Filed August 21, 2026

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

Clinical Laboratory Services

Laboratory Charges

Fees; Generally

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

Authorized By: Dr. Raynard E. Washington, Commissioner, Department of Health.

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

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

Proposal Number: PRN 2026-051.

Submit written comments by November 20, 2026, electronically to: www.nj.gov/health/legal/ecomments.shtml or by regular mail postmarked by November 20, 2026, to:

Kimberly Jenkins, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

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The agency proposal follows:

Summary

N.J.S.A. 26:2-110 and 111 directs the Newborn Screening Program in the Department of Health (Department) to screen all infants born in the State for the presence of certain biochemical and genetic disorders. N.J.S.A. 26:2-111 authorizes the Commissioner of the Department (Commissioner) 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 review and follow-up on positive cases. N.J.S.A. 26:2-111 authorizes the Commissioner to establish and charge a reasonable fee 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 (the 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 that the Department performs newborn screening for 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, Newborn biochemical screening, 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.A.C. 8:18-1.3 (42 N.J.R. 2526(a); 43 N.J.R. 835(a)). 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).

Thereafter, the Newborn Screening Laboratory and the Follow-Up Program were tasked with expanding the screening panel to include nine new disorders. Specifically, in May 2010, based on the recommendation of the Advisory Committee on Heritable Disorders in Newborns and Children, the Secretary of the U.S. Department of Health and Human Services 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 Newborn Screening Advisory Review Committee (NSARC) voted to recommend that the Department 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 and

brought New Jersey into the vanguard of states that screen newborns for all of the disorders on the RUSP.

Legislation enacted after the 2008 fee increase added 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."

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 authorized 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 acquire the capacity to screen for the additional disorders described above, and to upgrade the program's computer system and expand the services provided by the Follow-Up Program, the Department increased the newborn screening fee from $90.00 to $150.00 in March 2017. See 48 N.J.R. 1485(a); 49 N.J.R. 642(a).

In 2020, P.L. 2019, c. 390 (approved January 21, 2020, and effective August 1, 2020), codified at N.J.S.A. 26:2-111.8, mandated newborn screening for the genetic mutations associated with spinal muscular atrophy and required the Commissioner to develop a comprehensive program for follow-up services and procedures, including genetic counseling for parents about the risk that one or both may be a carrier of the mutation, that one of their other children may be born with spinal muscular atrophy or carry the mutation and pass it on to their children, and make information about treatment options available. It further authorized the Department to "charge a reasonable fee to administer" the screening tests.

In addition, P.L. 2019, c. 296 (approved January 13, 2020, and effective July 11, 2020) amended N.J.S.A. 26:2-110, revising the Legislature's findings and declarations to reaffirm that newborn screening is an essential public health activity and memorializing the Legislature's intent that: (1) the Newborn Screening Program incorporate ongoing advances in technology and treatment to enhance its capacity to screen and protect the health and quality of life of infants in the State; (2) newborn data collection be standardized; (3) conditions detected be tracked and monitored; and (4) information on newborn screening be readily accessible, current, and understandable to both health care providers and parents or guardians. That same law also amended N.J.S.A. 26:2-111 to expressly provide that the Newborn Screening Program screen all

infants born in the State for the disorders recommended by the NSARC and approved by the Commissioner with consideration of the RUSP. The amendments clarified that the fee charged by the Department is to be used not only for tests performed, but for the screening, follow-up, treatment, and education performed by the Department, as well as ongoing infrastructure upgrades, including electronic access for physicians to obtain screening results and follow-up recommendations. P.L. 2019, c. 296 also added a new section of law, codified at N.J.S.A. 26:2-110a, formally recognizing the existence and role of the NSARC and requiring that the NSARC annually review the panel of disorders for which screening is done, as well as current screening technologies, treatment options, and educational and follow-up procedures, and make recommendations to the Commissioner to improve the Newborn Screening Program.

In 2022, P.L. 2021, c. 413 (approved January 18, 2022, and codified at N.J.S.A. 26:2-111.9 and 111.10), mandated that all infants be tested for congenital cytomegalovirus (cCMV) infection upon the occurrence of several specific conditions — some of which are outside of the Department's control — such as the inclusion of screening for cCMV in the RUSP and the availability of quality assurance materials for the cCMV test from the Centers for Disease Control and Prevention (CDC). The law also requires the Commissioner to establish a public awareness campaign to educate pregnant women about cytomegalovirus and cCMV and the value of early detection and intervention, including the provision of educational materials to include the cause and nature of cytomegalovirus and cCMV, diagnostic procedures and indications for their use, lifestyle issues relating how a pregnant person can transmit cCMV to the fetus, and the availability of diagnostic and treatment services. That law also authorizes the

Department to charge a reasonable fee for the test in an amount to be determined by the Commissioner and provides that the fee may be periodically increased as the Commissioner determines necessary.

Since the last fee increase in 2017, the Newborn Screening Program has expanded the screening panel to include screenings for the five lysosomal storage disorders, mutations associated with spinal muscular atrophy, and X-linked adrenoleukodystrophy, and offers comprehensive follow-up services for all 61 disorders for which the Newborn Screening Program currently screens newborns. The Newborn Screening Program will be required to commence screening for mucopolysaccharidosis Type II (MPS II) and cCMV once all statutory prerequisites have occurred. These include, among other prerequisites, the NSARC's recommendation that the test be included in the screening panel, which occurred by letter dated October 30, 2022, to the Commissioner, as well as the Department's acquisition of equipment necessary to perform the test. In order to screen for MPS II and cCMV when the remaining statutory prerequisites are met, the Department will need to have acquired the new instrumentation, including multiple specialized mass spectrometers, service agreements for those instruments, multiple dedicated full-time staff, and required reagents and materials.

Consistent with the statutory directive that the Newborn Screening Program remain at the forefront of advances in technologies and treatment modalities, in July of 2022, the Newborn Screening Program enhanced the sensitivity of its cystic fibrosis (CF) screening, which has enabled the program to detect cases of CF that would have previously been missed. By adjusting its screening algorithm to increase the number of

CF transmembrane conductance regulator (CFTR) gene variants that are detectible — from one to 139 variants — the program is now better able to identify babies that have CF, are carriers of any of the gene variants, or have CFTR-related syndromes. Further, the Newborn Screening Program has been conducting educational and outreach activities aimed at hospitals and physicians to improve specimen quality and to ensure timely testing and reporting, which are critical program improvements.

The Newborn Screening Program has calculated that the current cost per sample of the screening and follow-up services provided — assuming 98,000 babies born per year — is $184.37, which exceeds the $150.00 fee currently charged to hospitals for the newborn screening kit. Approximately one third of the $150.00 fee is allocated to costs of providing follow-up services and two-thirds are allocated to the costs of screening by the Newborn Screening Laboratory.

The NSARC has informally indicated that it intends to recommend to the Commissioner that the Department screen for Guanidinoacetate Methyltransferase Deficiency (GAMT) as soon as an FDA-approved screening kit is available. GAMT is a disorder of creatine biosynthesis that is caused by variants in the GAMT gene that lead to cerebral creatine deficiency and neurotoxic levels of guanidinoacetate. When left untreated, GAMT deficiency is associated with significant intellectual disability, limited speech development, recurring seizures, behavioral problems, and involuntary movements. The future incorporation of GAMT into the screening panel will require the purchase of specialized instrumentation and associated service contracts. The NSARC has also indicated plans to review additional disorders for future recommendations following the conclusion of the NSARC's current review.

The Newborn Screening Program, in order to meet increasing operational costs, address the Newborn Screening Program's current operating deficit, and proactively develop the capacity and infrastructure to screen for MPS II, cCMV, and any disorders that the NSARC may recommend in the near future following its review, proposes to increase the newborn screening fee. The Commissioner's ability to determine and impose an appropriate fee for the newborn screening services is well established by statute and has been reiterated throughout additional amendments to N.J.S.A. 26:2-110 et seq. The Department proposes to amend N.J.A.C. 8:45-2.1, Fees; generally, to increase the fee for a newborn screening kit from $150.00 to $260.00.

The Department has determined that increasing the newborn screening panel fee from $150.00 to $260.00 is reasonable and necessary to offset the costs of new instrumentation, servicing of that instrumentation, staffing, required physical renovations, offering educational and outreach services, and expanding its ability to provide follow-up services and facilitate specialized treatment for the additional disorders. This increase will allow the Department to fulfill its statutory obligations, sustain quality and technological improvements, address its current operating deficit, and accommodate the additional disorders that have been either legislatively included in the screening panel or that will be recommended for inclusion by the NSARC.

The Department has provided a 60-day public comment period on this notice of proposal, therefore, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

Facilities that provide maternity services (mainly hospitals), healthcare practitioners, and insurance companies may express concerns regarding the increased fee. Conversely, program beneficiaries and child advocacy groups may experience a positive social impact as the fee increase would secure a stable funding source and advance technological services for newborn screening. Newborns and their families would continue to benefit from the Department's ability to continue offering 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 healthcare facilities that provide maternity services collect specimens from approximately 98,000 infants each year and send them to the Newborn Screening Laboratory for screening. The Newborn Screening Program identifies about 250 newborns each year who have a confirmed diagnosis of a disorder on the State's newborn screening panel, and just under 10,000 newborns may have abnormal screening results that require action by the Follow-Up Program.

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 severe, life-long disabilities and/or premature death. The Newborn Screening Program requires appropriate funding to continue to perform its mandated functions as required by law.

Economic Impact

The proposed amendment would 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 healthcare practitioners. The greatest economic impact would 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. The budgetary economic impact to these facilities will be proportional to the number of births occurring at these facilities.

Failure to adopt this proposed 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 Newborn Screening Laboratory and the Follow-Up Program.

Federal Standards Statement

There are no Federal standards applicable to the proposed amendment. The Department does not propose the amendment at N.J.A.C. 8:45-2.1 pursuant to the authority of, or to implement, comply with, or participate in a program established pursuant to Federal law, or State law that incorporates or refers to a Federal law, standard, or requirement. The Department proposes the amendment at N.J.A.C. 8:45-2.1 pursuant to the authority at N.J.S.A. 26:2-110 through 112, specifically 26:2-111. Therefore, a Federal standards 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. When screening commences for MPS II and should the NSARC formally recommend, and the Commissioner accepts the recommendation, that the Department screen for GAMT, the Department would then be screening for all of the Core Conditions on the Recommended Uniform Screening Panel as of July 2024, as well as most of the Secondary Conditions.

Jobs Impact

The Department does not anticipate that the proposed amendment would result in the creation of new jobs by entities subject to these rules, nor does it anticipate that the proposed amendment would result in the loss of jobs in the State.

Agriculture Industry Impact

The Department does not anticipate that the proposed amendment would have an impact on the agriculture industry in the State of New Jersey.

Regulatory Flexibility Statement

Over 95 percent of the in-State births take place in hospitals, none of which are 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 above Summary 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 at 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 no impact on the affordability of housing in New Jersey and would not evoke a change in the average costs associated with housing because the proposed amendment addresses newborn screening fees and would have no bearing on housing costs.

Smart Growth Development Impact Analysis

The proposed amendment would not have an impact on the achievement of smart growth and would not evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, pursuant to the State Development and Redevelopment Plan in New Jersey because the proposed amendment addresses newborn screening fees and would have no bearing on smart growth or housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated the proposed amendment and determined that it would not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

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

SUBCHAPTER 2. LABORATORY CHARGES

8:45-2.1 Fees; generally

(a)-(b) (No change.)

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

Newborn Screening Program:	[$150.00] **$260.00**