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TITLE 8. HEALTH
CHAPTER 18. NEWBORN BIOCHEMICAL SCREENING PROGRAM

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N.J.A.C. 8:18 (2017)

Title 8, Chapter 18 -- Chapter Notes

CHAPTER AUTHORITY:

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

CHAPTER 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:

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 18, Newborn Biochemical Screening Program, expires on March 8, 2018. See: *43 N.J.R. 1203(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 The Department of Health repealed the rules at *N.J.A.C. 8:18*, effective April 4, 1983, by R.1983 d.101.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, was 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.

NOTES:

Chapter Notes

Administrative Code

NEW JERSEY ADMINISTRATIVE CODE TITLE 8. DEPARTMENT OF HEALTH AND SENIOR SERVICES CHAPTER 18. NEWBORN BIOCHEMICAL SCREENING PROGRAM

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

CHAPTER 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).

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§ 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.

§ 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.

§ 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.

(f) Beginning May 2009, in addition to the disorders under (b) through (e) above, the following conditions were added to newborn screening:

1. Hemoglobin S/Beta-thalassemia;
2. Hemoglobin S/C disease;
3. 2,4-Dienoyl-CoA reductase deficiency;
4. Carnitine palmitoyltransferase I deficiency;
5. Carnitine palmitoyltransferase II deficiency;
6. Carnitine/acylcarnitine translocase deficiency;
7. Carnitine uptake defect;
8. Glutaric acidemia type II;
9. Long chain 3-Hydroxyacyl-CoA dehydrogenase deficiency;
10. Medium/Short chain 3-Hydroxy acyl-CoA dehydrogenase deficiency;
11. Medium chain ketoacyl-CoA thiolase deficiency;
12. Trifunctional protein deficiency;
13. 2-Methyl-3-hydroxybutyric acidemia;
14. 2-Methylbutyrylglycinemia;
15. 3-Methylglutaconic acidemia;
16. Beta-Ketothiolase deficiency;
17. Isobutyrylglycinemia;
18. Malonic acidemia;
19. Methylmalonic acidemia-Cobalamin A, B;
20. Methylmalonic acidemia-Cobalamin C, D;
21. Multiple carboxylase deficiency;
22. Argininemia;
23. Hyperphenylalanemia (benign);
24. Biopterin cofactor defect of biosynthesis;
25. Biopterin cofactor defect of regeneration;

26. Citrullinemia type II;
27. Homocystinemia;
28. Hypermethioninemia;
29. Tyrosinemia type I;
30. Tyrosinemia type II;
31. Tyrosinemia type III;
32. Galactoepimerase deficiency; and
33. Galactokinase deficiency.

§ 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.

§ 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.

§ 8:18-1.6 Responsibilities of the responsible physician

(a) The responsible physician shall:

1. Interpret all test results;
2. Comply with 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. Promptly collect or cause to be collected repeat specimens requested by the testing laboratory and submit the specimens to the testing laboratory;
4. Promptly collect or cause to be collected repeat specimens as recommended by the testing laboratory in the case of abnormal test results;
5. If a repeat specimen is not obtained within the time frame recommended on the test report, assure that written documentation is recorded in the infant's medical record of efforts made to secure a repeat specimen within 14 days of receipt of the laboratory report;
6. Include in the infant's health record the test results received from the chief executive officer or from the testing laboratory;
7. In the case of confirmed abnormal test results, arrange for diagnostic evaluation;
8. Provide case information, specimens, hard copy of test results, and other information requested by the Follow-up Program; and
9. Remain responsible for the follow-up until the responsibility is actively accepted by another physician.

§ 8:18-1.7 Responsibilities of the home health agency

(a) The home health agency shall:

1. Follow the specimen collection procedures specified in [N.J.A.C. 8:18-1.4\(a\)](#)5 through 8 and 15 through 16;
2. Provide notification to the hospital or birth attendant that the specimen has been collected; and
3. 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.

§ 8:18-1.8 Responsibilities of the public health officer

(a) The public health officer shall:

1. Provide assistance to the Follow-up Program, when requested, in locating families of infants;
2. Collect or cause a repeat specimen to be collected when notified of the need for a repeat specimen by the Follow-up Program. The specimen shall be submitted within 24 hours of collection;
3. Submit written documentation, within 14 days of receipt of the laboratory report to the infant's permanent medical record of efforts made to secure or cause to be secured such repeat specimen if a repeat specimen is not obtained within the time frame recommended by the Follow-up Program; and
4. Provide notification to the hospital or birth attendant that the specimen has been collected.

§ 8:18-1.9 Responsibilities of the testing laboratory

(a) The testing laboratory shall:

1. Determine if a specimen is satisfactory, according to the criteria listed in [N.J.A.C. 8:18-1.4\(a\)](#)7, 8, and 19;
2. Request a repeat specimen from the submitter for unsatisfactory specimens;
3. Test satisfactory specimens for disease and conditions, according to recognized clinical laboratory procedures;
4. Issue result reports of within acceptable limits to the chief executive officer or to the responsible physician, that is, the submitter of the specimen; and

5. Issue reports of abnormal results to the submitter of the specimen and to the responsible physician.

§ 8:18-1.10 Responsibilities of the Follow-up Program

(a) The Follow-up Program shall:

1. Make every reasonable effort to follow abnormal test results to case disposition as specified in the Follow-up Program Procedures Manual;
2. Assist families of children with abnormal test results to access health care as necessary;
3. Identify and maintain contact with medical consultants (neurologists, endocrinologists, geneticists, hematologists) for each disease tested;
4. Identify treatment resources to families and assure that they are receiving care;
5. Provide educational support for activities carried out under this rule; and
6. In conjunction with the testing laboratory:
 - i. Monitor compliance with this subchapter;
 - ii. Identify problems in compliance and assist in their remediation; and
 - iii. Prepare and distribute an annual report, to include outcome data, descriptive statistics, program evaluation and recommendations.

§ 8:18-1.11 Responsibility of the Department

The Commissioner shall determine an adequate laboratory fee and appropriate funding for testing, follow-up and treatment services which will enable the Department to carry out the responsibilities pursuant to P.L. 1988, c.24, § 3 (N.J.S.A. 26:2-111). The fee is specified under [N.J.A.C. 8:45-2.1](#).

§ 8:18-1.12 Exemption from testing

(a) This subchapter shall not apply in the case of any infant or child whose parent or guardian objects to the testing on the grounds that testing would conflict with his or her religious tenets or practices.

(b) In case of refusal to test pursuant to (a) above, the chief executive officer or responsible physician or birth attendant or home health agency shall assure that documentation of refusal to

test becomes part of the infant's permanent medical record.

(c) The chief executive officer or responsible physician or birth attendant or home health agency shall assure that a copy of documentation of refusal to test is forwarded to the testing laboratory.

§ 8:18-1.13 Confidentiality of reports

(a) The reports made pursuant to this subchapter are to be used only by the Department of Health and Senior Services and other agencies that may be designated by the Commissioner and shall not otherwise be divulged or made public so as to disclose the identity of any person and shall be deemed "information relating to medical history, diagnosis, treatment or evaluation" within the meaning of Executive Order No. 26, § 4b1 (McGreevey, August 13, 2002), and, therefore, not "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq., particularly N.J.S.A 47:1A-1.1.

(b) Inasmuch as the annual report issued by the Department pursuant to [N.J.A.C. 8:18-1.10\(a\)6iii](#) contains de-identified information and aggregate data, this section shall not apply to the annual report.

§ 8:18-1.14 Provision of notice of availability of supplemental newborn screening; Acknowledgement; retention

(a) A health care provider who provides care to an expectant parent or to a newborn infant shall, as applicable with respect to the expectant parent or the parent of the newborn (hereinafter both referred to as the "parent"):

1. Provide the Notice to the parent;
2. Provide the parent with a reasonable opportunity to read the Notice;
3. Make reasonable efforts to ensure that the parent understands the information provided in the Notice;
4. Obtain the signature of the parent on the Acknowledgment;
5. Retain the executed Acknowledgement in the patient's medical record; and
6. Permit the parent to keep the Notice.