CHAPTER 18

NEWBORN BIOCHEMICAL SCREENING PROGRAM

Authority

N.J.S.A. 26:2-110 and 26:2-111.

Source and Effective Date

R.2011 d.105, effective March 8, 2011.
See: 42 N.J.R. 2526(a), 43 N.J.R. 835(a).

Chapter Expiration Date

Chapter 18, Newborn Biochemical Screening Program, expires on March 8, 2016.

Chapter Historical Note

Chapter 18 was originally filed and became effective prior to September 1, 1969, as Chapter VI of the State Sanitary Code, Boarding Homes for Children, under the authority of N.J.S.A. 26:1A-7. The responsibility for these facilities was transferred from the Department of Health to the Department of Human Services by N.J.S.A. 30. The Department of Health repealed the rules at N.J.A.C. 8:18, effective April 4, 1983, by R.1983 d.101. See: 14 N.J.R. 1436(b), 15 N.J.R. 544(a).

Chapter 18, Catastrophic Illness in Children Relief Fund Program adopted as new rules by R.1989 d.557, effective November 7, 1989. See: 21 N.J.R. 1781(a), 21 N.J.R. 3501(a).

Pursuant to Executive Order No. 66(1978), Chapter 18 was readopted as R.1994 d.572, effective October 21, 1994. See: 26 N.J.R. 3573(a), 26 N.J.R. 4380(a). Chapter 18, Catastrophic Illness in Children Relief Fund Program, was recodified as N.J.A.C. 10:155 by R.1995 d.608, effective December 4, 1995. See: 27 N.J.R. 3554(a), 27 N.J.R. 4890(b).

Chapter 18, Newborn Biochemical Screening Program, was recodified from N.J.A.C. 8:19-2 by R.2005 d.346, effective October 17, 2005. See: 37 N.J.R. 1661(a), 37 N.J.R. 4018(a).

Chapter 18, Newborn Biochemical Screening Program, was readopted as R.2011 d.105, effective March 8, 2011. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 1. NEWBORN BIOCHEMICAL SCREENING

8:18-1.1 Purpose and scope

This subchapter constitutes the rules governing the implementation of N.J.S.A. 26:2-110 and 111 (P.L. 1988, c.24), an act providing for the testing of newborn children for the purpose of early detection and treatment of biochemical disorders.

Recodified from N.J.A.C. 8:19–2.1 by R.2005 d.346, effective October 17, 2005.
See: 37 N.J.R. 1661(a), 37 N.J.R. 4018(a).

8:18-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Acknowledgment of Receipt of Notice of Availability of Supplemental Newborn Screening" or "Acknowledgment" means the second page of the Notice.

"Biohazardous specimen" means a specimen collected from an infant who may have, or whose mother may have, an infectious disease agent transmissible by blood contact, as determined by the infectious disease officer of the responsible institution.

"Birth attendant" means the physician, nurse-midwife or other person who attends a non-hospital birth and who is required to register the birth of a child under N.J.S.A. 26:8-30 or 26:8-31.

"Chief executive officer" means the person who acts as the administrative officer of the institution and who is responsible to the governing body for overall management of the hospital or agency providing birthing services.

"Department" means the New Jersey State Department of Health and Senior Services.

"Follow-up Program" means Newborn Screening and Genetic Services, Special Child Health and Early Intervention Services, Division of Family Health Services, Public Health Services Branch, New Jersey Department of Health and Senior Services, PO Box 364, Trenton, NJ 08625-0364.

"Health care facility" means a facility licensed pursuant to Title 26 of the Revised Statutes that provides health care services to newborn infants, and includes responsible institutions.

"Health care professional" means a health care professional licensed pursuant to Title 45 of the Revised Statutes that provides health care services to newborn infants.

"Health care provider" means a health care professional or a health care facility.

"Home health agency" means a facility which is licensed by the New Jersey Department of Health and Senior Services to provide preventive, rehabilitative, and therapeutic services to the patients in the patient's home or place of residence.

"Newborn" means an infant who is zero to 28 days old.

"Notice of Availability of Supplemental Newborn Screening" or "Notice" means the document promulgated by the Department pursuant to N.J.S.A. 26:2-111.1b(1), that explains the availability of supplemental newborn screening.

1. The Notice and Acknowledgment are available on the website of the Follow-up Program at http://nj.gov/health/fhs/prenatal/screening.shtml and the Department's forms page at http://nj.gov/health/forms, form numbers SCH-7 for the English version and SCH-7A for the Spanish version, as amended and supplemented.

2. The Notice and Acknowledgment are available to health care providers who do not have access to the Follow-up Program website or otherwise are unable to download and print the Notice and Acknowledgment, upon request to the Follow-up Program, which shall mail a single Notice and Acknowledgment form to the requesting health care provider.

"Parent" means the infant's parent or legal guardian or other person legally responsible for the health and well-being of the infant.

"Public health officer" means the officer or commissioner of health of a city, town, county or region.

"Qualified laboratory" means that term as defined at N.J.S.A. 26:2-111.1.

"Repeat specimen" means an additional satisfactory specimen submitted to the testing laboratory.

"Responsible institution" means the hospital or center providing birthing services.

"Responsible physician" means the physician or other health care professional providing care at the time of specimen collection whose name is placed on the Inborn Errors of Metabolism (IEM) specimen collection form.

"Satisfactory specimen" means a specimen received by the testing laboratory in an acceptable condition for testing.

"Serum specimen" means a specimen of serum collected according to established criteria of the laboratory performing the assay; serum specimens are sent to the Department testing laboratory.

"Specimen" means a dried blood filter specimen collected on an approved specimen collection form.

"Specimen collection form" means the current specimen collection form as provided by the Department of Health and Senior Services.

"Supplemental newborn screening" means testing performed by qualified laboratories for disorders in infants for which testing is not required pursuant to N.J.S.A. 26:2-110 et seq. and this chapter.

"Testing laboratory" means the Inborn Errors of Metabolism Laboratory, Division of Public Health and Environmental Laboratories, New Jersey Department of Health and Senior Services, PO Box 371, Trenton, NJ 08625-0371.

"Unsatisfactory specimen" means a specimen which is received by the testing laboratory in a condition unacceptable for testing.

Amended by R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).
Rewrote "Follow-up Program" and "Responsible physician"; inserted "Home health agency"; and in "Serum specimen", added "; serum specimens are sent to the Department testing laboratory" at the end.
Recodified from N.J.A.C. 8:19–2.2 and amended by R.2005 d.346, effective October 17, 2005.
See: 37 N.J.R. 1661(a), 37 N.J.R. 4018(a).
In the introductory paragraph, substituted "chapter" for "subchapter"; rewrote definitions "Follow-up Program" and "Responsible physician"; added definitions "Health care professional" and "Newborn".
Amended by R.2007 d.43, effective February 5, 2007.
See: 38 N.J.R. 1973(a), 38 N.J.R. 3095(a), 39 N.J.R. 396(a).
In the introductory paragraph, substituted a colon for a period at the end; added definitions "Acknowledgement of Receipt of Notice of Availability of Supplemental Newborn Screening", "Health care facility", "Health care provider", "Notice of Availability of Supplemental Newborn Screening", "Qualified laboratory" and "Supplemental newborn screening".

8:18-1.3 Diseases and conditions tested

(a) The testing required by N.J.S.A. 26:2-111 and this subchapter shall be done by the testing laboratory according to recognized clinical laboratory procedures.

(b) Diseases and conditions to be tested shall include, but not be limited to:

1. Phenylketonuria;

2. Galactosemia;

3. Hypothyroidism;

4. Sickle cell anemia; and

5. Other hemoglobinopathies; as designated by the Commissioner.

(c) Beginning July 2001, in addition to the disorders under (b) above, the following conditions were added to newborn screening:

1. Maple syrup urine disease;

2. Congenital adrenal hyperplasia;

3. Cystic fibrosis; and

4. Biotinidase deficiency.

(d) Beginning July 2002, in addition to the disorders under (b) and (c) above, the following conditions were added to newborn screening:

1. Medium chain acyl-CoA dehydrogenase (MCAD) deficiency;