CHAPTER He-P 3000 MATERNAL AND CHILD HEALTH

Readopt with amendment He-P 3008, effective 9-28-18 (Document #12632), to read as follows:

PART He-P 3008 NEWBORN DRIED BLOOD SPOT SCREENING, CRITICAL CONGENITAL HEART DISEASE SCREENING AND NEWBORN HEARING SCREENING

He-P 3008.01 Purpose. The purpose of this part is to describe the requirements for the screening of all newborns pursuant to RSA 132:10-a, RSA 132:10-aa, and for newborn hearing screening pursuant to RSA 132:10-b, V.

He-P 3008.02 Scope. This part shall apply to:

(a) Birth facilities and laboratories performing newborn dried blood spot screening;

(b) Birth facilities performing newborn hearing screening;

(c) Birth facilities performing newborn critical congenital heart disease screening;

(d) Providers, certified midwives, and nurse midwives performing newborn dried blood spot screening, newborn hearing screening, and critical congenital heart disease screening, or providing care to infants or children with abnormal screening results;

(e) Audiologists providing pediatric diagnostic audiology services; and

(f) Organizations and agencies providing intervention and early supports and services to children between the ages of birth and 3 years with hearing conditions.

He-P 3008.03 Definitions.

(a) "Birth facility" means the hospital or birthing center where the infant was born.

(b) "Commissioner" means the commissioner of the New Hampshire department of health and human services, or his or her designee.

(c) "Critical congenital heart disease (CCHD) screening" means screening for 7 different heart disorders that can be detected via pulse oximetry.

(d) "Department" means the department of health and human services, state of New Hampshire.

(e) "Diagnostic hearing evaluation" means comprehensive testing of infants to determine type and classification of hearing loss.

(f) "Dried blood spot (DBS)" means a specimen of blood obtained from an infant through the heel stick procedure, which is then applied to a filter paper and dried.

(g) "Early hearing detection and intervention (EHDI) program" means a department program, which oversees the newborn hearing screening process in New Hampshire.

(h) "EHDI database" means the information collection system used by the department for the reporting of newborn hearing screening, diagnosis, and treatment information.

(i) "Filter paper" means the department-approved specimen collection card which is made specifically for the purpose of collecting an infant's blood, and which is used by the laboratory for testing.

(j) "Healthcare provider" means the licensed medical doctor, licensed doctor of osteopathy, licensed advanced practice nurse, licensed physician's assistant, or certified midwife, providing care to a person.

(k) "Laboratory" means the testing facility authorized by the state of New Hampshire to conduct DBS testing on its behalf.

(l) "Newborn hearing screening" means evaluating the hearing status of infants.

(m) "Newborn screening" means the DBS testing of infants.

(n) "Newborn screening program (NSP)" means the department program which has responsibility for managing all aspects of infant DBS screening pursuant to RSA 132:10-a.

(o) "Out of range (OOR) result" means a DBS test result that is outside of the reference range shown on the clinical laboratory report.

(p) "Pediatric audiologist" means a person who specializes in the assessment and rehabilitation of hearing loss in infants and children.

(q) "Unsatisfactory specimen" means a DBS specimen which is unacceptable for issuing a laboratory result interpretation on the formal laboratory report.

He-P 3008.04 Newborn DBS Screening.

(a) Newborn screening shall be required for all infants born in the state of New Hampshire, in accordance with RSA 132:10-a, unless the parent(s) or guardian(s) object.

(b) The infant's health care provider shall inform the infant's parent or guardian of their right to opt out of the performance of the DBS testing per RSA 132:10-c.

(c) If the infant's parent or guardian objects to the performance of DBS testing, he or she shall provide a statement of dissent for refusal of newborn screening to the infant's healthcare provider or designee, subject to the following:

(1) A statement of dissent for refusal of newborn screening shall be signed and dated by the infant's parent or guardian and include:

a. Name of infant;

b. Birth date;

c. Street address, city, state, and zip code;

d. Hospital of birth;

e. Medical record number; and

f. The following understandings:

1. "I refuse to have blood taken from my baby to determine if he or she might have a disorder that can be detected through newborn screening.";

2. “I understand that State Law requires Newborn Screening for all infants born in New Hampshire.”;

3. “I have been offered the Newborn Screening Brochure and discussed newborn screening with my baby’s doctor, midwife, a member of the hospital nursing staff, or other healthcare provider.”;

4. “I understand that newborn screening is done for the early detection of treatable disorders and that symptoms sometimes do not appear for several weeks or months.”;

5. “I understand that if undetected and untreated these disorders can cause permanent damage to my child, including serious intellectual disability, growth failure and, in some cases, death.”; and

6. “The benefits of newborn screening and the potential danger of not being screened have been explained to me. My decision to refuse the testing was made freely without force or encouragement by my doctor, my baby's doctor, hospital personnel or State officials.”;

(2) The statement of dissent for refusal of newborn screening shall be included in the infant’s medical record;

(3) The infant’s healthcare provider or designee shall submit a copy of the statement of dissent for refusal of newborn screening to the NSP; and

(4) A copy of the statement of dissent for refusal of newborn screening shall be provided to the parent or guardian.

(d) Newborn screening tests shall be conducted as follows:

(1) The DBS shall be collected from the infant through the heel stick procedure and directly applied to an unexpired filter paper obtained from the NSP; and

(2) If the newborn screening tests are performed by a laboratory other than that used by the NSP, the infant’s healthcare provider shall request all tests required by the NSP and provide a copy of these test results to the NSP.

(e) For homebirths, the attending physician, advanced practice registered nurse, certified midwife, or designee shall be responsible for conducting newborn screening, as described in (a) through (d) above, and the collection of the DBS specimen, as described in He-P 3008.05(a)-(h) below.

(f) The department shall restrict the quantity of filter papers made available to birth facilities during periods when changes to the program are being made.

He-P 3008.05 DBS Collection Procedures.

(a) Except as allowed by (b)-(i) below, the infant’s healthcare provider or designee shall collect the DBS between 24 and 48 hours after birth.

(b) The infant’s healthcare provider or designee shall obtain an initial DBS at time of discharge from a birth facility for infants discharged prior to the first 24 hours of life.

(c) When the initial DBS is obtained prior to the first 24 hours of life due to early discharge, the infant's healthcare provider or designee shall obtain a second DBS within 48 hours of discharge.

(d) For infants who are sick, premature, less than 1500 grams or receiving a higher level of care, the infant's healthcare provider or designee shall obtain:

(1) An initial DBS between 24 and 48 hours of the infant's life;

(2) A second DBS at 2 weeks of age;

(3) Additional repeat DBS specimens at 1 month, and monthly thereafter; and

(4) A final DBS specimen upon discharge or transfer from the higher level of care.

(e) Except as allowed by (f) below, the infant's healthcare provider shall ensure that a DBS is obtained prior to transfer to another medical facility.

(f) If an infant's medical condition prohibits DBS collection prior to transfer to another medical facility, the transferring birth facility shall:

(1) Notify the receiving medical facility that a DBS has not been obtained; and

(2) Submit a completed filter paper form without the blood specimen and with a comment explaining the circumstances preventing the collection of blood.

(g) Upon notice of non-collection from the birth facility, the receiving medical facility shall obtain a DBS for screening in accordance with He-P 3008.05.

(h) Infants receiving a blood transfusion shall have DBS collection performed in the following manner:

(1) For infants receiving blood transfusions, the infant's healthcare provider or designee shall obtain a DBS prior to transfusion, regardless of the infant's age;

(2) If the first DBS is obtained prior to 48 hours after transfusion, then a second DBS shall be obtained 48 hours after transfusion; and

(3) A final DBS shall be collected by the infant's healthcare provider 60 days after the final transfusion.

He-P 3008.06 Disposition of the DBS.

(a) The DBS shall be processed by the infant's healthcare provider or designee as follows:

(1) The infant's healthcare provider shall note in the infant's medical record the date and time the DBS is obtained;

(2) The filter paper shall be filled out completely, including the following information:

a. Whether the DBS is an initial or repeat sample;

b. The name of the birth facility where the infant was born;

c. The infant's medical record number;

d. The name of the hospital to which the infant has been transferred, if applicable;

e. The infant's mother's name, date of birth, address, and telephone number;

f. The name, address, and telephone number of the infant's healthcare provider;

g. The infant's first and last name;

h. The infant's sex;

i. Whether the infant's birth was a single birth or multiple birth, and if multiple, the infant's birth order;

j. The date and time of infant's birth;

k. The date and time of DBS collection;

l. The infant's birth weight and current weight;

m. Whether the infant was less than 24 hours old at the time the DBS was obtained;

n. Whether the infant has undergone transfusion preceding DBS collection, and, if so, the date of the most recent transfusion;

o. Whether the infant is a patient in a neonatal intensive care unit or special care unit;

p. The infant's feeding method; and

q. Whether the submitter is the birth facility, the transfer hospital, or the infant's healthcare provider; and

(3) The filter paper shall be sent within 24 hours of collection to the laboratory providing analysis of the DBS via secure courier service provided by the laboratory.

He-P 3008.07 DBS Analysis. The laboratory conducting analysis of the DBS shall provide such analysis which includes, but is not limited to the following disorders:

(a) Phenylketonuria (PKU);

(b) Maple syrup urine disease (MSUD);

(c) Homocystinuria (HCY);

(d) Galactosemia (GALT);

(e) Congenital hypothyroidism;

(f) Toxoplasmosis;

(g) Hemoglobinopathies;

(h) Biotinidase deficiency (BIOT);

(i) Congenital adrenal hyperplasia (CAH);

(j) Medium chain acyl CoA dehydrogenase deficiency (MCAD);

(k) Cystic fibrosis (CF);

(l) Argininosuccinic aciduria (ASA);

(m) Argininemia (ARG);

(n) Carnitine uptake defect (CUD);

(o) Carnitine palmitoyltransferase II deficiency (CPTII);

(p) Citrullinemia I, (ASA synthetase def) (CIT);

(q) Cobalamin A,B (Cbl A,B);

(r) Glutaric aciduria type I (GAI);

(s) 3-hydroxy-3-methylglutaryl-CoA Lysase deficiency (HMG);

(t) Hyperornithinemia hyperammoninemia, homocitrullinemia syndrome (HHH);

(u) Isovaleric acidemia (IVA);

(v) Long chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD);

(w) 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC);

(x) Methylmalonic acidemia (MUT);

(y) Mitochondrial acetoacetyl-CoA thiolase deficiency (BKT);

(z) Multiple acyl-CoA dehydrogenase deficiency (GA2);

(aa) Multiple carboxylase deficiency (MCD);

(ab) Propionic acidemia (PROP);

(ac) Severe combined immunodeficiency disorder (SCID);

(ad) Trifunctional protein deficiency (TFP);

(ae) Tyrosinemia;

(af) Very long chain acyl-CoA dehydrogenase deficiency (VLCAD);

(ag) Spinal muscular atrophy (SMA);

(ah) Mucopolysaccharidosis Type 1 (MPS1);

(ai) X-Linked Adrenoleukodystrophy (X-ALD); and

(aj) Pompe Disease (POMPE).

He-P 3008.08 Procedures for Unsatisfactory and OOR DBS Screening Results.

(a) A DBS for re-screening shall be collected by the infant's healthcare provider or birth facility of record in the following cases:

(1) When an infant's DBS was obtained prior to the first 24 hours of life;

(2) When an infant was transfused before an initial DBS could be collected; or

(3) When the laboratory deems any specimen as unsatisfactory or any result as OOR.

(b) Upon notification by the NSP, the infant's healthcare provider shall:

(1) Arrange for the repeat DBS collection or additional testing as requested by the NSP; or

(2) Verify that another provider performs the requested testing.

(c) Upon request by the NSP, the healthcare provider shall report via secure means of transmission such as secure fax to 603-271-4519 or secure file transfer protocol, the following information:

(1) Diagnosis and treatment information for infants whose newborn screening results warranted diagnostic evaluation for a newborn screening disorder;

(2) Any suspected or confirmed case of a genetic condition or metabolic disorder listed on the newborn screening panel; and

(3) Any additional, case follow-up information regarding these diagnoses as requested by the NSP.

(d) If the infant's healthcare provider elects to utilize a laboratory service other than that utilized by the NSP to perform the retesting, the infant's healthcare provider shall be responsible for providing the results of this testing to the NSP.

(e) If a requested repeat DBS is not received by the NSP within 4 weeks of the notice in (b) above, the department shall issue a certified letter to the infant's healthcare provider and birth facility of record indicating that newborn screening testing is incomplete.

(f) The NSP shall cease attempts to obtain the repeat DBS and close its file after notice in (e) above, indicating the DBS was not received after follow-up.

He-P 3008.09 Reporting of Results. Upon receipt of a completed newborn screening report from the department, the birth facility, and infant's current healthcare provider shall include a copy of the report in the infant's medical record.

He-P 3008.10 Disposal of DBS Residual.

(a) The testing laboratory shall store DBS specimens in sealed bags of low gas permeability containing a desiccant and humidity indicator at -20 degrees Celsius.

(b) The testing laboratory shall destroy DBS specimens 6 months after the collection date, in a manner consistent with applicable federal requirements relating to the disposal of human blood and body fluids per OSHA regulations 29 CFR 1910.1030.

(c) If the storage environment of any DBS specimen is found to have deviated from the required conditions described in (a) above, such that the stability of the specimen is likely to have been affected, the testing laboratory shall first notify the NSP and shall then destroy the DBS specimen.

He-P 3008.11 Requests for DBS or Related Records. Residual DBS specimens and related records may be retrieved for other purposes only with the written authorization of a parent or guardian.

He-P 3008.12 Training of Persons Collecting a DBS. All persons performing DBS collection for newborn screening shall comply with the proper collection, handling, short-term storage, and transport of DBS in accordance with the Clinical and Laboratory Standards Institute (CLSI) "NBS 01 Dried Blood Spot Specimen Collection for Newborn Screening, 7th Edition" (April 2021) available as noted in Appendix A.

He-P 3008.13 Newborn Screening Advisory Committee.

(a) The commissioner shall appoint members to a newborn screening advisory committee (NSAC), pursuant to RSA 132:10-a, III.

(b) The NSAC shall be comprised of at least one individual from each of the following:

(1) Health care sub-specialists with expertise relative to newborn screening including, but not limited to, such specialties as:

a. Endocrinology;

b. Pediatric neurology;

c. Genetics;

d. Hematology;

e. Metabolics;

f. Obstetrics; and

g. Neonatology;

(2) A member of the health and human services oversight committee, as established by RSA 126-A:13, appointed by the chair of that committee;

(3) A genetic counselor;

(4) An individual with a genetic or metabolic disorder or a parent or caregiver of a child affected by a genetic or metabolic disorder for which there is a nationally recommended newborn screening test;

(5) A midwife practicing outside the hospital setting;

(6) A representative from the New Hampshire Pediatric Society;

(7) A nurse with child health experience;

(8) A representative from the New Hampshire Hospital Association;

(9) A representative from the department's public health laboratory;

(10) A representative from the department's maternal and child health program;

(11) A representative from the department's children with special health care needs program;

(12) A representative from the department's medicaid program;

(13) A representative from a health insurance provider; and

(14) A representative from the New Hampshire Academy of Family Physicians.

(c) Additional staff from the department may participate in the NSAC, but shall not be voting members.

(d) The NSAC shall meet at least once annually to:

(1) Advise the department on clinical, educational, and operational aspects of the NSP;

(2) Advise the department on the inclusion of additional disorders in the current newborn screening panel based upon the criteria set forth by RSA 132:10-a, I; and

(3) Offer other advice as requested by the commissioner.

(e) Each member of the NSAC shall have one vote.

(f) The NSAC shall choose, by majority vote, 2 new members to serve as co-chairs for a term of 3 years, including:

(1) One co-chair employed by the department; and

(2) One co-chair not employed by the department.

(g) A quorum shall consist of a majority of all voting members.

(h) A quorum shall be present for a vote to take place.

(i) A majority vote shall be necessary to pass a motion.

(j) Recommendations by the NSAC shall be advisory, but not binding.

He-P 3008.14 Newborn Screening Test Fees.

(a) The department shall establish fees upon hospitals to be paid directly and entirety for the newborn screening tests performed.

(b) Fees for the testing, analysis, and ancillary costs of the newborn screening program shall be determined by calculating the total yearly costs for program services divided by the state-wide annual projection of births.

(c) The department shall re-calculate fee amounts upon commissioner approval of new or changed newborn screening tests.

(d) Any change in the fee amount as a result of adding or changing newborn screening tests shall take effect upon approval by the commissioner.

(e) The department shall notify hospitals of any new or increased fee at least 30 days prior to the fee's effective date.

He-P 3008.15 Reporting of Newborn Hearing Screening Information to EHDI Program.

(a) Within 2 weeks of testing, individuals conducting newborn hearing screening and diagnostic hearing evaluation shall report the following information to the EHDI program via the EHDI database:

(1) Demographic information, including:

a. The infant's name;

b. The infant's sex;

c. The infant's race;

d. The family of the infant's preferred language for communication;

e. The infant's date of birth;

f. The infant's medical record number;

g. The infant's birth facility;

h. Family contact information; and

i. The infant's health care provider; and

(2) Results from testing, including:

a. Birth facility;

b. Testing date;

c. Type of testing;

d. Testing results;

e. Diagnosis; and

f. Risk factors for progressive hearing loss.

(b) Birth facilities shall fax to the EHDI program within 48 hours the hearing screening and diagnostic hearing in (a) above for any infant who does not pass the final newborn hearing screening.

(c) Newborn screen and diagnostic hearing information shall be reported via secure means of transmission such as secure fax to 603-271-4519 or secure file transfer protocol.

(d) In addition to the information in (a), above, New Hampshire audiologists providing diagnostic hearing evaluation shall submit to the department the following information:

(1) Referral information for medical, genetic, and early support services; and

(2) Hearing follow-up information, such as post-referral disposition.

(e) In addition to the information in (a) above, New Hampshire organizations and agencies providing intervention and early supports and services to children between the ages of birth and three years with hearing conditions shall submit to the department the following information:

(1) Early supports and services, individual family service plan, start date and discharge date; and

(2) Nature of the services provided and post referral disposition date.

He-P 3008.16 Critical Congenital Heart Disease (CCHD) Screening.

(a) Newborn CCHD screening shall be required for all infants born in the state of New Hampshire in accordance with RSA 132:10-aa.

(b) CCHD screening shall be accomplished by pulse oximetry following the American Academy of Pediatrics (AAP) guidelines and screening algorithm "Strategies for Implementing Screening for Critical Congenital Heart Disease," (November 2011) available as noted in Appendix A.

He-P 3008.17 Reporting of CCHD Screening Results. Within 24 hours of screening completion, facilities and individuals performing the screening shall report the results to the NSP, via secure means of transmission such as secure fax to 603-271-4519 or secure file transfer protocol, the following demographic information:

(a) The infant's name;

(b) The infant's sex;

(c) The infant's date of birth;

(d) The infant's medical record number;

(e) The infant's birth facility;

(f) Mother's name and address;

(g) Screening date;

(h) Screening results following AAP guidelines "Strategies for Implementing Screening for Critical Congenital Heart Disease," (November 2011) available as noted in Appendix A;

(i) Further testing completed for infants with positive screening results; and

(j) Referral and transfer information.

He-P 3008.18 Complaints and Non-Compliance. Upon receiving a complaint that an individual or facility listed in He-P 3008.02(a)-(f) is not practicing in accordance with this part, the department shall:

(a) Investigate the complaint; and

(b) If founded, refer the complaint to a relevant disciplinary body, such as the New Hampshire board of medicine.

He-P 3008.19 Confidentiality and Security of Records.

(a) All records maintained by the NSP and EHDI or its contractors, including paper files, facsimile transmissions, or electronic data transfers, shall be strictly confidential.

(b) All confidential information shall be kept in a secured area at all times as follows:

(1) Paper records and external electronic storage media shall be kept in locked file cabinets;

(2) All electronic files shall be password protected; and

(3) All confidential notes or other materials that do not require storage shall be shredded immediately after use.

He-P 3008.20 Quality Assurance.

(a) Birth facilities shall allow periodic reviews of their newborn screening, CCHD, and newborn hearing screening activities by department staff for quality assurance purposes.

(b) Reviews shall include, but not be limited to:

(1) The review of policies and procedures regarding newborn screening, CCHD, newborn hearing screening, and diagnostic hearing evaluation;

(2) Interviews with staff performing any aspect of newborn screening, CCHD, and newborn hearing screening; and

(3) The on-site review of medical records.

(c) The NSP shall provide upon request:

(1) Information regarding acceptable procedures for the collection, handling, short-term storage, and transport of a DBS;

(2) Information regarding newborn screening that shall be given to and reviewed with the parent or guardian of each infant prior to testing; and

(3) Text to be used in statements of dissent for refusal of newborn screening described in He-P 3008.04(c).

(d) The NSP and the EHDI program shall compare the data sets of infants screened with New Hampshire birth certificate files, in order to ensure that every infant born in New Hampshire is screened, or had the opportunity to be screened, for hearing, CCHD, and for those conditions that are determined by DBS testing.

Appendix A: Incorporation by Reference Information

Rule	Title	Publisher; How to Obtain; and Cost
He-P 3008.12	The Clinical and Laboratory Standards Institute (CLSI), "NBS 01 Dried Blood Specimen Collection for Newborn Screening, 7th Edition" (April 2021)	Publisher: Clinical and Laboratory Standards Institute Cost: Members $54-$170/Nonmembers $200 The incorporated document is available at: https://clsi.org/standards/products/newborn-screening/documents/nbs01/

Rule	Title	Publisher; How to Obtain; and Cost
He-P 3008.16(b) and He-P 3008.17(h)	American Academy of Pediatrics (AAP), "Strategies for Implementing Critical Congenital Heart Disease" (November 2011)	Publisher: American Academy of Pediatrics (AAP) Cost: Free of Charge The incorporated document is available at: https://publications.aap.org/pediatrics/article/128/5/e1259/30947/Strategies-for-Implementing-Screening-for-Critical?autologincheck=redirected

APPENDIX B

RULE	STATUTE
He-P 3008.01	RSA 132:10-a, III; RSA 132:10-b, V
He-P 3008.02	RSA 132:1; RSA 132:10-a
He-P 3008.03	RSA 132:1
He-P 3008.04	RSA 132:10-a, I; RSA132:10-c
He-P 3008.05	RSA 132:10-a
He-P 3008.06	RSA 132:10-a
He-P 3008.07	RSA 132:10-a
He-P 3008.08	RSA 132:10-a
He-P 3008.09	RSA 132:10-a
He-P 3008.10	29 CFR 1910.1030
He-P 3008.11	45 CFR 164.524
He-P 3008.12	RSA 132:10-a, I(c)
He-P 3008.13	RSA 132:10-a, III
He-P 3008.14	RSA 132:10-a, II; RSA 541-A
He-P 3008.15	RSA 132:10-b, V; RSA 132:12
He-P 3008.16 and He-P 3008.17	RSA 132:10-aa
He-P 3008.18	RSA 132:3
He-P 3008.19	45 CFR 160 and 45 CFR 164
He-P 3008.20	RSA 132:3