# CHAPTER 19

# NEWBORN SCREENING PROGRAM

**Authority**

N.J.S.A. 26:2–101 et seq., 26:2–110, 26:2–111 and 26:2H–5.

**Source and Effective Date**

R.1990 d.289, effective May 11, 1990.
See: 22 N.J.R. 733(a), 22 N.J.R. 1764(a).

**Executive Order No. 66(1978) Expiration Date**

Chapter 19, Newborn Screening Program, expires May 11, 1995.

**Historical Note**

Chapter 19, Newborn Screening Program, became effective July 1, 1980 as R.1980 d.173. See: 12 N.J.R. 10(d), 12 N.J.R. 273(d). Chapter 19 was readopted with amendments, effective June 28, 1985, as R.1985 d.380. See: 17 N.J.R. 869(a), 17 N.J.R. 1892(a). Subchapter 2, Newborn Biochemical Screening, was added by R.1990 d.146, effective March 5, 1990. See: 21 N.J.R. 3633(b), 22 N.J.R. 844(a). Pursuant to Executive Order No. 66 (1978), Chapter 19 was readopted as R.1990 d.289. See: Source and Effective Date.

See section annotations for further amendments.

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## SUBCHAPTER 1. NEWBORN HEARING SCREENING

### 8:19–1.1 Hearing development literature supplied to parents

Prior to the discharge of a live newborn from any hospital or birthing center in the State of New Jersey, the hospital nursery, neonatal intensive care unit or birthing center shall provide all parents or legal guardians of the newborn with literature provided by the Department of Health describing the normal development of auditory function and the Newborn Hearing Screening Program. Such literature will be designed to provide parents with an understanding of the implications of hearing loss on the development of speech-language and provide information regarding normal auditory behavior. All literature shall be furnished free of charge to hospitals and birthing centers by the Department of Health.

### 8:19–1.2 Newborn hearing screening report form required

(a) All hospital nurseries, including neonatal intensive care units and birthing centers, shall complete a Newborn Hearing Screening Report Form (SCH–1) on all live newborns regardless of the presence or absence of a risk factor. This Newborn Hearing Screening Report Form contains high risk categories that are associated with possible hearing impairment. These high risk categories are defined in N.J.A.C. 8:19–1.5. The Newborn Hearing Screening Report Form is composed of three identical copies. Registered nurses in the hospital nursery and neonatal intensive care unit or the birth attendant shall complete the Newborn Hearing Screening Report Form.

(b) The hospital nursery, neonatal intensive care unit or birthing center shall forward one copy of the Newborn Hearing Screening Report Form to Special Child Health Services, New Jersey State Department of Health, CN 364, Trenton, New Jersey 08625–0364 upon discharge of each live newborn identified as having a risk factor(s) and for each live newborn transferred to a neonatal intensive care unit regardless of the presence or absence of a risk factor. The hospital or birthing center shall submit the Newborn Hearing Screening Report Form to the Department within one week of discharge or transfer. The second copy of the Newborn Hearing Screening Report Form shall be placed in the newborn's permanent medical record. The third copy shall be given to the infant's parent(s) or legal guardian.

(c) The hospital nursery, including neonatal intensive care units, and birthing centers shall assure that the newborn's parent or legal guardian is informed of the purpose and need for newborn hearing screening, shall obtain consent from the parent or legal guardian and shall document consent by obtaining the parent's or legal guardian's signature on the Newborn Hearing Screening Report Form. When a parent or legal guardian objects to the screening on the grounds screening would conflict with his or her religious tenets or practices, such refusal shall be documented on the Newborn Hearing Screening Report Form and placed in the newborn's permanent medical record.

(d) For those children who have no risk factors, a completed Newborn Hearing Screening Report Form shall be placed in the newborn's permanent medical record and one

copy shall be given to the infant's parent(s) or legal guardian.

(e) The screening shall be documented in the Nursery Log Book for each live newborn being discharged from the hospital nursery, neonatal intensive care unit or birthing center.

(f) Special Child Health Services personnel shall have the authority to review, on site, the Nursery Log Book and medical records.

**8:19–1.3 High risk infant registry**

Special Child Health Services shall maintain a registry of high risk infants for hearing impairment so as to remind parents or legal guardians of high risk infants for the need for a six month auditory screening of the high risk infant by a licensed physician, licensed audiologist or person(s) under their direction.

**8:19–1.4 Six month auditory screening report**

The person completing the six month auditory screening of the infants at high risk for hearing impairment shall report their results to Special Child Health Services, New Jersey State Department of Health, CN 364, Trenton, New Jersey 08625–0364. A Hearing Screening Follow–Up Form (SCH–2) shall be provided at no cost by Special Child Health Services to the parents of infants at high risk and to any other persons who may request such forms.

**8:19–1.5 High risk conditions**

(a) The following conditions will be screened for as risk factors associated with possible hearing impairment. These conditions shall be described in the literature as required by N.J.A.C. 8:19–1.1.

1. Five minutes Apgar Score of six or less;

2. Bacterial Meningitis, especially haemophilus influenza;

3. Confirmed or suspected congenital or perinatal infections including, but not limited to, rubella, herpes, toxoplasmosis, syphilis, cytomegalovirus;

4. Defects of head or neck (such as cranio-facial syndromal or non-syndromal abnormalities, overt or submucous cleft palate, morphologic abnormalities of the pinna) exclusive of isolated skin tags;

5. Elevated bilirubin exceeding indication for exchange transfusion;

6. Family history of childhood hearing impairment;

7. Birthweight of 1500 grams or less;

8. Ototoxic drugs (such as gentamycin or kanamycin) administered to the infant for 14 days or more or through multiple courses of therapy; and

9. Evidence of intracranial hemorrhage.

**8:19–1.6 Confidentiality of reports**

Any forms and reports furnished to the Department of Health as required by these rules shall not be made public so as to disclose the identity of the person to whom they relate. Information obtained from forms and reports furnished to the Department shall be used by the Department for purposes of follow up of high risk infants. No information shall be released for any other purpose without the written consent of the parent or legal guardian.

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## SUBCHAPTER 2. NEWBORN BIOCHEMICAL SCREENING

**8:19–2.1 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.

**8:19–2.2 Definitions**

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

"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.

"Follow-up Program" means the Newborn Biochemical Screening Program, Special Child Health Services, Division of Community Health Services, State of New Jersey Department of Health, CN 364, Trenton, NJ 08625–0364.

"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.

"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 licensed health care provider named on the specimen collection form, the infant's primary health care provider, if different, or the hospital staff physician as designated by the chief executive officer and identified to the testing laboratory.

"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.

"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.

"Testing laboratory" means the Inborn Errors of Metabolism Laboratory, Division of Public Health and Environmental Laboratories, State of New Jersey Department of Health, CN 371, Trenton, NJ 08625–0371.

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

**8:19–2.3 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.

**8:19–2.4 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 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 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 or scratched 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;

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 has been fed protein for fewer than 24 hours at the time of discharge;

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 child is 48 hours old. Repeat specimens shall be taken weekly until there have been 24 hours of normal oral feeding on full strength formula. If an infant is on prolonged hyperalimentation and the physician wishes to stop weekly testing, he or she should consult with a PKU specialist;

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 individually in a paper envelope. The outside of the envelope shall be labeled as a biohazardous specimen;

16. Assure that all specimens are forwarded to the testing laboratory within 24 hours of collection by first class mail or its equivalent;

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. Specimen collected before the child has received protein feeding for 24 hours;

iv. Incomplete elution from blotter during assay; and

v. Specimen received 14 days or more after collection date; and

20. Assure that written documentation is submitted to the testing laboratory of efforts made to secure a repeat specimen within 14 days of receipt of the laboratory report when either:

i. An initial specimen is not satisfactory for testing and repeat specimen is not obtained; or

ii. The responsible physician cannot be notified.

**8:19–2.5 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. 18:19–2.4;

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, submit to the testing laboratory written documentation of efforts made to secure or cause to be secured a repeat specimen within 14 days of receipt of the laboratory report.

**8:19–2.6 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. 18:19–2.4;

3. Promptly collect or cause to be collected repeat specimens requested by the testing laboratory. All repeat specimens shall be clearly marked REPEAT;

4. Promptly collect or cause to be collected repeat specimens or serum specimens as recommended by the laboratory in the case of abnormal test results. All repeat specimens shall be clearly marked REPEAT;

5. If a repeat specimen is not obtained within the time frame recommended on the test report, submit to the testing laboratory written documentation 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; and

8. Provide case information, specimens and other information requested by the Follow-up Program.

**8:19–2.7 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; and

3. Submit written documentation, within 14 days of receipt of the laboratory report, to the testing laboratory 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.

**8:19–2.8 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. 8:19–2.4(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 reports of not clinically significant results 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.

**8:19–2.9 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.

**8:19–2.10 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 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 shall assure that a copy of documentation of refusal to test is forwarded to the testing laboratory.