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HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF PUBLIC HEALTH INFRASTRUCTURE, LABORATORIES AND EMERGENCY PREPAREDNESS

PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

NEWBORN SCREENING LABORATORY

Clinical Laboratory Services

Laboratory Charges

Fees; Generally

Newborn Biochemical Screening Panel Fee

Proposed Amendment: N.J.A.C. 8:45-2.1

Authorized By: Cathleen D. Bennett, Commissioner, Department of Health.

Authority: N.J.S.A. 26:2-110 through 112, particularly 111.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2016-118.

Submit written comments electronically to:

http://www.nj.gov/health/legal/ecomments.shtml by September 30, 2016, or by regular mail postmarked by September 30, 2016, to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

N.J.S.A. 26:2-110 and 111 require the Department of Health (Department) to test all newborn children for the presence of certain biochemical and genetic disorders. N.J.S.A. 26:2-111 authorizes the Commissioner of the Department to require testing of newborn infants for other preventable biochemical disorders if reliable and efficient testing techniques are available. N.J.S.A. 26:2-111 also requires the Commissioner to promulgate rules to assure that all newborn infants are tested, to ensure that treatment services are available, and to provide a program of reviewing and following up on positive cases. N.J.S.A. 26:2-111 further authorizes the Commissioner to establish and charge reasonable fees for this testing, and requires the Commissioner to apply all revenues collected from these fees to the testing and follow-up services described above.

The Department implements these mandates through the Newborn Screening Program, which consists of the Newborn Screening Laboratory and the Newborn Biochemical Screening Program (Follow-Up Program). The Newborn Screening Laboratory tests blood specimens from newborns for the presence of certain disorders. The Follow-Up Program tracks infants with abnormal results, ensures access to confirmatory diagnostic testing and specialty treatment, and provides funding to specialized diagnostic, treatment, and management services. Many of the disorders for which the Department performs newborn screening are immediately life threatening and necessitate timely follow-up services. Without prompt identification and intervention, children who have these disorders will have life-long morbidities and/or premature deaths.

Follow-up services for these disorders include communication with parents, primary care physicians, and pediatric specialists to ensure that infants identified as having these disorders receive timely and appropriate medical care. N.J.A.C. 8:18 specifies the responsibilities of both programs, as well as health care providers.

In March 2009, the Department expanded the State's newborn biochemical and genetic screening panel from 20 to 54 disorders. See N.J.S.A. 8:18-1.3; 42 N.J.R. 2526(a), 43 N.J.R. 835(a). The Department based this expansion on recommendations from the New Jersey Newborn Screening Advisory and Review Committee (NSARC), which was originally established under Executive Order 126 (2001), in accordance with national guidance published by the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDNC) of the Secretary of the United States Department of Health and Human Services (Secretary).

This major expansion of the State's newborn screening panel required an upgrade to the newborn screening computer system, the acquisition of two tandem mass spectrometers (commonly referred to as MS/MS), additional laboratory reagents and supplies, and enhancements to the Follow-Up Program services to ensure that newborns identified as having disorders have access to specialized treatment centers. In support of this expansion, the Department increased the newborn screening fee from $71.00 to $90.00 in November 2008. See 40 N.J.R. 2181(a), 6457(a).

Since the last panel expansion in March 2009, the Newborn Screening Laboratory and the Follow-Up Program have been in the midst of again expanding the screening panel to include nine new disorders. Specifically, in May 2010, based on the recommendation of the ACHDNC, the Secretary added Severe Combined

Immunodeficiency and related T-cell lymphocyte deficiencies (hereinafter collectively referred to as SCID) to the national Recommended Uniform Screening Panel (RUSP). Subsequently, the NSARC voted to recommend that the State add SCID to New Jersey's newborn screening panel. The Commissioner accepted the recommendation and, in June 2014, the Department began screening all newborns in New Jersey for SCID. To add SCID to the screening panel, the Department invested in new instruments based in molecular biology and substantial automation to maximize efficiency. Screening for SCID increased the total number of disorders for which the Department screens newborns in New Jersey from 54 to 55.

Legislation was enacted subsequent to the last fee increase, which added a total of eight new disorders to the newborn screening panel. On January 6, 2012, Governor Christie signed Emma's Law, P.L. 2011, c. 175, codified at N.J.S.A. 26:2-111.5, which requires the Department's Newborn Screening Program to screen all newborns for five lysosomal storage disorders: Krabbe, Pompe, Gaucher, Fabry, and Niemann-Pick; and authorizes the Department to "charge a reasonable fee for the tests performed pursuant to this section." Subsequently, on August 7, 2013, Governor Christie signed P.L. 2013, c. 90, codified at N.J.S.A. 26:2-111.6, which requires the Newborn Screening Program to screen all newborns for adrenoleukodystrophy, and authorizes the Department to "charge a reasonable fee and any reasonable increase in this fee as necessary, for the test performed pursuant to this section." Finally, on September 10, 2014, Governor Christie signed the Let Them Be Little Act, P.L. 2014, c. 44, codified at N.J.S.A. 26:2-111.7, which requires the Newborn Screening Program to screen all newborns for mucopolysaccharidosis I and II (commonly known, among other names, as Hurler's and

Hunter's Syndromes, respectively), and authorizes the Department to "charge a reasonable fee and any reasonable increase in this fee as necessary, for the tests performed pursuant to this section." Thus, all three laws authorize the Department to increase the newborn screening fee as necessary to cover the costs of testing newborns for these eight additional conditions.

In order to add these eight additional disorders to the screening panel and continue to improve the existing newborn screening services and processes, the Department must acquire new laboratory equipment; purchase additional reagents and supplies; upgrade the Newborn Screening Program's computer system, including the provision of web-based results reporting; and expand the services provided by the Follow-Up Program. The Department has begun taking steps to implement these necessary requirements. Specifically, the Newborn Screening Laboratory is in the process of acquiring three new tandem mass spectrometers, which it will use to perform approximately 850,000 additional test determinations in support of the expanded newborn screening panel. The acquisition of this equipment is necessary because it is the primary laboratory technology used to detect these additional disorders. The laboratory room that will house the new instruments requires renovation to support the new technology, and these improvements are underway.

Additionally, the Department is upgrading the Newborn Screening Program's computer system, so to improve the existing newborn screening services and processes and incorporate the new disorders that are being added to the newborn screening panel. The new system will provide robust data encryption to protect individuals' health information, seamless integration of laboratory instrumentation, advanced quality control

reports for regulatory compliance, built-in statistical collection and reporting to monitor specimen workflow and efficiency, pre-configured Health Level Seven message support to connect with hospital systems, and 24-hour electronic access to patient reports by means of a web-based reporting module. The use of electronic reporting mechanisms will greatly streamline the Newborn Screening Program's interactions with the State's physicians and birthing facilities. Infrastructure improvements are also in process to provide real-time back up for critical newborn screening data.

As for the Follow-Up Program, it will administer funding to support regional specialized treatment centers to ensure access to specialized medical care for these eight additional disorders. Thus, as described above, the Department has incurred and continues to incur increased ongoing costs to perform screening and follow-up services and to implement its quality and infrastructure improvement efforts since the last fee increase in 2008. However, the existing fee of $90.00 is inadequate to cover the new costs attributable to the expansion of the newborn screening panel. Therefore, a fee-for-service increase is necessary to assure that the Newborn Screening Program can continue to perform, at levels of high quality, this mandated and critically important public health service.

To address the increase in costs that the Department has incurred and will continue to incur resulting from these events, the Department proposes to amend existing N.J.A.C. 8:45-2.1 to increase the fee for the newborn screening panel from $90.00 to $150.00. The Department has determined that increasing the newborn screening panel fee from $90.00 to $150.00 is reasonable and necessary to offset the costs of performing screening and follow-up, including new instrumentation and computer upgrades, and to

ensure access to specialized treatment as the Department expands the newborn screening panel. This increase will allow the Department to fulfill its statutory obligations.

As the Department has provided a 60-day comment period for this notice of proposal, it is excepted from the rulemaking calendar requirements pursuant to N.J.A.C 1:30-3.3(b).

Social Impact

The Department anticipates both positive and negative reaction to the proposed amendment. Facilities that provide maternity services (mainly hospitals), physicians, and insurance companies may express negative concerns regarding the increased fee. Conversely, program beneficiaries and child advocacy groups may react positively to the fee increase because it will secure a stable funding source and advance technological services for newborn screening. Newborns and their families benefit from the Department's ability to continue to offer high quality laboratory and follow-up services and to ensure that specialized diagnostic and treatment services are accessible to all affected newborns and their families. The State's facilities that provide maternity services collect specimens from approximately 100,000 infants each year and send them to the Newborn Screening Laboratory for screening. The Newborn Screening Program identifies over 300 newborns each year who have some form of a disorder on the State's newborn screening panel.

Existing technology can identify affected infants with disorders, often before signs and symptoms occur. If affected infants are not tested, identified early, and treated appropriately, they may suffer life-long severe disabilities and/or premature death. The

Newborn Screening Program requires appropriate funding to perform its mandated functions as required by law.

Economic Impact

The proposed amendment will affect all facilities that provide maternity services, including hospitals and birthing centers, as well as the entities that support the provision of maternity services, including insurance companies, companies providing maternity benefits for their employees, and some physicians. The greatest impact will be on hospitals with high birth volume. Although some of the facilities may pass the increased cost to insurance companies, parents, or charity care, those facilities that do not receive private or public reimbursement will have to absorb the cost. These facilities receive newborn testing laboratory services through the purchase of prepaid forms from the Department of Health. The budgetary economic impact to these facilities will be proportional to the number of births occurring at these facilities.

Failure to adopt this amendment could result in the Department's inability to maintain comprehensive newborn infant laboratory testing and follow-up services. Limited resources would result in testing and reporting backlogs, failure to identify and ensure that newborns are in treatment within nationally recognized timelines, and delays in modernization of technology. The economic impact of delays in identification and appropriate medical intervention is significant and may result in developmental disabilities, life-long morbidity, or premature death. Indeed, the cost of life-long morbidities could be exorbitant if adequate newborn screening and timely integrated follow-up intervention and treatment services are not provided.

Private laboratories provide testing for newborn screening disorders, at higher fees than the fee the Department proposes to establish. In addition, private laboratories provide only testing services. In contrast, the New Jersey Newborn Screening Program is comprehensive as it provides both testing and follow-up services. The requested fee increase will support the entire newborn screening program - the screening panel and the follow-up program.

Federal Standards Statement

There are no Federal standards or requirements that mandate the testing and follow-up of newborns for biochemical or genetic disorders, or that address the imposition of fees to support these activities. Therefore, a Federal standard analysis is not required.

As the Summary describes above, the RUSP is a recommendation, not a requirement, of the United States Department of Health and Human Services. There are currently 35 conditions listed on the RUSP, and the State newborn screening panel includes all but three of these conditions, namely, Pompe, Hurler Syndrome, and adrenoleukodystrophy. However, with the passage of the new State laws that require the Newborn Screening Program to add adrenoleukodystrophy, mucopolysaccharidosis I, which is also known as Hurler Syndrome, mucopolysaccharidosis II, and five lysosomal storage disorders, which includes Pompe, to the newborn screening panel, the number and types of biochemical and genetic disorders for which the Newborn Screening Program screens infants for and identifies infants with will exceed the national recommended standard, upon completion of the technological and infrastructural improvements required to implement screening for these additional conditions.

Jobs Impact

The Department does not anticipate that the proposed amendment would result in the creation or loss of any jobs.

Agriculture Industry Impact

The proposed amendment would not have any impact on the agriculture industry.

Regulatory Flexibility Analysis

Over 95 percent of the in-State births take place in hospitals, none of which is a "small business" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Fewer than one percent of births occur at home, in doctor's offices, or in birthing facilities. Most of these are small businesses within the meaning of the Regulatory Flexibility Act. The place of birth is not known (that is, not stated on birth certificates) for the remaining births.

As the Summary above describes, the proposed amendment would increase the fee-per-service for the newborn screening panel, without regard to business size. However, the total cost to entities required to comply with N.J.A.C. 8:45-2.1 would be proportional to the number of births each entity performs. Thus, those entities that require greater use of the Newborn Screening Program's services would incur a greater overall compliance cost than those that use the services less frequently.

The proposed amendment would not modify other existing compliance requirements that apply to facilities subject to the newborn screening requirements set forth in N.J.A.C. 8:18, such as the need to purchase prepaid forms from the Department, collect samples from newborn infants, and transmit completed forms and samples to the Newborn Screening Program.

The Department is proposing no lesser or differing standard based on business size, as the cost to the Department to perform each newborn screening panel is the same regardless of where each infant is born. Moreover, as described above, the cost to facilities performing maternity services overall will inherently be proportional to business size, when viewed in terms of the number of births each facility performs.

Housing Affordability Impact Analysis

The proposed amendment would have an insignificant impact on the affordability of housing in New Jersey and it is extremely unlikely that it would evoke a change in the average costs associated with housing because the proposed amendment only affects the fee for the newborn screening program.

Smart Growth Development Impact Analysis

The proposed amendment would have an insignificant impact on smart growth development and it is extremely unlikely that it would evoke a change in housing production within Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey, because the proposed amendment only affects the fee for the newborn screening program.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 2. LABORATORY CHARGES

8:45-2.1 Fees; generally

(a) The following [fee-for-service cost structure shall] **fees-for-service** apply to **laboratory tests that** the [New Jersey] Department of Health [and Senior Services] **performs**:

Laboratory Test	
[Inborn Errors of Metabolism	$90.00]
(PKU, T4 Galactosemia, Sickle Cell, Biotinidase Deficiency, CAH, Cystic Fibrosis, MSUD, MCAD, SCAD, LCAD, VLCAD, Citrullinemis, Argininosuccinic Acidemia, PA, MMA, GA-1, IVA, HMG, 3-MMC)	

…

(b) (No change.)

(c) The following fee-for-service applies:

Newborn Screening Program:	**$150.00**