative officer of each facility caring for infants or their contractor(s) shall designate a program manager responsible for management and oversight of the infant hearing screening program.

(1) The program manager shall be a licensed audiologist, physician, physician's assistant, registered nurse or nurse practitioner.

(2) If the program manager is not an audiologist, infant hearing screening procedures and training shall be established and monitored in consultation with an audiologist.

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

(1) training and supervision of the individuals performing the screening;

(2) review, recording and documentation of screening results;

(3) data reporting;

(4) staff and parent education; and,

(5) coordination of services and follow-up including referrals for re-screening or diagnostic audiologic evaluation as appropriate.

(c) All personnel performing infant hearing screening must be supervised and trained in the performance of infant hearing screening.

(d) Training shall include the following:

(1) the performance of infant hearing screening;

(2) the risks including psychological stress for the parent;

(3) infection control practices;

(4) the general care and handling of infants in hospital settings according to established hospital policies and procedures;

(5) the recording and documentation of screening results as directed; and,

(6) procedures for communicating screening results to parents.

(e) Personnel other than licensed audiologists may perform infant hearing screening provided that:

(1) the screening equipment and protocol used are fully automated;

(2) equipment parameters are not accessible for alteration or adjustment by such personnel; and,

(3) the results of the screening are determined without clinical decision-making and are reported as pass or fail.

(f) Equipment that requires clinical decision-making shall be used to conduct infant hearing screenings only by personnel licensed under State Education Law and authorized to perform infant hearing screening.

(g) Equipment used for infant hearing screening shall be maintained and calibrated in accordance with section 405.24 (c)(2) of this title.

(h) The facility shall provide adequate physical space for equipment and supplies and an environment suitable to obtain reliable infant hearing screening results.

Section 69-8.4 Procedures for Infant Hearing Screening

(a) All infants born in the facility shall receive an initial hearing screening prior to discharge from the facility except as provided in section 69-8.2(c) of this Part.

(b) Prior to the hearing screening, parents shall be provided educational materials, supplied by the Department to the facility, or consistent in content with Department-supplied materials, regarding infant hearing screening.

(c) If the infant passes the hearing screening, the results shall be documented in the infant's record by the individual who performed the screening and documented in the discharge summary.

(1) The parent shall be informed of the screening results prior to the infant’s discharge from the facility.

(d) The parent shall be provided educational materials, supplied by the Department to the facility, on developmental milestones for communication and signs of hearing loss in young children.

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

(1) The parent is offered the opportunity to schedule an appointment for the infant to be screened for hearing loss on an outpatient basis within four weeks from the infant's discharge from the facility. Whenever practicable, the parent shall be afforded such opportunity to schedule an outpatient screening prior to the infant's discharge from the facility.

(2) If the parent is not provided the opportunity to schedule an appointment for an outpatient screening prior to the infant's discharge from the facility following birth, a minimum of two documented attempts, either by United States mail or by telephone, excluding busy signals or no answer, shall be made to contact the parent post-discharge to schedule an appointment for an outpatient screening for the infant.

(3) If the parent agrees to schedule an appointment for an outpatient hearing screening by the facility or a provider under contract with the facility, the appointment shall be scheduled and documented in the infant’s record.

(4) If the parent returns to the facility or provider under contract with the facility for an outpatient screening, the screening results shall be documented in the infant's record and reported to the Department as prescribed by the commissioner.

(5) If the parent declines to schedule an appointment for an outpatient hearing screening for the infant by the facility or by a provider under contract with the facility, such declination shall be documented in the infant's record and discharge summary.

(i) The parent shall be provided instead with a prescription for the infant to obtain an outpatient hearing screening from an article 28 facility or provider licensed by and authorized under State Education Law to perform infant hearing screening.

(ii) The prescription shall specify that the results of the hearing screening shall be returned to the facility.

(f) If the infant fails the 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.

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

(1) The parent shall be informed of the infant’s screening results by an individual trained as required in subdivisions (c) and (d) of section 69-8.3 to counsel the parent(s) on the importance of a follow-up screening.

(2) The parent shall be provided with educational materials on the importance of early detection of hearing loss, supplied by or consistent with Department materials.

(3) The parent shall be provided, prior to the infant's discharge, a prescription to obtain follow-up infant hearing screening post-discharge to be performed at the facility or by a provider under contract with the facility.

(4) If the parent agrees, an appointment shall be scheduled prior to the infant's discharge from the facility except under circumstances where such scheduling is not practicable, such as on weekends, or within ten days post-discharge.

(5) The appointment shall be documented in the infant's record and discharge summary to facilitate follow-up by the infant's primary health care provider.

(6) If an infant does not present for a scheduled appointment for a follow-up screening based on the infant's failure of an in-patient screen, the facility or provider under contract with the facility shall make at least two documented attempts either by United States mail or by telephone, excluding a busy signal or no answer, to contact the parent and reschedule the appointment.

(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 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.

(8) If the parent declines to schedule a follow-up screening with the facility or provider under contract with the facility for an infant who has failed the inpatient infant hearing screening, the following procedures shall be used:

(i) The parent(s) shall be provided with a prescription issued by the facility for the infant to obtain a follow-up screening from a provider licensed under State Education Law and authorized under such law to perform infant hearing screening.

(a) The prescription shall include a request that results of the screening be submitted back to the facility.

(ii) The parent shall be provided with a list of qualified providers of infant hearing screening, which shall consist of providers licensed under state education law and authorized under such law to perform infant hearing screening and article 28 facilities.

(iii) The individual counseling the parent shall document in the infant's record and discharge summary the parent(s)' decision not to schedule an appointment with the facility and the issuance of a prescription to obtain follow-up screening from another qualified provider.

(iv) The infant's primary health care provider, when such provider is known, shall be notified of the parents' decision to obtain a follow-up outpatient screening.

(v) If the prescription is filled and the results of the follow-up screening are returned to the facility, such results shall be documented in the infant's record.

(i) 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:

(1) The parent shall be informed that the screening should be completed within four weeks from the infant's discharge from the facility if possible and not later than twelve weeks following birth.

(2) The parent shall be provided with educational materials on the importance of early detection of hearing loss, supplied by the Department to the facility, or consistent in content with Department-supplied materials, and a list of licensed providers and/or article 28 facilities where infant hearing screening may be obtained.

(3) The parent shall receive a prescription for an outpatient screening by a provider licensed under the State Education Law and authorized under such law to perform infant hearing screening, or by an article 28 facility. Such prescription shall state that results shall be returned to the facility.

(4) The parent shall be informed that if results of a follow-up outpatient screening are not returned to the facility, 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.

(5) The referral, including issuance of a prescription, shall be documented in the infant's record and discharge summary to facilitate follow-up by the infant's primary health care provider.

(6) The infant's primary health care provider, when such provider is known, shall be notified of the inpatient results and need for a follow-up outpatient screening.

(7) If results of a follow-up outpatient screening are not returned to the facility within seventy-five 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.

Section 69-8.5 General Requirements for Institutions Caring for Infants that Provide a Referral for Infants to Obtain Hearing Screening.

(a) This section shall apply to those exempt from direct administration of the infant hearing screening program. The administrative officer of a facility as described in subdivision (c) of section 69-8.2 of this Part shall designate a program manager responsible for infant hearing screening who shall ensure infants are referred for an outpatient screening for hearing loss.

(b) The program manager for infant hearing screening shall ensure that infants are referred, prior to discharge from the facility, to a provider licensed under State Education Law and authorized under such law to perform infant hearing screening or an article 28 facility.

(1) The parent shall be informed that the screening should be completed within four weeks of the infant's discharge from the facility if possible and not later than twelve weeks following birth.

(2) The parent shall be provided with educational materials on the importance of early detection of hearing loss, supplied by or consistent with department materials; and, a list of licensed providers and/or article 28 facilities where infant hearing screening may be obtained.

(3) The parent shall receive a prescription for an outpatient screening by an article 28 provider or a provider licensed under the State Education Law and authorized by such law to perform infant hearing screening. The prescription shall require that results be returned to the facility issuing the prescription.

(4) The referral, including issuance of a prescription, shall be documented in the infant’s record and discharge summary to facilitate follow-up by the infant's primary health care provider.

(c) The program manager shall be responsible for ensuring that results of infant hearing screening reported to the facility are documented in the infant's record and reported to the Department as prescribed by the commissioner.

(d) 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 Responsibilities of Institutions Caring for Infants in Special Circumstances

(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 in a manner consistent with the applicable provisions set forth in this part.

If the infant fails both an initial and follow-up 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.

(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 forego such screening may be made and documented in the medical record.

REGULATORY IMPACT STATEMENT

Statutory Authority

Public Health Law (PHL) section 2500-g and Chapter 585 of the laws of 1999, require the commissioner to promulgate regulations to implement a program to screen newborn infants for hearing problems as early in life as possible and to provide for the reimbursement of health care providers performing such services under the program.

Legislative Objectives

The legislative objective of Chapter 585 of the Laws of 1999 is to establish a statewide newborn hearing screening program to screen newborn infants for hearing problems as early in life as possible. Provisions of the program include incorporation of consensus medical guidelines and protocols reflecting the most cost-effective methods for detecting hearing loss, and follow-up including referrals for screening or care.

Needs and Benefits

Hearing loss is the most common congenital disorder in newborns, twenty times more prevalent than phenylketonuria (PKU), a condition for which all newborns are currently screened. Significant hearing loss is present in approximately 1 to 3 infants per 1,000. It is estimated that another 3 infants per 1,000 born with moderate hearing loss could be identified through universal newborn hearing screening programs according to figures from the American

Speech-Language-Hearing Association.[1] The average age that children with hearing loss are identified in the United States is 12 to 25 months of age.[2] When hearing loss is detected late, critical time for stimulating the auditory pathways to the hearing centers in the brain is lost.

Infants identified with hearing loss can be fit with amplification by an audiologist as young as four weeks of age. With appropriate early intervention these infants' language, cognitive and social development may be on par with their hearing peers. Recent research[3] concluded that children born with a hearing loss who are identified and who receive appropriate intervention before six months of age had significantly better language skills than those identified after six months of age. Studies have also indicated that detection of hearing loss during infancy followed with appropriate intervention minimizes the need for rehabilitation during the school years.

Advances in technology have made universal newborn hearing screening feasible and cost-effective. In the past, many hospitals conducted hearing screening only for infants considered at risk for hearing loss, due to conditions such as low birth weight, a family history of hearing loss, or other specified medical conditions. However, research indicates that 30 to 40% of infants with significant hearing loss do not have risk indicators and will be missed if only those infants with risk indicators receive hearing screening.[4]

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[1] American Speech-Language-Hearing Association (1999). Facts on Hearing Loss in Children. www.asha.org/infant hearing/facts.htm.
[2] Ibid.
[3] Yoshinaga-Itano, C., Sedley, A.L., Coulter, D.K., & Mehl, A.L. (1998). Language of early- and later- identified children with hearing loss. *Pediatrics*, 103, 1161-1171.
[4] Prieve, B.A. and Stevens, F. (2000). The New York State Universal Newborn Demonstration Project: Introduction and Overview. *Ear and Hearing*, Volume 21, Number 2., 85-91.

Approximately 10% of infants born in New York State currently receive newborn hearing screening.[5] The proposed regulations make possible early identification of newborns with communicatively significant hearing impairment and provide the opportunity for infants identified with hearing loss and their families to benefit from early intervention. The proposed new rules establish general requirements for the newborn hearing screening program, define the responsibilities of administrative officers or designees of facilities under the program, establish general requirements for direct administration of the newborn hearing screening program and for those facilities that may provide a referral for infants to obtain hearing screening, and defines responsibilities of facilities caring for newborn infants in special circumstances.

Costs

Costs to State Government

Based on actual 1998 Statewide Planning and Research Cooperative System (SPARCS) data for newborns, the aggregate Medicaid expenditure for newborn hearing screening is estimated to be up to $ 540,000 in SFY 2000-01 and up to $2.16 million in SFY 2001-02. Federal financial participation in the program at 50% is estimated to be up to $270,000 in SFY 2000-01 and up to $1.08 million in SFY 2001-02. The State share at 25% is estimated to be up to $135,000 in SFY 2000-01 and up to $540,000 in SFY 2001-02.

PHL section 2500-g provides for the reimbursement of health care providers performing newborn hearing screening services under the program. The cost to State government is based on the enhanced Medicaid reimbursement available to facilities for providing this service.

[5] Spivak, L., Dalzell, L., Berg, A., Bradley, M., Cacace, A., Campbell, D., DeCristofaro, J., Gravel, J., Greenberg, E., Gross, S., Orlando, M., Pinhiero, J., Regan, J., Stevens, F., and Prieve, B. (2000). New York State Universal Newborn Hearing Screening Demonstration Project: Inpatient Outcome Measures. *Ear and Hearing*, Volume 21, Number 2, 92-103.

The reimbursement methodology relied upon cost data from the New York State Universal Hearing Screening Demonstration Project (1995 – 1997) to identify additional costs incurred by facilities to meet the new state mandate. The incremental 1997 clinical and administrative operating costs for newborn hearing screening services were included in determining the rate adjustment. Capital costs for existing and new equipment required for newborn hearing screening were not included as they are currently reimbursed as actual and budgeted capital costs in the provider's inpatient and outpatient rates. A cost per-screen methodology was employed that also accounted for the estimated 4% of newborns that required a second stage screen. Costs were trended to the rate year 2001 to determine the rate adjustment amount. Birth institutions that directly administer the program will be permitted to bill for the enhanced reimbursement in addition to the inpatient newborn DRG rate as the newborn hearing screen is provided. For facilities with 400 or fewer annual births that elect to refer the service, the actual provider of the newborn hearing screen will be entitled to Medicaid reimbursement at the applicable New York State Medicaid Fee Schedule amount.

To determine overall costs to State government, the percentage of children eligible for Medicaid was estimated utilizing actual SPARCS data by payor source.

The Governor's Executive Budget for the 2001-2002 state fiscal year includes a proposed $5 million appropriation for services and expenses related to the newborn hearing screening program.

Costs to Local Government

The local government share of Medicaid expenditures is 25%. Therefore, the gross estimated costs to local government for newborn hearing screening is estimated to be up to

$135,000 in SFY 2000-01 and up to $540,000 in SFY 2001-02. See discussion under "Costs to State Government."

An increase in Early Intervention Program costs may be anticipated consistent with an increase in the number of infants identified with suspected hearing impairment by newborn hearing screening and referred for follow-up diagnostic audiologic evaluations and early intervention services.

Costs to Private Regulated Parties

Hospitals and birthing centers with more than 400 births annually will be required to directly administer a program to screen each newborn for hearing impairment prior to discharge. Consequent to this newly mandated service and to the extent that such services are not currently provided by the facility, birth institutions may incur the following additional costs:

1) Personnel costs - for time spent in planning and implementing the facility's newborn hearing screening program; for staff training in screening procedures; for time spent performing the screening service including tracking/reporting of data and follow-up for infants who do not pass the screening. Personnel costs may include costs for new staff as needed to effectively administer the newborn hearing screening program.

2) Equipment costs

3) Consumable medical supplies and office supplies

4) Data gathering and reporting costs

The Medicaid rate adjustment will offset Medicaid's share of the incremental cost to birth institutions for newborn hearing screening services provided to Medicaid patients

Costs related to providing newborn hearing screening to the insured population will be borne in whole or in part by health insurance policies currently providing coverage for primary and preventive health care services for children to age nineteen. Sections 3216, 3221 and 4303 of the New York State Insurance Law currently require coverage of well child visits, as well as the services to be provided at such visits, in accordance with the prevailing clinical standards of the American Academy of Pediatrics. The American Academy of Pediatrics includes newborn hearing screening in its periodicity chart for routine primary health care for infants. In addition, in the development of this notice of proposed rulemaking, the Department requested and received written confirmation from the American Academy of Pediatrics (November 2000) that newborn hearing screening is considered a national prevailing clinical standard of newborn infant care. As such, newborn primary care services are within the scope of preventive and primary care services to be covered under the Insurance Law. Where appropriate, the costs to third party payors for newborn hearing screening will be negotiated between providers and payors consistent with other covered primary and preventive health care services governed by the Insurance Law.

In addition, the Governor's Executive Budget for the 2001-2002 state fiscal year includes a proposed $5 million appropriation for services and expenses related to the newborn hearing screening program.

Costs to the Department of Health

The Department of Health will incur costs of approximately $40,000 annually for printing and distribution of educational materials and forms to be supplied to facilities

implementing newborn hearing screening programs. Existing personnel will be used to provide oversight, administration, and monitoring of newborn hearing screening programs.

Local Government Mandates

These regulations will not impose any new program services, duties or responsibilities upon any county, city, town, village, school district, fire district or any other special district, except for those local governments operating hospitals with maternity services providing services to newborn infants.

County and New York City agencies administering the Early Intervention Programs will experience an increase in the number of referrals for follow-up of children at risk of hearing impairment (children who fail an inpatient hearing screening and do not return for a follow-up outpatient screening) and children suspected of having a hearing impairment (children who fail two screens) as a result of implementation of the newborn hearing screening program and where parent(s) do not object to the referral.

Paperwork

Facilities administering newborn hearing programs must develop and maintain written policies and procedures indicating how they will accomplish training and oversight of individuals performing the screening, review, recording and documentation of screening results; data reporting; staff and parent education; and coordination of services and follow up.

Paperwork requirements related to the newborn hearing screening program include documentation of inpatient hearing screening results; documentation of outpatient hearing screening results known to the facility; documentation of referrals to the Early Intervention

Program, and issuance of a prescription by the facility for those infants who fail or do not receive an inpatient screening to receive follow-up screening.

Facilities will be required to report aggregate data to the Department of Health as necessary to monitor the effectiveness of the newborn hearing screening program. Data reporting requirements will include quarterly reports on: number of inpatient screens conducted (pass, fail); number of missed inpatient screens; number of outpatient screens conducted (pass, fail); number of referrals for outpatient screening; and, number of results returned to the facility by other providers conducting outpatient screens (pass, fail); number of infants referred to the Early Intervention Program as at risk for follow-up. The Department is examining the feasibility of providing for electronic submission of aggregate data using the Health Provider Network.

The proposed amendments will not result in any new paperwork requirements related to billing.

In addition, providers may need to seek or amend current contracts with providers of newborn hearing screening either to provide such screening prior to discharge or to provide follow up hearing screening services for those infants who require them.

Duplication

These regulations do not duplicate existing State and Federal regulations.

Alternatives

The legislative objective of Chapter 585 of the Laws of 1999 is to establish a statewide newborn hearing screening program to screen newborn infants for hearing problems as early in

life as possible and allows birth institutions to either provide directly or make a referral for infants to receive newborn hearing screening from another qualified provider.

The Department convened a work group in May 2000, comprised of industry representatives, health care providers, advocates, and parents of children with hearing impairments to assist in the development of proposed rules for the newborn hearing screening program. Although the work group (including Department of Health representatives) concurred that both inpatient and outpatient follow-up screening were essential for appropriate care, there were significant differences of opinion as to how to interpret the referral option provided for in State statute. Health care providers, advocates, Department representatives, and parents were committed to ensuring that appropriate safeguards were in place to ensure that all infants would receive an initial inpatient screening and all those who failed the initial screening would receive an outpatient screening. Hospital representatives, while sharing the commitment to appropriate newborn hearing screening, were also concerned about the burden for small rural hospitals in providing for inpatient newborn hearing screening and for all hospitals in provision of follow-up outpatient screening for infants who fail an inpatient screening. In addition, differences of opinion existed about the amount and type of data necessary to evaluate whether universal newborn hearing screening was being achieved.

A number of options were considered related to these two issues, including: requiring all hospitals to provide the initial inpatient hearing screening and follow-up activities necessary to schedule and complete an outpatient screening for infants who fail the inpatient screening; providing an exemption for rural hospitals from direct provision of newborn hearing screening; requiring all hospitals to provide an initial inpatient screening while allowing referral of certain infants who fail the inpatient screen to other facilities for follow-up; allowing for the

establishment of contractual agreements for the provision of newborn hearing screening; and, requiring infant-specific reporting of hearing screening results to the Department of Health.

The work group agreed, through a series of meetings convened between May and August, 2000, on the following requirements included in the proposed rulemaking: hospitals with four hundred or fewer births annually, based on a three-year rolling average, will be permitted to refer all infants for newborn hearing screening on an outpatient basis with a prescription requiring that results be returned to the discharging facility; hospitals with 401 or more births annually will be required to provide inpatient newborn hearing screening but may refer all infants who fail the inpatient screen to another qualified provider for outpatient follow-up screening with a prescription for the service requiring that results be returned to the discharging facility; and, aggregate data will be required for program evaluation purposes. These requirements will ensure an appropriate and quality standard of care for newborn hearing screening while minimizing the burden for institutions required to implement these regulations.

Federal Standards

The proposed rule does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule

The regulations will be effective upon publication of a notice of adoption in the New York State Register.

Contact Person: Mr. William R. Johnson
Office of Regulatory Reform
NYS Department of Health
Mayor Erastus Corning 2nd Tower Building
Room 2415
Albany, New York 12237
(518) 473-7488
(518) 486-4834 FAX
REGSQNA@health.state.ny.us

Studies Contact Person:
Donna M. Noyes, PhD
Director, Early Intervention Program
NYS Department of Health
Mayor Erastus Corning 2nd Tower Building
Room 208
Albany, New York 12237
(518) 473-7016
(518) 486-1090 – FAX

Comments submitted to Department personnel other than this contact person may not be included in any assessment of public comment issued for this regulation.

CONSOLIDATED REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect on Small Business and Local Governments

For purposes of this regulatory flexibility analysis, small businesses were considered to be birth institutions (hospitals licensed to provide maternity services and birthing centers) that employ 100 or fewer full-time equivalent employees. Based on recent cost report data, the proposed rule will have an effect on an estimated four (4) hospitals and five (5) birthing centers, which meet the definition of a small business.

The proposed regulations establish general requirements for the newborn hearing screening program; define the responsibilities of institutions caring for newborn infants under the program; establish general requirements for direct administration of the newborn hearing screening program; provide an exemption for administration and a referral option for institutions with 400 births per year or fewer; and, define responsibilities of facilities caring for newborn infants in special circumstances.

Compliance Requirements

The proposed new training and education requirements may affect providers who do not currently employ or contract with individuals trained to perform or qualified to supervise the provision of newborn hearing screening. Facilities may need to add equipment and/or staff or develop contracts with qualified personnel to build capacity for provision of newborn hearing screening and/or the required tracking/follow up for infants who do not pass the screening.

The reporting, recordkeeping and other affirmative acts that impacted small businesses or local governments would have to undertake to comply with this proposed rule include provision of information regarding newborn hearing screening to parents, performance of the screening procedure, reporting of the screening results to parents and primary health care providers as required, and reporting data to the Department of Health as prescribed by the Commissioner.

With the exception of facilities with 400 or fewer births annually, facilities would be required to comply with the proposed standards relative to policies and procedures for newborn hearing screening including performance of the test and follow up, qualifications for program managers, supervision and training for non-licensed personnel engaged in the performance of newborn hearing screening.

Requirements for facilities with fewer than 400 births annually include provision of a prescription, including a request for the results of the hearing screening to be returned to that facility, for infants to receive newborn hearing screening from a provider licensed under state education law and authorized under such law to provide newborn hearing screening services or from an Article 28 facility.

Paperwork

Facilities administering newborn hearing programs must develop and maintain written policies and procedures indicating how they will accomplish training and oversight of individuals performing the screening, review, recording and documentation of screening results; data reporting; staff and parent education; and coordination of services and follow up.

Paperwork requirements related to the newborn hearing screening program include documentation of inpatient hearing screening results; documentation of outpatient hearing screening results known to the facility; documentation of referrals to the Early Intervention Program, and issuance of a prescription by the facility for those infants who fail or do not receive an inpatient screening to receive follow-up screening.

Facilities will be required to report aggregate data to the Department of Health as necessary to monitor the effectiveness of the newborn hearing screening program. Data reporting requirements will include quarterly reports on: number of inpatient screens conducted (pass, fail); number of missed inpatient screens; number of outpatient screens conducted (pass, fail); number of referrals for outpatient screening; and, number of results returned to the facility by other providers conducting outpatient screens (pass, fail); number of at risk infants referred to the Early Intervention Program for follow-up. The Department is examining the feasibility of providing for electronic submission of aggregate data using the Health Provider Network.

Professional Services Requirements

Impacted small businesses and local governments may need to procure consultative services from a licensed audiologist for the purpose of establishing and monitoring newborn hearing screening program procedures and training if a licensed audiologist is not on staff at the facility. In addition, the proposed regulation specifies who may oversee newborn hearing screening programs and allows for the provision of newborn hearing screening by non-licensed personnel when automated equipment requiring no clinical decision making is used to perform infant hearing screenings. In addition, the proposed new rules establish minimum standards for the supervision and training of non-licensed individuals performing newborn hearing screening.

Other than the above considerations, implementation of the newborn hearing screening program can be accomplished with existing staff.

Economic and Technological Feasibility Assessment

The proposed regulatory program is economically and technologically feasible since additional staff requirements are minimal and the equipment/technology necessary for hearing screening is widely available.

Compliance Costs

Hospitals and birthing centers with more than 400 births annually will be required to directly administer a program to screen each newborn for hearing impairment prior to discharge. Consequent to this newly mandated service and to the extent that such services are not currently provided by the facility, birth institutions may incur the following additional cost:

(1) Personnel costs - for time spent in planning and implementing the facility's newborn hearing screening program; for staff training in screening procedures; for time spent performing the screening service including tracking/reporting of data and follow-up for infants who do not pass the screening. Personnel costs may include costs for new staff as needed to effectively administer the newborn hearing screening program.

(2) Equipment costs

(3) Consumable medical supplies and office supplies

(4) Data gathering and reporting costs

The Medicaid rate adjustment will offset Medicaid's share of the incremental cost to birth institutions for newborn hearing screening services provided to Medicaid patients.

Hospitals and birthing centers with more than 400 births annually will be required to directly administer a program to screen each newborn for hearing impairment prior to discharge. Consequent to this newly mandated service and to the extent that such services are not currently provided by the facility, birth institutions may incur the following additional costs:

1) Personnel costs - for time spent in planning and implementing the facility's newborn hearing screening program; for staff training in screening procedures; for time spent performing the screening service including tracking/reporting of data and follow-up for infants who do not pass the screening. Personnel costs may include costs for new staff as needed to effectively administer the newborn hearing screening program.

2) Equipment costs

3) Consumable medical supplies and office supplies

4) Data gathering and reporting costs

The Medicaid rate adjustment will offset Medicaid's share of the incremental cost to birth institutions for newborn hearing screening services provided to Medicaid patients.

Costs related to providing newborn hearing screening to the insured population will be borne in whole or in part by health insurance policies currently providing coverage for primary and preventive health care services for children to age nineteen. Sections 3216, 3221 and 4303 of the New York State Insurance Law currently require coverage of well child visits, as well as the services to be provided at such visits, in accordance with the prevailing clinical standards of the American Academy of Pediatrics. The American Academy of Pediatrics includes newborn hearing screening in its periodicity chart for routine primary health care for infants. In addition, in the development of this notice of proposed rulemaking, the Department requested and received written confirmation from the American Academy of Pediatrics (November 2000) that

newborn hearing screening is considered a national prevailing clinical standard of newborn infant care. As such, newborn primary care services are within the scope of preventive and primary care services to be covered under the Insurance Law. Where appropriate, the costs to third party payors for newborn hearing screening will be negotiated between providers and payors consistent with other covered primary and preventive health care services governed by the Insurance Law.

In addition, the Governor's Executive Budget for the 2001-2002 state fiscal year includes a proposed $5 million for services and expenses related to the newborn hearing screening program.

Minimizing Adverse Impact

The Department considered the approaches in Section 202-b(1) of the State Administrative Procedures Act (SAPA) and modified requirements for facilities with 400 or fewer births annually, as previously described.

Outreach activities were conducted throughout the process of developing these standards to ensure that the proposed standards are achievable for facilities as defined in the proposed rule and/or in PHL Article 28. Specifically, steps leading to the development of the proposed amendments included:

- Hospital survey – a survey of birth hospitals was conducted in the first quarter of 2000 to assess the status of facilities' newborn hearing screening efforts.
- Convening of an Ad Hoc Work Group including representatives of major provider organizations and advocates (Health Care Association of New York State and Greater New York Hospitals Association) to assist with drafting regulations.

The current proposal reflects input from the groups noted above.

Specific training and technical assistance activities to assist service providers and all affected parties to implement newborn hearing screening programs are under consideration by the Ad Hoc Work Group. Work is underway to arrange for two workshops (one upstate and one downstate). These workshops provide technical support for facilities that have begun or are planning to initiate newborn hearing screening programs. The workshop content includes an overview of newborn hearing screening as well as concrete suggestions for implementation, and information on communicating with parents and others regarding newborn hearing screening.

The Department has initiated the development of clinical practice guidelines for families, practitioners, and public officials to provide recommendations for the assessment and intervention of young children with hearing loss. These guidelines will be available and disseminated at no cost in 2001.

The reimbursement methodology establishes the availability of enhanced Medicaid reimbursement to facilities for providing this service and incorporates appropriate cost standards and regional wage adjustment factors to account for valid economic differences in various parts of the State. This also accommodates small and large businesses in various parts of the State. Exemption of small businesses from coverage of the rate is not necessary or appropriate.

Opportunity for Small Business and Local Government Participation

In advance of publication, the proposed regulations were discussed with representatives of the Health Care Association of New York State and the Greater New York Hospitals Association which have small businesses as members.

Small business was represented in discussions of the Ad Hoc Work Group convened to assist the Department in the development of these regulations. Newborn Hearing Screening Ad Hoc Work Group meetings held between May 12, 2000 and October 11, 2000 included detailed discussions of the proposed newborn hearing screening program, including the development of policies and procedures for newborn hearing screening, tracking, and follow-up as necessary to ensure successful statewide implementation of universal newborn hearing screening in New York State. Drafts of the proposed regulations were discussed at its August 16, 2000 and September 18, 2000 meetings, and the major points and principles included in the regulations were reviewed on those dates. Representatives of the Office of Health Systems Management reviewed the factors that may be considered in setting reimbursement rates for newborn hearing screening services as well.

In addition, the Department has received comments on drafts of the proposed regulation from various interested parties, including representatives of the hospital associations specified above.

RURAL AREA FLEXIBILITY ANALYSIS

Effect on Rural Areas

Rural areas are defined as counties with a population less than 200,000 and, for counties with a population greater than 200,000, includes towns with population densities of 200 persons or less per square mile. The following 44 counties have a population less than 200,000:

Allegany	Hamilton	Schenectady
Cattaraugus	Herkimer	Schoharie
Cayuga	Jefferson	Schuyler
Chautauqua	Lewis	Seneca
Chemung	Livingston	Steuben
Chenango	Madison	Sullivan
Clinton	Montgomery	Tioga
Columbia	Ontario	Tompkins
Cortland	Orleans	Ulster
Delaware	Oswego	Warren
Essex	Otsego	Washington
Franklin	Putnam	Wayne
Fulton	Rensselaer	Wyoming
Genesee	St. Lawrence	Yates
Greene	Saratoga	

An additional eleven (11) counties have certain townships with population densities of 200 persons or less per square mile.

The proposed regulation applies to hospitals and birthing centers statewide, and therefore, will impact those facilities located in rural areas in 55 counties. Facilities with 400 or fewer births annually may provide a referral for infants to receive hearing screening and will be required to submit data received to the department. Impact will be greater for facilities with more than 400 births annually, since they will be required to conduct inpatient infant hearing screening prior to discharge from the facility and submit data to the department. Analysis of hospitals and birthing centers relative to county designation as rural, utilizing 1998 SPARCS

data, indicated that approximately 31 rural facilities would be impacted by this proposed regulation.

Compliance Requirements

The reporting, recordkeeping and other affirmative acts that will impact hospitals in rural areas would have to be undertaken to comply with this proposed rule. The proposed regulations require hospitals with more that 400 births annually to screen newborn infants for hearing loss prior to discharge. Under the proposed regulations, facilities must also designate personnel to communicate the results of the screening to the infant's parents and primary health care provider, including documentation of such results in the infant's hospital record, and report data on newborn hearing screening as required to the department.

In addition, with the exception of facilities with 400 or fewer births annually, facilities would be required to comply with the proposed standards for newborn hearing screening including qualifications for program managers, supervision and training for non-licensed personnel engaged in the performance of newborn hearing screening.

Requirements for facilities with fewer than 400 births annually include provision of a prescription, including a request for the results of the hearing screening to be returned to that facility, for infants to receive newborn hearing screening from a provider licensed under state education law and authorized under such law to provide newborn hearing screening services or from an Article 28 facility.

Paperwork

Facilities administering newborn hearing programs must develop and maintain written policies and procedures indicating how they will accomplish training and oversight of individuals performing the screening, review, recording and documentation of screening results; data reporting; staff and parent education; and coordination of services and follow up.

Paperwork requirements related to the newborn hearing screening program include documentation of inpatient hearing screening results; documentation of outpatient hearing screening results known to the facility; documentation of referrals to the Early Intervention Program, and issuance of a prescription by the facility for those infants who fail or do not receive an inpatient screening to receive follow-up screening.

Facilities will be required to report aggregate data to the Department of Health as necessary to monitor the effectiveness of the newborn hearing screening program. Data reporting requirements will include quarterly reports on: number of inpatient screens conducted (pass, fail); number of missed inpatient screens; number of outpatient screens conducted (pass, fail); number of referrals for outpatient screening; and, number of results returned to the facility by other providers conducting outpatient screens (pass, fail); number of at risk infants referred to the Early Intervention Program for follow-up. The Department is examining the feasibility of providing for electronic submission of aggregate data using the Health Provider Network.

The proposed amendments will not result in any new paperwork requirements related to billing.

Professional Services Requirements

Impacted rural facilities may need to procure consultative services from a licensed audiologist for the purpose of establishing and monitoring newborn hearing screening program

procedures and training if a licensed audiologist is not on staff at the facility. In addition, the proposed regulation specifies who may oversee newborn hearing screening programs and allows for the provision of newborn hearing screening by non-licensed personnel in certain circumstances. In addition, the proposal establishes minimum standards for the supervision and training of non-licensed individuals performing newborn hearing screening. Other than the above considerations, implementation of the newborn hearing screening program can be accomplished with existing staff.

Compliance Costs

Hospitals and birthing centers with more than 400 births annually will be required to directly administer a program to screen each newborn for hearing impairment prior to discharge. Consequent to this newly mandated service and to the extent that such services are not currently provided by the facility, birth institutions may incur the following additional cost:

1) Personnel costs - for time spent in planning and implementing the facility's newborn hearing screening program; for staff training in screening procedures; for time spent performing the screening service including tracking/reporting of data and follow-up for infants who do not pass the screening. Personnel costs may include costs for new staff as needed to effectively administer the newborn hearing screening program.

2) Equipment costs

3) Consumable medical supplies and office supplies

4) Data gathering and reporting costs

The Medicaid rate adjustment will offset Medicaid's share of the incremental cost to birth institutions for newborn hearing screening services provided to Medicaid patients.

Costs related to providing newborn hearing screening to the insured population will be borne in whole or in part by health insurance policies currently providing coverage for primary and preventive health care services for children to age nineteen. Sections 3216, 3221 and 4303 of the New York State Insurance Law currently require coverage of well child visits, as well as the services to be provided at such visits, in accordance with the prevailing clinical standards of the American Academy of Pediatrics. The American Academy of Pediatrics includes newborn hearing screening in its periodicity chart for routine primary health care for infants. In addition, in the development of this notice of proposed rulemaking, the Department requested and received written confirmation from the American Academy of Pediatrics (November 2000) that newborn hearing screening is considered a national prevailing clinical standard of newborn infant care. As such, newborn primary care services are within the scope of preventive and primary care services to be covered under the Insurance Law. Where appropriate, the costs to third party payors for newborn hearing screening will be negotiated between providers and payors consistent with other covered primary and preventive health care services governed by the Insurance Law.

In addition, the Governor's Executive Budget for the 2001-2002 state fiscal year includes a proposed $5 million for services and expenses related to the newborn hearing screening program.

Minimizing Adverse Impact

The Department considered the approaches in Section 202-b(1) of the State Administrative Procedures Act (SAPA) and modified requirements for facilities with 400 or fewer births annually, as previously described.

Outreach activities were conducted throughout the process of developing these standards to ensure that the proposed standards are achievable for facilities as defined in the proposed regulation and/or PHL Article 28. Specifically, steps leading to the development of the proposed amendments included:

- Hospital survey – a survey of birth hospitals was conducted in the first quarter of 2000 to assess the status of facilities' newborn hearing screening efforts (copy attached).
- Convening of an Ad Hoc Work Group including representatives of major provider organizations (Health Care Association of New York State and Greater New York Hospitals Association) to assist with drafting regulations.

Specific training and technical assistance activities to assist service providers and all affected parties to implement newborn hearing screening programs are under consideration by the Ad Hoc Work Group. Work is underway to arrange for two workshops (one upstate and one downstate). These workshops provide technical support for facilities that have begun or are planning to initiate newborn hearing screening programs. The workshop content includes an overview of newborn hearing screening as well as concrete suggestions for implementation, and information on communicating with parents and others regarding newborn hearing screening.

The Department has initiated the development of clinical practice guidelines for families, practitioners, and public officials to provide recommendations for the assessment and intervention of young children with hearing loss. These guidelines will be available and disseminated at no cost in 2001.

The reimbursement methodology establishes the availability of enhanced Medicaid reimbursement to facilities for providing this service and incorporates appropriate cost standards and regional wage adjustment factors to account for valid economic differences in various parts of the State. This also accommodates small and large businesses in various parts of the State. Exemption of small businesses from coverage of the rate is not necessary or appropriate.

Opportunity for Rural Area Participation

In advance of publication, the proposed regulations were discussed with representatives of the Health Care Association of New York State which has members in rural areas.

Rural providers were represented in discussions of the Ad Hoc Work Group convened to assist the Department in the development of these regulations. Newborn Hearing Screening Ad Hoc Work Group meetings held between May 12, 2000 and October 11, 2000 included detailed discussions of the proposed newborn hearing screening program, including the development of policies and procedures for newborn hearing screening, tracking, and follow-up as necessary to ensure successful statewide implementation of universal newborn hearing screening in New York State. Drafts of the proposed regulations were discussed at its August 16, 2000 and September 18, 2000 meetings, and the major points and principles included in the regulations were reviewed at that time. Representatives of the Office of Health Systems Management reviewed the factors that may be considered in setting reimbursement rates for newborn hearing screening services as well.

In addition, the Department has received comments on drafts of the proposed regulation from various interested parties, including representatives of the hospital associations specified above which have members in rural areas.

JOB IMPACT STATEMENT
NEGATIVE DECLARATION STATEMENT

A Job Impact Statement is not required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature and purpose of the proposed rule, that it will not have a substantial adverse impact on jobs or employment opportunities. The proposed rule implements a newborn hearing screening program which will only increase job opportunities for health professionals.