TITLE 7 HEALTH
CHAPTER 30 FAMILY AND CHILDREN HEALTH CARE SERVICES
PART 6 NEWBORN GENETIC SCREENING PROGRAM

7.30.6.1 ISSUING AGENCY: New Mexico Department of Health.
[7.30.6.1 NMAC - Rp, 7 NMAC 30.6.1, 10/30/12]

7.30.6.2 SCOPE: Universal screening of all infants born in New Mexico (NM) for the congenital conditions listed and defined herein shall be done through a statewide screening program established through the public health division. The department shall institute and carry on such laboratory services or may contract with another agency or entity to provide such services as are necessary to detect the presence of congenital disorders.
[7.30.6.2 NMAC - Rp, 7 NMAC 30.6.2, 10/30/12]

7.30.6.3 STATUTORY AUTHORITY: The statutory authority for these regulations is contained in Section 9-7-6 NMSA 1978 and Section 24-1-6 NMSA 1978 as amended Laws 1981, Chapter 95, Sec. 1.
[7.30.6.3 NMAC - Rp, 7 NMAC 30.6.3, 10/30/12]

7.30.6.4 DURATION: Permanent.
[7.30.6.4 NMAC - Rp, 7 NMAC 30.6.4, 10/30/12]

7.30.6.5 EFFECTIVE DATE: October 30, 2012, unless a later date is cited at the end of a section.
[7.30.6.5 NMAC - Rp, 7 NMAC 30.6.5, 10/30/12]

7.30.6.6 OBJECTIVE: The purpose of these regulations is to establish standards and procedures to assure congenital metabolic conditions and other genetic disorders which can cause significant mental or physical retardation or significant morbidity or mortality can be detected by screening newborn infants. Early detection and prompt referral for treatment may help prevent death and alleviate the effects of these disorders. These rules provide for screening tests to be performed on every newborn except where, in accordance with these rules, the parents or guardians waive this requirement in writing.
[7.30.6.6 NMAC - Rp, 7 NMAC 30.6.6, 10/30/12]

7.30.6.7 DEFINITIONS:

A. "Children's medical service" ("CMS") is a unit of the public health division in the NM department of health that engages in:

(1) identification of children and youth with, or at risk for having, special health care needs (CYSHCN);

(2) provision of preventive, diagnostic, treatment services and care coordination toward the attainment of maximum health for children with special health care needs, and adults with cystic fibrosis;

(3) promotion of the development of quality health care and outcome measures for this population (children and youth with special health care needs);

(4) monitoring these outcomes and the impact of changes in the health care system for this population;

(5) technical assistance and training for individuals serving this population; and

(6) administration of the universal newborn hearing screening program and the newborn genetic screening program, and other necessary administrative services to assess the needs of this population, facilitating access to care, and providing services.

B. "Hospital" means a hospital or other institution having facilities for childbirth.

C. "Neonatal intensive care unit" ("NICU") means an intensive care unit specializing in the care of ill or premature newborn infants.

D. "Newborn genetic screening program" means a unit of the public health division under children's medical services department that engages in:

(1) surveillance, assurance and policy development;

(2) public and provider education;

(3) follow-up (both short-term and long-term) to assure quality of care for infants who have abnormal results on screening; and

(4) provision of efficient service coordination between families and their infants, between the contracted laboratory and other involved entities.

E. "Primary care physician" ("PCP") means a family practitioner, pediatrician, physicians assistant, nurse practitioner, general practitioner, or midwife that will be assuming the continuing care of the infant after discharge from the birth facility or after homebirth.

F. "Parents or guardians" means persons with legal decision making authority for the child.

[7.30.6.7 NMAC - Rp, 7 NMAC 30.6.7, 10/30/12]

7.30.6.8 DISORDERS:

A. Disorders for which screening shall be performed include the following:

(1) 3-mthylcrotonyl-CoA deficiency;
(2) 3-OH 3-CH3 glutaric aciduria;
(3) argininosuccinic academia;
(4) mitochondrial acetoacetyl-CoA;
(5) biotinidase deficiency;
(6) carnitine uptake defect;
(7) citrullinemia;
(8) congenital adrenal hyperplasia;
(9) congenital hypothyroidism;
(10) cystic fibrosis;
(11) galactosemia;
(12) glutaric academia type I;
(13) Hb S/beta-thalassemia;
(14) hearing deficiency;
(15) homocystinuria;
(16) isovaleric academia;
(17) long-chain L-3-OH acyl-CoA dehydrogenase deficiency;
(18) maple syrup urine disease;
(19) medium chain acyl-CoA dehydrogenase deficiency;
(20) methylmalonic academia;
(21) multiple carboxylase deficiency;
(22) phenylketonuria;
(23) proponic academia;
(24) sickle cell anemia;
(25) trifunctional protein deficiency;
(26) tyrosinemia type I; and
(27) very long-chain acyl-CoA dehydrogenase deficiency.

[7.30.6.8 NMAC - N, 10/30/12]

7.30.6.9 NEWBORN BLOOD SAMPLE COLLECTION:

A. Every newborn infant, whether born in a hospital, birthing center, or at home shall receive tests on two newborn screening blood samples; unless the parents or guardians, after being informed of the reasons for the tests, waive the requirements for the tests in writing.

(1) The first blood sample shall be obtained, between 24-48 hours of age.
(2) The second blood sample shall be obtained between the 10th and 14th day after birth.
(3) Second screens may be taken at a hospital, outpatient medical clinic and facility, outpatient laboratory, primary care provider's office or by a midwife.

B. All birthing facilities, and midwives, in NM are required to practice uniform discharge screening regardless of the age or feeding status of the newborn.

C. Prematurity and transfusion status will be noted on the collection form in the space provided. Newborns who require any anticipated blood transfusion shall have a blood sample taken before the procedure. In those rare events where a screen was obtained after a transfusion, the facility is still required to submit the specimen for screening.

D. All birthing hospitals, birthing centers, and midwives will inform the parents of the requirement for a second screen prior to discharge. The PCP, birthing hospital, midwives, nurses, nurse practitioner or physician

shall give the parents educational brochures supplied by program, and shall advise them where the test may be obtained.

E. In the case of inter-hospital transfer of an infant, the transferring hospital shall provide written notification to the receiving hospital indicating whether or not a specimen has been taken prior to transfer.

(1) Infants who are transferred to another facility within 48 hours of birth shall be tested by the receiving facility.

(2) If a newborn screening kit has been issued by the birth hospital to the infant, it shall be sent with the infant ensuring that both facilities are notified of the results.

(3) Following transfer, the receiving hospital shall assume responsibility for collection of the specimen in accordance with these rules.

[7.30.6.9 NMAC - Rp, 7 NMAC 30.6.8, 10/30/12]

7.30.6.10 WAIVER:

A. Pursuant to Section 24-1-6 NMSA 1978, parents or guardians may waive the requirements for newborn screening tests in writing.

B. The department's newborn screening program will provide the hospital, birthing centers, and midwives with forms for waiver.

C. The infant's PCP, midwife, or nurse shall provide parents or guardians with both written and oral explanations before the parents or guardians may sign a waiver for newborn screening test. The decision to waive screening will be acknowledged by signature of the parents or guardian on the form provided by the department. The document of waiver shall be placed in the child's hospital medical record and a copy shall be sent to the children's medical services newborn screening program and a copy to the parent(s).

D. The waiver will not be used for the purpose of changing the times of the screening or for submitting only a single screen; it is used to waive the newborn screening tests in their entirety. No modifications can be placed on the form.

[7.30.6.10 NMAC - Rp, 7 NMAC 30.6.9, 10/30/12]

7.30.6.11 COLLECTION AND SCREENING PROCEDURES:

A. Newborn screening collection kits shall only be purchased from the NM department of health's children's medical services newborn screening program.

B. The department of health's newborn screening program shall set the rate for newborn screening kits. The fees collected from purchase of the kits shall be utilized by the program for testing, quality assurance, and follow up of newborn screening conditions.

C. Each newborn screening kit shall be completely filled out for each blood sample. The following is required to be completed on each newborn screening kit:

(1) demographic area. All contact information for mother must be completed as well as additional contact information for the mother or a relative;

(2) name and phone number of PCP or provider who will be following the newborn after discharge;

(3) specimen date and time; and

(4) name and signature of person collecting specimen.

D. Types of kits that can be used.

(1) Hospitals, birthing centers, and midwives may only purchase newborn screening double kits.

(2) NICUs, outpatient laboratories, clinics, and PCP offices may purchase a limited number of newborn screening single kits at a time.

(3) NICUs in NM shall purchase triple kits to be used in their units only, and they shall be used in accordance with clinical and laboratory standards institute guidelines for collection of newborn screening for pre-term, low birth weight, and sick newborns.

(4) Newborn screening single kits are only to be used in NICUs for additional screening, or only in the event a parent misplaces kits, or the birthing facility does not give the kit to the parent at discharge.

(5) Each newborn screening double kit is for one newborn and is not to be split between two newborns.

(6) A limited number of single kits will be placed at public health offices across the state as a safety net for parents to obtain kits in the event they misplace, lose a kit, or the birthing facility in error does not send the second half of the double kit home with the parent.

E. All first newborn screens will be shipped by overnight courier assigned by the department of health newborn genetic screening program. Specimens will be shipped to the address indicated on the collection form within 24 hours of the time that the sample is taken.
[7.30.6.11 NMAC - N, 10/30/12]

7.30.6.12 FOLLOW-UP PROCEDURES:

A. All results will be reported to the hospital and infants PCP for placement in the child's medical record.

B. In the event of positive or questionable screening test results, the department of health's children's medical services newborn screening program and or contracted outreach lab short-term follow-up program will immediately contact and inform the PCP of the need for further testing. The primary care physician will be responsible for contacting and informing the parents or guardians of the need for further testing.

C. In the event no PCP is named on the newborn screening form the newborn screening program will pursue follow-up with the parents or guardians directly.
[7.30.6.12 NMAC - N, 10/30/12]

7.30.6.13 STORAGE OF NEWBORN SCREENING SPECIMENS:

A. The newborn screening program of the department of health or contracted laboratory may store the blood samples of newborns collected for the screening of genetic disorders for up to one year. After that time, the blood samples shall be destroyed.

B. The newborn screening program may change the length and conditions of storage if the program determines that such a change is necessary.

C. Bloodspot cards shall not be disseminated after blood spot testing for any purpose unrelated to newborn screening, except to parents or guardians who may request them in writing during the retention period.
[7.30.6.13 NMAC - N, 10/30/12]

HISTORY OF 7.30.6 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the State Records Center:
HSSD 77-2, Regulations On Phenylketonuria, 5/4/77.
HED 79-HSD-1, Newborn Screening Program Regulations, 6/28/79.
HED 89-8 (PHD), Newborn Screening Program Regulations, 9/12/89.
DOH 92-02 (PHD), Newborn Screening Program Regulations, 10/5/92.

History of Repealed Material:
7 NMAC 30.6, Newborn Genetic Screening Program, filed 10/18/1996 - Repealed effective 10/30/2012.