ADOPTIONS SECTION

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF FAMILY HEALTH SERVICES

SPECIAL CHILD HEALTH AND EARLY INTERVENTION SERVICES

NEWBORN SCREENING AND GENETIC SERVICES

DIVISION OF PUBLIC HEALTH INFRASTRUCTURE, LABORATORIES, AND EMERGENCY PREPAREDNESS

PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

Notice of Readoption

Newborn Biochemical Screening Program

Readoption: N.J.A.C. 8:18

Authority: N.J.S.A. 26:2-110, 111, 111.1, 111.2, 111.5, 111.6, and 111.7.

Authorized By: Shereef M. Elnahal, MD, MBA, Acting Commissioner, Department of Health.

Effective Date: February 6, 2018.

New Expiration Date: February 6, 2025.

Take notice that, pursuant to N.J.S.A. 52:14B-5.1, the Acting Commissioner (Commissioner) of the Department of Health (Department) hereby readopts N.J.A.C. 8:18, Newborn Biochemical Screening Program, which was scheduled to expire on March 8, 2018.

Newborn biochemical screening (NBS) is a public health activity aimed at the early identification of biochemical disorders (also called “metabolic disorders” or “inborn

errors of metabolism") in infants. Early identification of these conditions is particularly crucial, as timely intervention can lead to a significant reduction of morbidity, mortality, and associated disabilities in affected infants.

N.J.S.A. 26:2-110 et seq., mandates that newborns be tested for hypothyroidism, galactosemia, phenylketonuria, and other preventable biochemical disorders. N.J.A.C. 8:18 establishes standards implementing this mandate. N.J.S.A. 26:2-111 authorizes the Commissioner to add conditions to the State NBS panel of tests performed, following notice to the State Legislature, "if reliable and efficient testing techniques [become] available."

The Department's NBS Program comprises two units, the NBS Laboratory and the NBS Follow-up Program. N.J.A.C. 8:18 identifies the responsibilities of health care providers and facilities that are subject to N.J.S.A. 26:2-110 et seq. The following entities participate in the State NBS system: primary health care providers, health care specialists, parents, tertiary care centers, birth attendants including midwives, local public health officials, and hospital, laboratory, administrative, and follow-up personnel. The system must function smoothly and efficiently to ensure that all newborns receive screening, rescreening, as may be indicated, follow-up testing if initial or repeat screening results are abnormal, and treatment in accordance with established protocols. The NBS Follow-up Program maintains communication with appropriate health care providers and other system participants to ensure that newborns with presumptively abnormal screening results receive, as the circumstances indicate, rescreening, confirmatory testing, treatment, and access to available services.

N.J.S.A. 26:2-111.1 requires the Department to establish procedures by which parents receive notification of the availability of supplemental newborn screening for disorders for which the Department does not screen, and by which responsible facilities would implement parents' requests for that screening.

N.J.S.A. 26:2-111.5 (enacted in 2012), 111.6 (enacted in 2013), and 111.7 (enacted in 2014), respectively, mandate newborn screening for the lysosomal storage disorders known as Krabbe, Pompe, Gaucher, Fabry, and Niemann-Pick diseases; adrenoleukodystrophy (ALD); and mucopolysaccharidosis I (MPS I), also known as Hurler syndrome, Hurler-Scheie syndrome, or Scheie syndrome, and mucopolysaccharidosis II (MPS II), also called Hunter syndrome. The Department has already added some of these conditions to the newborn screening panel, and is adding the remaining conditions to the panel, as "reliable and efficient testing techniques [become] available" to screen for these conditions, by the acquisition and installation of necessary equipment, technology, and staff, the implementation of pilot testing, and the performance of other requisites. See N.J.S.A. 26:2-111.

The readopted rules set forth the following: N.J.A.C. 8:18-1.1 establishes the purpose and scope of the chapter; 1.2 defines words and terms used in the chapter; 1.3 identifies disorders and conditions for which the NBS Laboratory performs testing of specimens for biochemical and genetic disorders in accordance with recognized clinical laboratory procedures; 1.4 through 1.8, respectively, establish the responsibilities of chief executive officers, birth attendants, responsible physicians, home health agencies, and public health officers, to implement the State NBS system; 1.9 establishes the responsibilities of the testing laboratory; 1.10 establishes the responsibilities of the NBS

Follow-up Program and the process to assist families of children with abnormal test results to obtain access to health care and other services as indicated; 1.11 reiterates the Commissioner's statutory responsibility pursuant to N.J.S.A. 26:2-111.1 to determine adequate laboratory fees and appropriate funding for testing, follow-up, and treatment services (N.J.A.C. 8:45-2.1 establishes the applicable fee schedule); 1.12 establishes the standard for exemption from testing; 1.13 lists the conditions that necessitate a report, identifies the entities that can use the report, and establishes the parameters of the confidentiality of the report; and 1.14 implements N.J.S.A. 26:2-111(b)1, by establishing procedures by which health care providers are to provide notice of the availability of supplemental newborn screening to parents, obtain parental acknowledgment of receipt of notice, retain proof of acknowledgment in the medical record, and permit parents to retain the notice.

The Department has reviewed N.J.A.C. 8:18 in consultation with the Newborn Screening Annual Review Committee (Committee), which consists of parents, family members, nurses, physicians, specialists, scientists, health care organization representatives, attorneys, advocates, and others, all having the common goal of collaborating to ensure that the New Jersey NBS Program conforms to the state-of-the-art and remains responsive to the needs of New Jersey’s newborns and their families. For additional background on the Committee, see 37 N.J.R. 1661(a), 1662. In addition to working with the Committee, the NBS Program consults on an ongoing basis with specialists in the areas of metabolic and genetic medicine, hematology, endocrinology, and pulmonology, to continually evaluate the quality, appropriateness, and effectiveness

of State NBS system procedures and technology, and to update the list of screened-for conditions.

As a result of these consultations, the Department is developing rulemaking to amend N.J.A.C. 8:18 to make it more user-friendly, articulate updated specimen collection and submission procedures, list additional conditions for which the Department has commenced or will commence screening, including those that N.J.S.A. 26:2-111.5, 111.6, and 111.7 identify and the dates upon which the Department added or is adding these conditions to the State NBS panel, and ensure conformity with national standards, recommendations, and best practices for NBS. The Department anticipates filing this rulemaking with the Office of Administrative Law for processing in the ordinary course. However, this rulemaking will not be concluded prior to the expiration of existing N.J.A.C. 8:18. The Acting Commissioner has reviewed existing N.J.A.C. 8:18 and determined that, pending the conclusion of the anticipated rulemaking process described above, the existing chapter remains necessary, proper, reasonable, efficient, understandable, and responsive to the purposes for which the Department originally promulgated it and should be readopted. Therefore, pursuant to N.J.S.A. 52:14B-5.1.c(1), N.J.A.C. 8:18 is readopted and shall continue in effect for seven years.