

CHAPTER 18

NEWBORN BIOCHEMICAL SCREENING PROGRAM

Authority

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

Source and Effective Date

R.2005 d.346, effective October 17, 2005.
See: 37 N.J.R. 1661(a), 37 N.J.R. 4018(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 18, Newborn Biochemical Screening Program, expires on March 19, 2011. See: 42 N.J.R. 2526(a).

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 The Department of Health repealed the rules at N.J.A.C. 8:18, effective April 4, 1983, by R.1983 d.101.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: Source and Effective Date. See, also, section annotations.

CHAPTER TABLE OF CONTENTS

SUBCHAPTER 1. NEWBORN BIOCHEMICAL SCREENING

- 8:18-1.1 Purpose and scope
- 8:18-1.2 Definitions
- 8:18-1.3 Diseases and conditions tested
- 8:18-1.4 Responsibilities of the chief executive officer
- 8:18-1.5 Responsibilities of the birth attendant
- 8:18-1.6 Responsibilities of the responsible physician
- 8:18-1.7 Responsibilities of the home health agency
- 8:18-1.8 Responsibilities of the public health officer
- 8:18-1.9 Responsibilities of the testing laboratory
- 8:18-1.10 Responsibilities of the Follow-up Program
- 8:18-1.11 Responsibility of the Department
- 8:18-1.12 Exemption from testing
- 8:18-1.13 Confidentiality of reports
- 8:18-1.14 Provision of notice of availability of supplemental newborn screening; Acknowledgement; retention

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;

2. Short chain acyl-CoA dehydrogenase (SCAD) deficiency;
3. Long chain acyl-CoA dehydrogenase (LCAD) deficiency;
4. Very long chain acyl-CoA dehydrogenase (VLCAD) deficiency;
5. Citrullinemia; and
6. Argininosuccinic acidemia.

(e) Beginning October 2003, in addition to the disorders under (b) through (d) above, the following conditions were added to newborn screening:

1. Methylmalonic acidemia;
2. Propionic acidemia;
3. Glutaric acidemia type I;
4. Isovaleric acidemia;
5. 3-Hydroxy-3-methylglutaryl CoA lyase deficiency; and
6. 3-Methylcrotonyl-CoA carboxylase deficiency.

Amended by R.2004 d.333, effective September 7, 2004.

See: 35 N.J.R. 4193(a), 36 N.J.R. 4135(a).

Added (c) and (d).

Recodified from N.J.A.C 8:19-2.3 and amended by R.2005 d.346, effective October 17, 2005.

See: 37 N.J.R. 1661(a), 37 N.J.R. 4018(a).

Added (e).

8:18-1.4 Responsibilities of the chief executive officer

(a) The chief executive officer shall:

1. Cause the development and implementation of written policies and procedures, to be reviewed by the Department and revised as required, for the early detection and treatment of biochemical disorders, pursuant to N.J.S.A. 26:2-110 and 111;
2. Designate a staff person to coordinate hospital or agency screening practice and function as a contact person with the Follow-up Program;
3. Assure that a satisfactory specimen is submitted to the testing laboratory for each infant born in the hospital, or admitted to the hospital within the first 28 days of life with no satisfactory specimen having been previously collected.
4. Assure that the infant's parent is informed of the purpose and need for newborn screening and given newborn screening educational materials provided by the Follow-up Program;
5. Assure that specimen collection forms are properly stored upright in a cool and dry environment prior to use;

6. Assure that specimens are taken utilizing correct specimen collection techniques as described on the back of the specimen collection form;

7. Assure that specimens conform to the following criteria for satisfactory specimens:

- i. The specimen collection forms shall be filled in completely, accurately and legibly;
- ii. The sample shall be collected on S & S 903 blotter paper (located on the right side of the collection form);
- iii. The blotter paper shall be attached to the forms; and
- iv. The specimen quantity shall be sufficient to run all assays;

8. Assure that satisfactory specimens are collected according to the following criteria:

- i. The circles on the blotting paper shall be completely and evenly saturated;
- ii. The specimen shall not be contaminated or diluted;
- iii. The blood shall not be clotted or caked; and
- iv. The blotting paper shall not be torn, scratched, or distorted because of faulty or improper collection techniques;

9. Assure that specimens are taken before the infant is 48 hours old. If an infant is transferred or discharged from a facility prior to 48 hours of life, a specimen shall be collected prior to discharge unless there are medical reasons to prevent specimen collection;

10. Assure that the parent shall be instructed directly and in writing of the need to collect a repeat specimen between the third and seventh day of life if the infant is less than 24 hours of age;

11. Assure that every effort is made to obtain a specimen prior to any anticipated blood transfusion;

12. Assure that, in the event of prolonged hospitalization for specialized medical care, a specimen is taken when the infant is 48 hours old, and that:

- i. If an infant is on prolonged hyperalimentation, the "hyperalimentation" box on the specimen collection form is checked and "NICU," "SICU," or "SCN" is written in the "Remarks" box on the form; and
- ii. A repeat specimen is taken on infants with prolonged hospitalization at seven days and 14 days, and at either 42 days or discharge, whichever comes first, and "NICU," "SICU," or "SCN" is written in the "Remarks" box on the form;

13. Assure that in the case of inter-hospital transfer of the infant, the transferring hospital shall provide written notification to the receiving hospital indicating whether or not a specimen has been taken prior to transfer. Following transfer, the chief executive officer of the receiving hospital shall assume responsibility for collection of the specimen in accordance with these regulations;

14. Assure that the date and time of specimen collection are recorded on the infant's permanent health record;

15. Assure that biohazardous specimens are thoroughly dried and then placed in a paper envelope provided by the testing laboratory;

16. Assure that all specimens are forwarded to the testing laboratory within 24 hours of collection by next day delivery, or in the event service is unavailable with respect to Sundays and Federally designated holidays, then as soon thereafter as is practicable, using an account number the Department shall establish with an overnight package delivery service, which number the Department shall make available upon request;

17. Assure that all test results forwarded to the chief executive officer or his designee by the testing laboratory are included in the infant's permanent health record;

18. Transmit or cause to be transmitted a copy of test results to the physician of record;

19. Assure that repeat specimens are collected when requested by the testing laboratory for specimens not satisfactory for testing according to criteria in (a)7 and 8 above, or specimens for which assay results cannot be interpreted because of any of the following conditions:

- i. Transfusion(s) given before specimen collection;
- ii. Antibiotics given before specimen collection (if effects cannot be removed);
- iii. Ethylene diamine tetra-acetic acid (EDTA) in the specimen secondary to improper collection using an EDTA collection device;
- iv. Incomplete elution from blotter during assay;
- v. Specimen received 14 days or more after collection date; and
- vi. Specimen collected before infant is 24 hours of age;

20. Assure that written documentation is recorded in the infant's permanent medical record of efforts made to secure a repeat specimen within 14 days of receipt of the laboratory report when an initial specimen is not satisfactory for testing and a repeat specimen is not obtained;

21. Assure that infants weighing 1,500 grams or less have repeat screening specimens taken at seven days, 14 days, 42 days of age or at discharge, whichever comes first; and

22. Cause the development and implementation of written policies and procedures, to be reviewed by the Department and revised as required, for the timely processing of supplemental newborn screening specimen collection test kits in accordance with directions contained in the kits if a parent timely provides such a kit to the health care facility of which the chief executive officer is in charge;

- i. At minimum, the policies and procedures required pursuant to (a)22 above shall address memorializing the time and date of receipt of test kits from parents, obtaining parents' informed consent to the collection of specimens in accordance with the instructions in the test kit, and ensuring that appropriate personnel execute or arrange for the execution of such forms and collect or arrange for the collection of such specimens, and otherwise take such steps that are within the health care facility's ability as may be required by a qualified laboratory to assist in and enable the performance of supplemental newborn screening in accordance with instructions accompanying a test kit, subject to applicable standards of care depending upon the particular health situations of newborns from whom supplemental screening specimens are to be collected.

Amended by R.2000 d.200, effective May 15, 2000.

See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Rewrote (a).

Amended by R.2004 d.333, effective September 7, 2004.

See: 35 N.J.R. 4193(a), 36 N.J.R. 4135(a).

In (a), rewrote 16.

Recodified from N.J.A.C. 8:19-2.4 and amended by R.2005 d.346, effective October 17, 2005.

See: 37 N.J.R. 1661(a), 37 N.J.R. 4018(a).

Rewrote (a)10, 12, and 19iii.

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 (a)20, deleted "and" from the end; in (a)21, substituted "; and" for a period at the end; and added (a)22.

8:18-1.5 Responsibilities of the birth attendant

(a) The birth attendant shall:

1. Submit or cause to be submitted to the testing laboratory an initial blood specimen taken before the infant is 48 hours old from all infants born outside of, and not admitted to, a hospital;

2. Follow the specimen collection and submission procedures specified in N.J.A.C. 8:18-1.4(a)5 through 8 and 15 through 16;

3. Collect or cause to be collected a repeat specimen when requested by the testing laboratory, and shall submit or cause such repeat specimen to be submitted to the testing laboratory within 24 hours of collection; and

4. If a repeat specimen is not obtained, place on the infant's medical record written documentation of efforts made to secure or cause to be secured a repeat specimen within 14 days of receipt of the laboratory report.