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

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

Proposed: August 1, 2016, at 48 N.J.R. 1485(a).

Adopted: March 13, 2017, by Cathleen D. Bennett, Commissioner, Department of Health.

Filed: March 13, 2017, as R.2017 d.064, **without change**.

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

Effective Date: April 3, 2017.

Expiration Date: November 20, 2020.

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received timely comments from the following commenters during the 60-day public comment period, which ended on September 30, 2016:

1. Billee Wolff, RN, Doula, Childbirth Educator and Birth Advocate
2. Dina Aurichio, New Birth Experiences Home Birth Midwifery
3. Elizabeth Ryan, Esq. President & CEO, New Jersey Hospital Association
4. Eileen Horton, RN, MSN, MSM, NEA-BC Senior Vice President, Hospital Administration / Chief Quality Officer, Capital Health System
5. Laura Maimone, CentraState Medical Center
6. Sarah Lechner, Esq., Assistant Vice President, Policy Development and Government Affairs, RWJBarnabas
7. Peter A. Kaprielyan Vice President, Government and External Relations, Inspira Health Network
8. Robyn D'Oria MA, RNC, APN Executive Director, Central Jersey Family Health Consortium
9. Suzanne Ghee, MPA, Director, Health Policy and Programs, Virtua
10. Vicki Hedley, Licensed Birth Midwife
11. Wendy Jonesepstein, no affiliation provided
12. Douglas E. Shirley, Senior Executive Vice President and Chief Financial Officer, Cooper University Health Care
13. Kimberly O. Simensen, Senior Vice President, Systems & Network Planning, Business Development, Atlantic Health System
14. Robert P. Wise, FACHE, President & CEO, Hunterdon Healthcare

Quoted, summarized, and/or paraphrased below, are the comments and the

Department's responses thereto. The numbers in parentheses following each comment below correspond to the commenters listed above.

General Comments

1. COMMENT: The commenter appreciates "DOH's efforts and enthusiastically supports the screening of newborns to provide early detection and treatment for certain inborn genetic and metabolic disorders and prevent their serious or life-threatening complications. It is our mission as the safety net providers in our communities to provide these vital services to the newborns we deliver each and every day." (3)

2. COMMENT: The commenter states that "[w]e applaud the Department for its work the past seven years increasing the number of screening of newborns for diseases and conditions. New Jersey continues to lead the country with 55 disorders screened for newborns." (4)

3. COMMENT: The commenter appreciates "the Department's support of the screening of newborns to provide early detection and treatment for certain inborn genetic and metabolic disorders and prevent their serious or life-threatening complications. It is a vital part of our mission to provide these important services to the newborns that we deliver every day." (7)

4. COMMENT: The commenter states that "the consortium and the hospitals applaud the Department of Health for their work over the past seven years to increase the number of diseases and conditions screened for in New Jersey. It is greatly appreciated that recommendations from the NJ Newborn Screening Advisory and

Review Committee were recognized and adopted. New Jersey remains a leader in the country with 55 disorders screened for in the newborn period, which can affect the health and wellness of our most vulnerable citizens, our infants. Many of these disorders, when identified early, can lead to early treatment and prevention of the devastating consequences if left untreated including significant morbidity and in some cases mortality." (8)

5. COMMENT: The commenter provides that "'[w]e at Virtua applaud the efforts of the Department in proposing rule changes that aim to reduce infant mortality and morbidities for genetic and metabolic disorders." (9)

6. COMMENT: The commenter expresses appreciation for "DOH's efforts and enthusiastically supports the screening of newborns to provide early detection and treatment for certain inborn genetic and metabolic disorders and prevent their serious or life-threatening complication. It is our mission as a safety net provider in our community to provide these vital services to the newborns we deliver each and every day." (12)

7. COMMENT: The commenter "strongly supports the screening of newborns to provide early detection and treatment for certain inborn genetic and metabolic disorders. We are committed to providing robust screening services to the newborns we deliver each and every day." (13)

RESPONSE TO COMMENTS 1 THROUGH 7: The Department recognizes the commenters long-standing commitment to newborns in New Jersey and appreciates the commenters acknowledgement of the Newborn Screening Program's leadership nationally.

Individual's Concerns Regarding the Fee Increase

8. COMMENT: The commenter states that it is "unacceptable that NJ is raising the cost of the Newborn Screening cards" because it "puts an unnecessary burden on homebirth midwives and families having a homebirth." (1)

9. COMMENT: The commenter expresses concern that the "fee increase will cause me to not be able to offer this test to my clients" and that parents "will not want to prepay for these tests, as they will be cost prohibitive." (2)

10. COMMENT: The commenter states that she is a home birth midwife and has been "paying $90 per newborn screening form since her licensure in 2008" and that the costs are absorbed into her practice "as most of our clientele cannot afford to pay for their newborn screening forms." The commenter further states that "this cost has already been a burden on my practice. To increase the cost to $150 will create a huge burden, both on myself as a practitioner and on my clients, who will now have to absorb a cost they cannot afford. We will have to send clients to a pediatrician to do this test, and most pediatricians do not carry newborn screening forms in their offices, except for repeat forms." (10)

11. COMMENT: The commenter states that "the Price raise from $90 to $150 is not fair. It is extreme to nearly double the price. This excluded some babies from being tested due to the cost." (11)

RESPONSE TO COMMENTS 8 through 11: While the Department understands the commenters' concerns about the increased cost for newborn screening, the Department is unable to avoid the fee increase, as it is necessary to maintain and expand the

State's comprehensive newborn screening system, which includes education, laboratory testing, follow-up, diagnostic testing, and treatment services. Specifically, the fee increase is essential not only for the inclusion of eight new disorders that were recently added to the screening panel pursuant to legislation, but also for the continued improvement of the existing newborn screening services and processes. To add the new disorders to the panel and improve the existing screening services and processes, the Department must acquire new laboratory equipment; renovate the laboratory room that will house the new 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 by providing funding to support regional specialized treatment centers to ensure access to specialized medical care for the eight additional disorders. Thus, 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. The existing fee of $90.00 is inadequate to cover the new costs attributable to the expansion and maintenance of the Newborn Screening Program. Therefore, a fee-for-service increase to $150.00 is necessary to ensure that the Newborn Screening Program can continue to perform, at levels of high quality, this mandated and critically important public health service. Accordingly, the Department will make no change upon adoption in response to these comments.

Additionally, the Department reminds the commenters that the collection of newborn screening samples is mandatory, not discretionary, pursuant to N.J.S.A. 26:2-111. In accordance with this mandate, N.J.A.C. 8:18-1.5 requires all birth attendants,

including midwives, to collect a newborn screening specimen from all infants born outside of, and not admitted to, a hospital before the infant is 48 hours old and submit the specimen to the Department for testing.

Cost of Newborn Screening in Other States

12. COMMENT: The commenter states that “New York State does not charge for this mandatory test!!!” (1)

13. COMMENT: The commenter questions how “the NBS test in NY and PA are given to midwives at no cost, where we, in NJ are now wanting to raise the fee to $150.00.” (2).

14. COMMENT: The commenter states that “the amount of fees nationwide vary greatly state by state, with some states charging hospitals $0 for each test.” (7)

15. COMMENT: The commenter states that “New Jersey’s newborn screening costs are already some of the highest in the country” and “with this new proposal of an increase to $150, New Jersey will be the highest cost in the country.” (9)

16. COMMENT: The commenter states that the increased cost for newborn screening will be passed on to consumers, but “passing on a cost like this to consumers, when newborn screening in NY is cost-free to consumers and practitioners, will in all likelihood result in a reduction in compliance with screening. Folks simply cannot afford this!” (10)

17. COMMENT: The commenter states that “hospitals are rated nationally for the cost of care against neighboring states. Hunterdon Medical Center is located in a broader

county next to Pennsylvania. As such, there is an increased risk of losing patients to out of state hospitals due to impacts on service fees and delivery." (14)

RESPONSE TO COMMMENTS 12 THROUGH 17: As with many government services, individual states finance their newborn screening programs in different ways. Most states collect a fee for screening, but health insurance or other programs often cover all or part of the cost. In New Jersey, the Newborn Screening Program collects a reasonable fee from healthcare providers for the screening kits, which is authorized by statute. See N.J.S.A. 26:2-111 et seq. Although New York and Pennsylvania do not charge providers for their newborn screening kits, there are states that charge the same or higher fees than New Jersey. For example, Alabama and Minnesota charge $150.00 for newborn screening, while Alaska and Rhode Island charge $159.50 and $162.98, respectively. In addition, Pennsylvania only mandates screening for nine disorders with the option for parents to have their children screened for up to 50 additional disorders, which is known as supplemental screening. While Pennsylvania does not charge for a newborn to be screened for the nine mandated disorders, there is a cost associated with the supplemental screening, which may be covered by insurance. In contrast, New Jersey will have one of the most comprehensive newborn screening programs in the country with screening for 63 disorders at the conclusion of the current expansion. All 63 disorders are screened for by the Department and are covered by the newborn screening fee. In order to provide this extensive screening program to all newborns born in this State, the Department must increase its fee for this service. Indeed, most of the disorders for which the Department screens are life-threatening and necessitate timely identification, diagnosis, and intervention to prevent life-long morbidity and/or

premature death. The proposed fee increase will ensure that newborns inflicted with such disorders are caught early, so that the infant may receive prompt treatment services. Accordingly, the Department will make no change upon adoption in response to these comments.

Transparency of Fee Increase

18. COMMENT: The commenter states "NJHA strongly objects to the unfair financial burden that hospitals must bear to support the increase in funding for the program. Prior to 1999, the DOH assessed a fee on hospitals of $27 for every newborn delivered in a facility to cover the costs of tests administered by the state laboratory. Since 1999, the assessment on hospitals for these tests has increased incrementally throughout the years to $71 in 2004 and recently to $90 in 2008. NJHA estimates that the current proposal to raise the fee to $150 (more than a 50 percent increase) would increase the cost by an estimated $6.5 million annually, bringing the total cost for the service to over $16 million statewide. While DOH identifies additional costs that the state laboratory must incur due to an increase in tests and services/processes for performing these tests, the proposal provides no transparency in the justification for the amount of the increase. We respectfully request a breakdown of the cost estimates used to determine the rate of the increase in the proposal." (3)

19. COMMENT: The commenter states that the RWJ Barnabas health care system "represents approximately one quarter of the statewide births, having delivered more than 23,000 babies in 2015. The proposed $60 increase, if promulgated, would

increase the delivery fees paid by RWJ Barnabas Health to the State by almost $1.4 million and would result in our system paying a nearly $3.5 million annually in birth screening fees. Of note, two of our safety net hospitals, Monmouth Medical Center and Newark Beth Israel Medical Center, which deliver the second and third most babies within in our system, would sustain significant fee increases of approximately $300,000 and $181,000, respectively, as a result of this proposal. Our concerns, expressed in this comment letter, do not stem from the appropriateness or desirability of these tests, but rather the amount of the increase sought by the Department." The commenter goes on to state that "the Department noted in its proposal, this increase is the result of multiple legislative initiatives as well as the Department's adoption of national recommendations made by a national advisory council within the Health Resources and Services Administration ("HRSA"). In total, since the last fee increase in 2008, nine (9) new disorders have been added to the newborn screening panel. It is unclear, however, based on the Department's proposal, how the increase by a mere nine screens could justify a $60 fee increase when, in 2008, the Department only sought a $19 fee increase to support the so-called "major" expansion by 23 disorders to the screening panel." (6)

20. COMMENT: The commenter has "significant concerns regarding the unfair financial burden that our health system must bear to support the increase in funding for the program. To this extent, and based on current projections, we estimate that annual fees will increase from $276,840 to $461,400, representing an increase of $184,560 (67%) for the Inspira Health Network. While the Department indicates that additional costs that the state laboratory must incur due to an increase in tests and services/processes

for performing these tests, the proposal provides no clarity for the basis of the increased amount. It would be very helpful to understand the basis for the increase." (7)

21. COMMENT: The commenter urges the Department to "cancel the proposed rate increase for the Newborn Biochemical Screening Panel." The commenter further states that "at Virtua, we deliver nearly 8,000 babies a year and take great pride in affording our patients top decile quality at an affordable cost. As we strive to achieve the best care experience for our patients, we are on the journey to becoming "Baby-Friendly." Our health system has invested significant resources to be awarded this coveted status. Becoming a Baby-Friendly facility is a comprehensive, detailed process. It compels facilities to examine, challenge and modify long standing policies and procedures with the goal of achieving optimal infant feeding outcomes and mother/baby bonding." The commenter further states that "[w]e do not bill for this service and do not have the ability to collect a fee for this" and "respectfully request[s] a breakdown of the cost estimates used to determine the rate of the increase in the proposal." (9)

22. COMMENT: The commenter states that Cooper University Hospital "strongly objects to the unfair financial burden this amendment directly places on the Hospital community to support the increase in funding for the program. With the current fee at $90 per test, the fee CUH currently supports is approximately $190,000 annually. The proposed amendment would increase this burden to approximately $316,000, or $126,000 increase annually. While the DOH identifies additional costs that the state laboratory must incur due to an increase in tests and services/processes for performing these tests, the proposal provides no transparency in the justification for the amount of

the increase. We respectfully request a breakdown of the cost estimates used to determine the rate of the increase in the proposal." (Emphasis removed) (12)

23. COMMENT: The commenter "finds the increase in fee objectionable. Prior to 1999, the DOH accessed a fee on hospitals for $27 for every newborn delivered in a facility to cover the costs of tests administered by the state laboratory. Since 1999, the assessment on hospitals for these tests has increased incrementally throughout the years to $71 in 2004 and recently to $90 in 2008. NJHA estimates that the current proposal to raise the fee to $150 (more than a 50 percent increase) would increase the cost by an estimated $6.5 million annually, bringing the total cost for the services to over $16 million statewide. While the DOH identifies additional costs that the state laboratory must incur due to an increase in tests and services/processes for performing these tests, the proposal provides no clarity or justification for the amount of the increase. In order to understand the basis of the proposed fees, we respectfully request a breakdown of the cost estimates used to determine the rate of the increase in the proposal." (13).

24. COMMENT: The commenter states "the proposed fee increase appears arbitrary and is costly to hospitals at a time when healthcare systems are seeking ways to decrease expense to maintain services and stability. Therefore, instituting a more than 50 percent fee increase for this important screening is not good for hospitals in New Jersey." (14)

RESPONSE TO COMMENTS 18 THROUGH 24: The Newborn Screening Program (Program) fee was increased to $90.00 per newborn in 2008, to cover expansion and operating costs for both the laboratory ($61.00) and follow-up program ($29.00). The

current proposed fee increase was calculated to fund the Program for the next five fiscal years and includes increased operating, as well as new disorder expansion costs. At the conclusion of the current expansion, which will add screening for eight additional disorders, New Jersey will have one of the most comprehensive Newborn Screening Programs in the country. The newborn screening laboratory's portion of the fee will increase to $93.00. This $32.00 increase for the Laboratory includes $15.00 for inflationary costs since the last increase; the addition of screening for severe combined immunodeficiency (SCID) in 2014, which was performed without increasing the fee; and ongoing quality improvement initiatives for the existing newborn screening processes, including replacement of obsolete instrumentation. The remaining $17.00 of the laboratory portion of the increase will be dedicated to the disorder panel expansion efforts, including new equipment, additional reagents and supplies, an upgrade to the Newborn Screening Program's computer system, and additional staff. However, newborn screening is much more than laboratory testing. It is a coordinated and comprehensive system consisting of education, screening, follow-up, diagnosis, treatment and management, and program evaluation. The New Jersey Newborn Screening Program is part of a coordinated and comprehensive system that includes all of these activities. As a result, approximately 40 percent of the newborn screening fee, $57.00, will be allocated to the Department's Follow-up Program. This part of the Newborn Screening Program makes every reasonable attempt to connect each newborn with an out-of-range screen to an appropriate medical specialist who will perform the required diagnostic tests and initiate treatment, if necessary. The Department's Follow-up Program also provides education to parents and providers and

health service grants to fund a safety net of subspecialists who provide the necessary follow-up on infants with out-of-range screens. All of these services play an important role in avoiding delays in making critical diagnoses that save the lives of newborns. Because it is necessary to increase the fee to $150.00 to ensure that these essential services are available to all newborns, the Department will make no change to the fee upon adoption in response to these comments.

Private Laboratory Testing

25. COMMENT: The commenter states that “hospitals are required by the state to take part in this program and they are not permitted to substitute the state laboratory with the services of private laboratories to perform these tests. Therefore, hospitals are not able to search for and provide the testing services at a more reasonable fee. As the healthcare industry looks for ways to reduce costs, this is a great opportunity to provide a quality service at a lesser cost. We respectfully request that DOH allow hospitals to utilize private laboratories for the purpose of testing and require the labs to submit the results to the state laboratory for recordkeeping and follow-up.” (3)

26. COMMENT: The commenter states that “the absence of outside competition does not allow for consideration of other potential cost effective alternatives for the same service.” (5)

27. COMMENT: The commenter states that “hospitals are required by the state to take part in this program and they are not permitted to substitute the state laboratory with the services of private laboratories to perform these tests. Therefore, hospitals are not able

to search for and provide the testing services at a more reasonable fee. As the healthcare industry looks for ways to reduce costs, this is would present a great opportunity to provide a quality service at a lesser cost. To this end, we respectfully ask that the Department allow hospitals to utilize private laboratories for the purpose of testing and require the labs to submit the results to the state laboratory for record keeping and follow-up." (7)

28. COMMENT: The commenter "respectfully requests the DOH to permit hospitals to use private laboratories for the purpose of testing, inclusive of requirements for the labs to submit the results to the state laboratory for record keeping and follow-up." (9)

29. COMMENT: The commenter states that "hospitals are required by the state to take part in this program and they are not permitted to substitute the state laboratory with the services of private laboratories to perform these tests. Therefore, hospitals are not able to search for and provide the testing services at a more reasonable fee. As the healthcare industry looks for ways to reduce costs, this is a great opportunity to provide a quality service at a lesser cost. We respectfully request that DOH allow hospitals to utilize private laboratories for the purpose of testing and require the labs to submit the results to the state laboratory for record keeping and follow-up." (Emphasis removed) (12)

30. COMMENT: The commenter states that "the State has maintained a monopoly on this mandatory testing service. Hospitals are not permitted to contract with private laboratories to perform these tests, thereby prohibiting hospitals from seeking a more cost efficient way to provide this service. As the healthcare industry looks for ways to reduce costs, this is a great opportunity to provide a quality service at a lesser cost. We

respectfully request that DOH allow hospitals to follow a competitive process to utilize private laboratories for the purpose of testing and require the labs to submit the results to the state laboratory for recordkeeping and follow-up." (13)

31. COMMENT: The commenter states that hospitals are "mandated to utilize the state laboratory to perform the tests, removing the option for service expense savings by contracting with private laboratories." (14)

RESPONSE TO COMMENTS 25 THROUGH 31: First and foremost, the use of private laboratories to screen newborns for the disorders required by the Department is not contemplated by the Newborn Screening Act (Act), N.J.S.A. 26:2-110 et seq. Specifically, N.J.S.A. 26:2-111 provides that "the State Department of Health may charge a reasonable fee for the tests performed pursuant to this act. The amount of the fee and the procedures for collecting the fee shall be determined by the commissioner. The commissioner shall apply all revenues collected from the fees to the testing and treatment procedures performed pursuant to this act." Further, N.J.S.A. 26:2-111.5, 111.6, and 111.7 all provide that testing for the disorders named therein is to begin after the Department of Health acquires "the equipment necessary to implement the expanded screening tests." Moreover, the Act only references the use of private laboratories for testing when the parents of a newborn decide to have their child tested for a disorder that is not required by the Department. See N.J.S.A. 26:2-111.1. When all these statutory provisions are read as a whole, which is necessary when interpreting legislation, so that the Legislature's intent can be effectuated, it becomes evident that the Department of Health, and not private laboratories, is required to perform the

newborn screening tests required under the Act. To hold otherwise would render the above mentioned statutory provisions meaningless.

Even more, the legislative history for the Act supports the conclusion that the Department, and not a private laboratory, is required to conduct the mandated newborn screen testing. As stated above, when a statute is analyzed, effect must be given to the Legislature's intent, which is evidenced by the language of the statute, the policy behind the statute, concepts of reasonableness, and legislative history. The history for this legislation provides that the Act "**requires** the Department of Health to test newborns" for the disorders mandated thereunder. Senate Institutions, Health and Welfare Committee, No. 78 of 1980 (Emphasis added). Thus, the plain language of the Act coupled with its legislative history demonstrate that the Department is required to conduct the newborn testing, not private laboratories.

Even if private testing was contemplated by the Act, the use of private laboratories for all newborn screenings would not be possible or appropriate. At the conclusion of the current expansion, which will add screening for eight additional disorders, New Jersey will have one of the most comprehensive newborn screening programs in the country. Not all private laboratories offer the same all-inclusive panel as the State Laboratory. In addition, most of the disorders for which the Department screens are life-threatening and necessitate timely identification, diagnosis, and intervention to prevent life-long morbidity and/or premature death. As a result, unlike many private laboratories, the Department's Newborn Screening Program provides overnight courier service to transport these critical specimens and operates six days per week and holidays. That said, newborn screening is much more than laboratory testing.

It is a coordinated and comprehensive system consisting of education, screening, follow-up, diagnosis, treatment and management, and program evaluation, which are required by the Act. See N.J.S.A. 26:2-111(stating that "[t]he commissioner shall provide a program of reviewing and following up on positive cases in order that measures may be taken to prevent mental retardation or other permanent disabilities" and that "[t]he department shall conduct an intensive educational and training program among physicians, hospitals, public health nurses and the public concerning those biochemical disorders. This program shall include information concerning the nature of the disorders, testing for the detection of these disorders and treatment modalities for these disorders)." Due to these statutory mandates, the New Jersey Newborn Screening Program is part of a coordinated and comprehensive system that includes all of the above-listed activities. Private laboratories provide only testing services and do not cover follow-up, diagnostic testing, or ensure access to treatment services. While a portion of the fee is utilized by the laboratory to acquire new equipment, purchase additional reagents and supplies, upgrade the Newborn Screening Program's computer system, and hire additional staff; 40 percent of the newborn screening fee is allocated to the Department's Follow-up Program to provide extensive follow-up services. This part of the Newborn Screening Program makes every reasonable attempt to connect each newborn with an out-of-range screen to an appropriate medical specialist who will perform the required diagnostic tests and initiate treatment, if necessary. The Department's Follow-up Program also provides education to parents and providers and health service grants to fund a safety net of appropriate subspecialists who provide the necessary follow up on infants with out-of-range screens. All of these services play an

important role in avoiding delays in making critical diagnoses that save the lives of newborns. Thus, the requested fee increase will support this entire comprehensive program, and utilization of a private laboratory will not alter the need for a fee increase to cover the increased costs of expanded follow-up, diagnostic testing, and treatment services.

Based upon the foregoing, the Department cannot permit healthcare providers to utilize private laboratories for the testing mandated by the Act. Accordingly, the Department will make no change upon adoption in response to these comments.

Support for Follow-Up

32. COMMENT: A commenter applauded the Department's "efforts to ensure that affected populations receive follow up testing and treatment," however, they did "not believe that the appropriate mechanism to pursue those goals is through a unilateral fee increase on hospitals." Moreover, the commenter questioned the Department's authority to include additional follow-up costs in any fee increase. Specifically, the commenter wrote "instead of seeking a fee increase to cover the costs associated with the additional nine new disorders added to the panel, the Department will be utilizing funding from the hospitals through the birth screening fees to support additional programming. The Department indicated in its proposal that it will expand a follow-up program to 'administer funding to support regional specialized treatment centers to ensure access to specialized medical care for these eight additional disorders.'" The commenter further stated that "the clear language of the enabling statutes indicates that

the Department has the authority to increase fees strictly for testing. See N.J.S.A. 26:2-11.5 (enabling the Department to charge a 'reasonable fee for the tests performed pursuant to this section); N.J.S.A. 26:2-111.6 (allowing the Department to charge 'a reasonable fee and any reasonable increase ... for the test performed pursuant to this section'); and N.J.S.A. 26:2-111.7 (authorizing the Department to charge 'a reasonable fee and any reasonable increase ... for the tests performed pursuant to this section') (emphasis added). This specific language is contrary to that found in other statutes requiring certain birth screens, which expressly indicate that the fees collected can be used for 'testing and treatment procedures.' See N.J.S.A. 26:2-111. Thus, the Legislature clearly expressed its intent that the Department expand the birth screening panels; however, limited its authority in increasing fees to cover only the actual cost incurred as a result of such expansion. In sum, RWJ Barnabas Health respectfully requests that the Department limit the increase sought strictly to the additional amounts required to add nine (9) disorders to the birth screening panel." (6)

RESPONSE: The Department disagrees with the commenter's reading of the Newborn Screening Act, N.J.S.A. 26:2-110 et seq. When interpreting a statute, the statutory words must be given their ordinary meaning and significance, and they must be read in context with related provisions in order to give sense to the legislation as a whole. When the Act is read as a whole, it becomes clear that the Department is permitted to charge a reasonable fee for newborn screening and apply that fee to both the testing and follow-up programs. Specifically, N.J.S.A. 26:2-111 provides that "[t]he commissioner shall ensure that treatment services are available to all identified individuals. **The State Department of Health may charge a reasonable fee for the**

tests performed pursuant to this act. The amount of the fee and the procedures for collecting the fee shall be determined by the commissioner. **The commissioner shall apply all revenues collected from the fees to the testing and treatment procedures performed pursuant to this act."** (Emphasis added). This statutory provision establishes that when the Commissioner collects a fee for any of the tests outlined under the Act, the fee is to be applied to both the testing and treatment procedures. Sections 111.5, 111.6, and 111.7 of the Act all mandate newborns to be tested for certain disorders. Because these tests are required to be performed under the Act, the fees collected for them must be applied to not only the testing procedures but also the follow-up program, pursuant to N.J.S.A. 26:2-111. Thus, the Department's application of the newborn screening fee to both testing and follow-up services is authorized by the Act.

In addition to the plain language of the Act, it is also proper for the Department to apply the testing fee to both testing procedures and follow-up services because the Act recognizes that newborn screening is much more than laboratory testing. Pursuant to N.J.S.A. 26:2-111, "[t]he commissioner shall provide a program of reviewing and following up on positive cases in order that measures may be taken to prevent mental retardation or other permanent disabilities" and "[t]he department shall conduct an intensive educational and training program among physicians, hospitals, public health nurses and the public concerning those biochemical disorders. This program shall include information concerning the nature of the disorders, testing for the detection of these disorders and treatment modalities for these disorders." Due to these statutory mandates, the New Jersey Newborn Screening Program is part of a coordinated and

comprehensive system consisting of education, screening, follow-up, diagnosis, treatment and management, and program evaluation. This part of the Newborn Screening Program makes every reasonable attempt to connect each newborn with an out-of-range screen to an appropriate medical specialist who will perform the required diagnostic tests and initiate treatment, if necessary. This part of the Program also provides education to parents and providers and health service grants to fund a safety net of subspecialists who provide the necessary follow up on infants with out-of-range screens. All of these services play an important role in avoiding delays in making critical diagnoses that save the lives of newborns. Thus, in addition to the plain language set forth in N.J.S.A. 26:2-111, it is also reasonable and logical to interpret the Act to require all of the testing fee to be applied to both testing procedures and follow-up services. Indeed, to charge a fee that only applies to the testing for some disorders, while then charging a fee for both testing and follow-up services for other disorders would run counter to the very purpose and intent of the Act, which, as stated in N.J.S.A. 26:2-110, is to not only detect biochemical and genetic disorders in newborn infants but to also treat those affected individuals.

Based upon the above, the Department has the statutory authority to collect a reasonable fee for the testing of newborns for biochemical and genetic disorders required under the Act and to apply that fee to both testing and follow-up services. Thus, the Department will not make any change upon adoption in response to this comment.

Stakeholder Involvement

33. COMMENT: The commenter states that "[o]ur system is committed to improving the overall health of our populations, regardless of the care setting. Those efforts require a greater understanding of our populations and the health needs of our demographics and often requires a collaborative effort between health systems, providers and insurers. We believe that the expansion of follow up services sought by the Department is one such example of the need for a collaborative process, to ensure all healthcare stakeholders are fully engaged and working in concert to improve the health and well-being of these individuals and their families. This process should include a review and understanding of current treatment services and the identification of gaps. We do believe that the Department is committed to driving all healthcare stakeholders toward improving population health and that it plays an important role in this discussion. Therefore, our system urges the Department to convene such a stakeholder group to pursue cost-effective and research based mechanisms to expand these services. We believe that this is not only the more appropriate approach, but one that is consistent with the statutory mandates of the recent birth screening panel expansions." With this, the commenter requests that the Department "engage in a multi-stakeholder collaborative process in order to determine current resources and gaps in treatment services available to affected newborns and their families." (6)

RESPONSE: New Jersey is fortunate to have the Newborn Screening Advisory Review Committee (NSARC). NSARC is a multi-stakeholder collaborative advisory committee of devoted health professionals, parents, and representatives from health insurance plans and the New Jersey Hospital Association that advise the Commissioner of Health on

matters related to Newborn Screening in New Jersey, including the determination of current resources and gaps in treatment services available to affected newborns and their families. Thus, the Department is already engaged in the multi-stakeholder collaborative process suggested by the commenter. As such, the Department will not make any changes upon adoption in response to this comment.

Insurance Reimbursement

34. COMMENT: The commenter states that the fee increase "will be a financial hardship on my business to pay out over $600.00/month for these tests with no reimbursement coming from my client's insurance companies." (2)

35. COMMENT: The commenter states that "the proposal is silent on the hospital's ability to negotiate higher rates with insurance companies to cover the increase in cost. Early detection nationwide vary greatly state by state, with some states charging hospitals $0 for each test. We respectfully request a directive to require insurance companies to increase reimbursement to facilities for newborn screening tests, even if the contract between the hospital and insurer is not up for immediate renewal." (3)

36. COMMENT: The commenter states that "the current healthcare landscape is dramatically evolving as healthcare providers face challenges around reimbursement, technological advancements, and increasing regulatory and governmental regulations. The proposed increase of $60 per test (from $90 to $150) will have to be completely absorbed by the hospital placing a significant burden on an already complex system. Particularly for those who have a high volume of births and those with a high number of

charity care and Medicaid patients where the cost of delivering their infant already exceeds the funds available to reimburse the institution. In addition to our patients whose insurance coverage is contracted or have fixed rates would not include or cover the increase." (4)

37. COMMENT: The commenter states that they oppose the "proposed amendment to N.J.A.C. 8:45-2.1 whereby the Newborn Screening Program fee will increase from $90 to $150. The magnitude of this increase (at 67%) far exceeds any reasonable inflationary increase and places additional financial pressure on healthcare facilities that are already faced with challenges related to continued reduction in charity care funding during the current state fiscal year, federal government mandated rate adjustments as a result of the Patient Affordable Care Act and the changing insurance landscape within New Jersey." (5)

38. COMMENT: The commenter states that "the proposal does not address our ability to negotiate higher rates with insurance companies to cover the increase in cost. Early detection of these disorders is vital, yet we bear the primary financial burden to cover the proposed cost increase." The commenter then requests "a directive to require insurance companies to increase reimbursement to facilities for newborn screening tests, even if the contract between the hospital and insurer is not up for immediate renewal." (7)

39. COMMENT: The commenter states that "[w]e realize that with the increased number of screenings that are performed there is a commensurate increase in cost for the NJ Department of Health. The cost of personnel to run the tests, the cost of equipment and other related infrastructure needs, as well as staff to perform follow-up

has significantly raised the price of running a comprehensive screening program. However, the concern the consortium and many of our hospitals have is the increased cost that will be passed onto the individual hospitals. The proposed increase of $60 per test (from $90 to $150) will be cost prohibitive to many of our hospitals, particularly those who have a high volume of births and those with a high number of charity care and Medicaid patients where the cost of providing maternity care already exceeds the funds available to reimburse the institution. The burden this will impose among our hospitals will be significant, particularly to those mentioned above, as well as for other hospitals with health insurance contracts with fixed rates that would not include or cover the increase." (8)

40. COMMENT: The commenter states that "the proposal is silent on the hospital's ability to negotiate higher rates with insurance companies to cover the increase in cost. Early detection of these disorders is a societal mission, yet hospitals unfairly bear the primary financial burden to cover the costs. The amount of fees nationwide vary greatly state by state, with some states charging hospital's $0 for each test. We respectfully request a directive to require insurance companies to increase reimbursement to facilities for newborn screening tests, even if the contract between the hospital and the insurer is not up for immediate renewal." (Emphasis removed) (12)

41. COMMENT: The commenter states that "the proposal is silent on the hospital's ability to negotiate higher rates with insurance companies to cover the increase in cost. Early detection of these disorders is a societal mission, yet we alone must bear the primary financial burden to cover the costs. These fees are charged in every state but the fees vary greatly state by state, with some states not charging hospitals at all for

these tests. We respectfully request a directive to require insurance companies to increase reimbursement to facilities for newborn screening tests, even if the contract between the hospital and the insurer is not up for immediate renewal." (13)

42. COMMENT: The commenter states that "the proposed fee increases financial burden on hospitals during a time of reduced insurance reimbursements and Medicaid payments. As area community hospitals close their maternity programs, Hunterdon Medical Center will be impacted by higher operation costs due to regional care requirements." (14)

RESPONSE TO COMMENTS 34 THROUGH 42: The Department does not have control or authority over health insurance matters. As such, it is unable to provide a directive to health insurance carriers to increase reimbursement to facilities for newborn screening tests. While the Department is without authority over insurance matters, it can assist any individual or institution that submits newborn specimens with selecting the appropriate Current Procedural Terminology (CPT) codes to ensure that the individual or facility receives proper reimbursement as there are specific CPT codes for the tests included in New Jersey's Newborn Screening Program. Realizing that CPT codes do not dictate reimbursement rates, the Department recommends that the commenters work with the Department of Banking and Insurance, which is the State agency with regulatory oversight over insurance matters, on any issues they may have with receiving proper reimbursement from insurance companies for newborn screening. Accordingly, the Department will make no change upon adoption in response to these comments.

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. While 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) makes recommendations for disorders to be screened for by newborn screening programs throughout the country and includes these disorders on the National Recommended Uniform Screening Panel (RUSP), the RUSP is only a recommendation, not a requirement. Therefore, a Federal standard analysis is not required.

Full text of the adoption follows:

TEXT