

CHAPTER 19

NEWBORN SCREENING PROGRAM

Authority

N.J.S.A. 26:2-101 et seq., 26:2-110 and 26:2-111.

Source and Effective Date

R.2000 d.200, effective April 19, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 19, Newborn Screening Program, expires on October 16, 2005. See: 37 N.J.R. 1661(a).

Chapter Historical Note

Chapter 19, Newborn Screening Program, was adopted as R.1980 d.173, effective July 1, 1980. See: 12 N.J.R. 10(d), 12 N.J.R. 273(d).

Pursuant to Executive Order No. 66(1978), Chapter 19, Newborn Screening Program, was readopted as R.1985 d.380, effective June 28, 1985. See: 17 N.J.R. 869(a), 17 N.J.R. 1892(a).

Subchapter 2, Newborn Biochemical Screening, was adopted as 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, Newborn Screening Program, was readopted as R.1990 d.289, effective May 11, 1990. See: 22 N.J.R. 733(a), 22 N.J.R. 1764(a).

Pursuant to Executive Order No. 66(1978), Chapter 19, Newborn Screening Program, was readopted as R.1995 d.274, effective May 8, 1995. See: 27 N.J.R. 807(a), 27 N.J.R. 2213(a).

Pursuant to Executive Order No. 66(1978), Chapter 19, Newborn Screening Program, was readopted as R.2000 d.200, effective April 19, 2000. See: Source and Effective Date. See, also, section annotations.

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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 and Senior Services (hereafter, the Department) 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 to hospitals and birthing centers by the Department.

Amended by R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

Deleted "free of charge" following "furnished" in the last sentence.

8:19-1.2 Modules 3, 5, and 6 of the Electronic Birth Certificate System

(a) All hospital nurseries, including neonatal intensive care units and birthing centers, shall complete Modules 3, 5, and 6 of the Electronic Birth Certificate (EBC) System on all live newborns regardless of the presence or absence of indicators associated with hearing loss. Modules 3, 5, and 6 contain indicators associated with possible hearing loss. These indicators are defined in N.J.A.C. 8:19-1.6. Registered nurses in the hospital nursery and neonatal intensive care unit or the birth attendant shall complete Modules 3, 5, and 6. If the hospital or birthing center has designated them to do so, licensed audiologists shall complete information regarding electrophysiological screening on Module 5, and the Parental Informed Consent section and document parental/legal guardian refusal to participate in the Newborn Hearing Program for religious reasons on Module 6.

(b) Effective May 15, 2000, all newborns with one or more indicators associated with hearing loss as described in N.J.A.C. 8:19-1.6 shall be required to have an electrophysiological hearing screening done prior to discharge or before one month of age. The electrophysiologic hearing screening measure used is to be determined by the hospital, birthing center or pediatrician. Results of electrophysiologic hearing screening measures shall be documented on Module 5 of the EBC.

(c) Effective January 1, 2002, all newborns, regardless of risk status, shall be required to be screened for hearing impairment with electrophysiologic measures prior to discharge or before one month of age. The electrophysiologic hearing screening measure used is to be determined by the hospital, birthing center or pediatrician. Results of the electrophysiologic hearing screening measures shall be documented on Module 5 of the EBC.

(d) If a birth occurs outside a hospital or birthing center and the baby is then transferred to a hospital or birthing center, it shall be the responsibility of these receiving facilities to ensure that Modules 3, 5, and 6 are completed. From May 15, 2000 to December 31, 2001, if one or more of the indicators associated with hearing loss as described in N.J.A.C. 8:19-1.6 are present, an electrophysiologic hearing screening shall be done. Beginning January 1, 2002, all newborns, regardless of the presence or absence of an indicator associated with hearing loss, shall have an electrophysiologic hearing screening done prior to discharge or before one month of age.

(e) From May 15, 2000 to December 31, 2001, if a birth occurs outside a hospital or birthing center and the baby is not transferred to a hospital or birthing center, or a newborn is discharged before electrophysiological hearing screening is done, then the midwife or pediatrician caring for the newborn shall ensure that an electrophysiologic hearing screening is performed prior to one month of age, if one or more of the indicators associated with hearing loss as described in N.J.A.C. 8:19-1.6 are present. Beginning January 1, 2002, all newborns, regardless of the presence or absence of an indicator associated with hearing loss, shall have an electrophysiologic hearing screening done prior to one month of age.

(f) The hospital nursery, neonatal intensive care unit, birthing center or facility to which a newborn is transferred shall, upon discharge or transfer and regardless of the presence or absence of an indicator associated with hearing loss, forward Modules 3, 5, and 6 of the EBC to the Department via modem at PO Box 360, Trenton, New Jersey 08625-0360. The hospital or birthing center shall submit Modules 3, 5, and 6 of the EBC to the Department within one week of discharge or transfer.

(g) The hospital nursery, including neonatal intensive care units, and birthing centers shall assure that the newborn's parent, legal guardian or custodian is informed of the purpose and need for newborn hearing screening, shall obtain consent from the parent, legal guardian or custodian and shall document consent by obtaining the legal guardian's or custodian's signature on Module 6 of the EBC. When a parent, legal guardian or custodian objects to the screening on the grounds screening would conflict with his or her religious tenets or practices, such refusal shall be documented on Module 6. Module 6 shall be placed in the newborn's permanent medical record.

Amended by R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).
Rewrote the section.

8:19-1.3 Hearing screening follow-up

The hospital or birthing center shall inform the parent, legal guardian or custodian of an infant who failed electrophysiological hearing screening of the need for follow-up screening by three months of age by a licensed physician, licensed audiologist or person(s) under their direction or supervision, and provide the parent, legal guardian or custodian with a Newborn Hearing Follow-Up Report (see N.J.A.C. 8:19-1.4). If diagnostic testing is indicated, personnel providing the testing shall include a licensed physician and a licensed audiologist. The hospital shall provide information regarding resources for referrals including the Special Child Health Services County Case Management offices.

Repeal and New Rule, R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).
Section was "High risk infant registry".

8:19-1.4 Newborn hearing follow-up report

(a) The person completing the Newborn Hearing Follow-up Report for infants who failed electrophysiological screening prior to discharge or before one month of age, shall report their results to Special Child, Adult and Early Intervention Services, New Jersey Department of Health and Senior Services, PO Box 364, Trenton, New Jersey 08625-0364. The Newborn Hearing Follow-up Report shall be submitted when a formal diagnostic impression is obtained or by six months of age. When a hearing loss is confirmed, the person completing the Newborn Hearing Follow-up Report shall register the child with the Special Child Health Services Registry and indicate this by checking "yes": The child has been registered with Special Child Health Services Registry in the "Impressions" section of the follow-up form. A Newborn Hearing Follow-up Report shall be provided at no cost by Special Child, Adult and Early Intervention Services to the parents of infants who are to be screened and to any other persons who may request such forms.

(b) If a newborn is not screened prior to discharge from a hospital or birthing center or is born outside a hospital or birthing center and not transferred to a hospital or birthing center, the baby shall be screened with electrophysiological measures prior to one month of age. The pediatrician or midwife shall ensure that the electro-physiological screening is done and that the "Electrophysiological Responses" section of the Newborn Hearing Follow-up Report is completed and sent to Special Child, Adult and Early Intervention Services, New Jersey Department of Health and Senior Services, PO Box 364, Trenton, New Jersey 08625-0364. The Newborn Hearing Follow-up Report shall be sent to the Department within one week of the screening/testing.

(c) The Newborn Hearing Program shall establish a system to evaluate the extent to which infants who fail the electrophysiologic screen are receiving timely diagnostic 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 the section.

8:19-1.5 Screening/testing personnel

Personnel designated by hospitals and birthing centers to do electrophysiological screening include licensed physicians and licensed audiologists, and persons under their supervision. Personnel designated by the hospitals and birthing centers to do diagnostic testing include licensed physicians and licensed audiologists.

New Rule, R.2000 d.200, effective May 15, 2000.

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

Former N.J.A.C. 8:19-1.5, High risk conditions, recodified to N.J.A.C. 8:19-1.6.

8:19-1.6 High risk indicators

(a) The indicators in (b), (c) and (d) below are associated with possible hearing loss.

(b) The following indicators are for use with newborns (birth through age 28 days), when universal newborn hearing screening is not in effect, and shall be described in the literature as required by N.J.A.C. 8:19-1.1:

1. Apgar score 0-4 at one minute or 0-6 at five minutes;
2. Birth weight less than 1,500 grams;
3. Meningitis (bacterial or viral);
4. Craniofacial anomalies exclusive of isolated skin tags including, but not limited to, abnormalities of the pinna and ear canal, low hairline, cleft palate;
5. Stigmata or other findings associated with a syndrome known to include a sensorineural and/or conductive hearing loss, including, but not limited to, Waardenberg, Klippel-Feil, Down;
6. Hyperbilirubinemia requiring exchange transfusion;
7. Ototoxic drugs given to baby, including, but not limited to, the aminoglycosides, used in multiple courses or in combination with loop diuretics, for example, gentamicin, kanamycin; furosemide;
8. ECMO (extra corporeal membrane oxygenation);
9. Prolonged mechanical ventilation five days or longer;
10. Persistent pulmonary hypertension;
11. In utero infection (TORCH); and
12. Family history of hereditary childhood sensorineural hearing loss.

(c) The following indicators for use with infants (age 29 days through two years) when certain health conditions develop that require rescreening:

1. Parent/care giver concern regarding hearing, speech, language and/or developmental delay;
2. Meningitis and other infections associated with sensorineural hearing loss;
3. Head trauma associated with loss of consciousness or skull fracture;
4. Stigmata or other finding associated with a syndrome known to include a sensorineural and/or conductive hearing loss;
5. Ototoxic medications, including, but not limited to, chemotherapeutic agents or aminoglycosides, used in multiple courses or in combination with loop diuretics; and
6. Recurrent or persistent otitis media with effusion for at least three months.

(d) The following indicators are for use with infants (age 29 days through three years) who require periodic monitoring of hearing to detect delayed-onset sensorineural and/or conductive hearing loss. These infants require hearing evaluation at least every six months until three years of age, and at appropriate intervals after three years of age.

1. Indicators associated with delayed-onset sensorineural hearing loss include:
 - i. Family history of hereditary childhood hearing loss;
 - ii. In utero infection, such as cytomegalovirus, rubella, syphilis, herpes, or toxoplasmosis; and
 - iii. Neurofibromatosis Type II and neurodegenerative disorders.
2. Indicators associated with conductive hearing loss include:
 - i. Recurrent or persistent otitis media with effusion;
 - ii. Anatomic deformities and other disorders that affect eustachian tube function; and
 - iii. Neurodegenerative disorders.

Recodified from N.J.A.C. 8:19-1.5 and amended by R.2000 d.200, effective May 15, 2000.

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

Rewrote the section. Former N.J.A.C. 8:19-1.6, Confidentiality of reports, repealed.

8:19-1.7 Education and follow-up

(a) The hospital or birthing facility shall establish guidelines for the provision of follow-up services for newborns who have or are at risk of developing a hearing loss and are so identified. Follow-up services shall include, but are not limited to, confirmatory pediatric audiologic assessment and diagnosis of newborns with abnormal or inconclusive test results, submission of the completed Newborn Hearing Follow-Up Report to Special Child, Adult and Early Intervention Services (see N.J.A.C. 8:19-1.4), counseling and ed-

educational services for the parent(s), guardian(s), or custodian(s), and an explanation of the potential effects of hearing loss on the development of a newborn's speech, language and cognitive skills as well as the potential benefits of early identification and intervention.

(b) The Department shall collaborate with the Early Intervention Program, Special Child Health County Case Management, and the New Jersey Department of Education to:

1. Determine unmet needs of families of children with hearing loss;
2. Plan and implement solutions to meet these needs;
3. Establish appropriate and comprehensive tracking and follow-up programs;
4. Evaluate appropriateness, availability and accessibility of identification and intervention services; and
5. Evaluate tracking, follow-up and outcomes from identification and intervention services.

New Rule, R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

8:19-1.8 Confidentiality of reports

Any forms and reports furnished to the Department as required by this subchapter 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 including those failing electrophysiological screening.

New Rule, R.2000 d.200, effective May 15, 2000.
See: 31 N.J.R. 3943(b), 32 N.J.R. 1785(b).

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 and Senior Services.

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

"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.

"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 whose name has been placed on the Inborn Errors of Metabolism (IEM) specimen collection form by the hospital of birth or birth attendant and is responsible for all follow-up.

"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.

“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.

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.

(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.

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).

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 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 has been fed protein for fewer than 24 hours at the time of discharge or 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. If an infant is on prolonged hyperalimentation and is receiving greater than 2.5 grams of protein/kilogram, a repeat specimen shall be taken. The greater than 24 hours box on the specimen collection form shall be checked and hyperalimentation noted on the form. For those infants not on hyperalimentation, a repeat specimen shall be taken weekly until there have been 24 hours of normal oral feeding on full strength formula;

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. Specimen collected before the infant has received protein feeding for 24 hours;
- 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; and

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.

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.

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. 8:19-2.4(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.

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

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

In (a), changed N.J.A.C. reference in 2, and substituted "place on the infant's medical record" for "submit to the testing laboratory" following "obtained,".

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

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

Amended the N.J.A.C. reference in (a)2.

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. 8:19-2.4(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.

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).

Amended N.J.A.C. reference in (a)2.

8:19-2.7 Responsibilities of the home health agency

(a) The home health agency shall:

1. Follow the specimen collection procedures specified in N.J.A.C. 8:19-2.4(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.

New Rule, R.2000 d.200, effective May 15, 2000.

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

Former N.J.A.C. 8:19-2.7, Responsibilities of the public health officer, recodified to N.J.A.C. 8:19-2.8.

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

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

Amended the N.J.A.C. reference in (a)1.

8:19-2.8 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.

Recodified from N.J.A.C. 8:19-2.7 and amended by R.2000 d.200, effective May 15, 2000.

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

In (a), rewrote 3 and added 4. Former N.J.A.C. 8:19-2.8, Responsibilities of the testing laboratory, recodified to N.J.A.C. 8:19-2.9.

8:19-2.9 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. 8:19-2.4(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 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.

Recodified from N.J.A.C. 8:19-2.8 by R.2000 d.200, effective May 15, 2000.

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

Former N.J.A.C. 8:19-2.9, Responsibilities of the Follow-up Program, recodified to N.J.A.C. 8:19-2.10.

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)4, substituted "result reports of within acceptable limits" for "reports of not clinically significant results".

8:19-2.10 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.

Recodified from N.J.A.C. 8:19-2.9 by R.2000 d.200, effective May 15, 2000.

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

Former N.J.A.C. 8:19-2.10, Exemption from testing, recodified to N.J.A.C. 8:19-2.12.

8:19-2.11 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.

New Rule, R.2000 d.200, effective May 15, 2000.

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

8:19-2.12 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.

Recodified from N.J.A.C. 8:19-2.10 and amended by R.2000 d.200, effective May 15, 2000.

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

In (b) and (c), inserted references to home health agencies.

8:19-2.13 Confidentiality of reports

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. Such reports shall not be included under materials available to public inspection pursuant to P.L. 1963, c.73 (N.J.S.A. 47:1A-1 et seq.).

New Rule, R.2000 d.200, effective May 15, 2000.

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