

Title 181 SPECIAL HEALTH PROGRAMS

Chapter 10 SCREENING OF NEWBORNS FOR CRITICAL CONGENITAL HEART DISEASE

10-001 SCOPE: These regulations implement the law governing screening of newborns for critical congenital heart disease, Neb. Rev. Stat. §§71-553 through 71-557. These regulations define terms; state the requirements for screening for critical congenital heart diseases; specify the diseases for which the test is required; specify the time periods for performance and reporting of results of the tests by physicians, hospitals, and births not attended by a physician; and prescribe test methods and techniques, and such reports and reporting procedures as are necessary to implement the law.

10-002 DEFINITIONS: As used in these regulations, unless the context otherwise requires:

Birthing Facility means any facility defined under Neb. Rev. Stat. §71-555(1)

Critical Congenital Heart Disease (CCHD) means one of seven targeted lesions for which newborn screening by pulse oximetry is intended to detect. The seven lesions are hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

Department means the Department of Health and Human Services of the State of Nebraska.

Echocardiogram means a diagnostic test that uses ultrasound waves to create an image of the heart muscle. Echocardiograms can show the size, shape, and movement of the heart's valves and chambers as well as the flow of blood through the heart.

Hospital means any facility defined under Neb. Rev. Stat §71-419.

Hypoplastic Left Heart Syndrome means a structural birth defect that involves a number of underdeveloped or too small of structures on the left side of the heart including the left ventricle, mitral valve, aortic valve, ascending portion of the aorta. Often babies with this syndrome will also have an atrial septal defect, or hole between the left and right atria.

Inconclusive Screen Result is a result of the screening algorithm which is neither positive (failed) or negative (passed) but requires further screening to make a determination of positive or negative.

Negative screen result means an oxygen saturation screening test result that is above the cut-off, and the difference in measurement of the oxygen saturation between the right hand and foot is below a specified percent. A passed screen is a negative screen result for critical congenital heart disease.

Newborn means a child from birth through twenty-nine days old

Newborn Screening for critical congenital heart disease means a testing procedure or procedures intended to detect hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus;

NICU means neonatal intensive care unit. A hospital unit staffed and equipped to provide intensive care to premature, low birthweight and seriously ill newborns.

Parent means a natural parent, a stepparent, an adoptive parent, a legal guardian, or any other legal custodian of a child.

Physician means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to the Medicine and Surgery Practice Act.

Positive screen result means an oxygen saturation screening test result that is below the cut off, or the difference in measurement of the oxygen saturation between the right hand and foot exceeds a specified percent. A failed screen is a positive screen result for possible critical congenital heart disease.

Prenatal care provider means a licensed health care professional providing care to pregnant women before delivery of the newborn.

Pulmonary Atresia means a structural birth defect in which the pulmonary valve between the right ventricle and pulmonary artery is abnormal and does not open. This may also result in a small or missing right ventricle.

Pulse Oximetry means a non-invasive method of measuring the percent oxygen saturation of hemoglobin in the arterial blood.

Tetralogy of Fallot means structural birth defects of the heart affecting four parts. Ventricular septal defect is a hole in the wall between the two lower chambers of the heart. Pulmonary stenosis is a narrowing of the pulmonary valve and main pulmonary artery. The aortic valve is enlarged and open to both ventricles instead of just the left ventricle. Right ventricular hypertrophy is a thickening of the lower right chamber muscle wall.

Total anomalous pulmonary venous return means a condition present at birth in which the oxygen rich blood returns from the lungs to the right atrium or a vein flowing to the right atrium instead of the left side of the heart.

Transposition of the great of arteries means a birth defect in which the two main arteries going out of the heart, the pulmonary artery and the aorta, are switched in position.

Tricuspid atresia means a structural birth defect in which the tricuspid heart valve is either missing or abnormally developed.

Truncus arteriosus means a structural birth defect in which only one vessel comes out of the right and left ventricles instead of the two normal vessels (pulmonary artery and aorta). There is usually also a ventricular septal defect or large hole between the two ventricles.

10-003 HOSPITAL AND BIRTHING FACILITY RESPONSIBILITIES

- 10-003.01 Policies and Procedures. Hospital and Birthing Facilities must ensure policies and procedures consistent with these regulations are developed and implemented to screen all newborns for critical congenital heart disease as defined at 10-002. Screening must be done using pulse oximetry at 24 hours of life or soon after on day 2 of life, or prior to discharge whichever occurs first.
- 10-003.02 Transfer to NICU: If a newborn is transferred to a neonatal intensive care unit the transferring hospital must document that they notified the receiving hospital of the CCHD screening results. If no results were available, the transferring facility must document they notified the receiving facility that the CCHD screen needs to be completed.
- 10-003.03 Screening Method: Screening must be completed using pulse oximetry. The probe and sensors must be placed on the right hand and one foot. If reusable probes and sensors are used, proper sanitation to prevent infection and communicable disease must be maintained. False negatives are possible. Therefore negative screening results should not delay referral for pediatric cardiology evaluation of an infant otherwise suspected of having CCHD.
- 10-003.03A Negative Screen Results or Passed Screen: Infants with oxygen saturation percentages of 95 percent or more in the right hand or foot and the difference between the hand and foot is 3 percent or less, pass the screen. The results must be recorded in the newborn's medical record.
- 10-003.03B Inconclusive screen results: Oxygen saturation percentages between 90 percent and less than 95 percent on both the right hand and foot, or a difference of more than 3 percent between the hand and foot is an inconclusive result. The newborn shall not be discharged and must be rescreened in one hour. If the rescreen remains inconclusive a third screen must be done in one hour. If on the third screen the results continue to not meet the pass criteria, this is a failed screen. Immediately notify the newborn's physician. All results must be recorded in the newborn's medical record.
- 10-003.03C Positive screen results or failed screen: Oxygen saturation percentages less than 90 percent on any screen (initial or rescreen) is a failed screen. This is a positive result for possible critical congenital heart disease. Immediately notify the newborn's physician. The results must be recorded in the newborn's medical record.

10-003.04 Screening Method for newborns admitted to the neonatal intensive care unit.

10-003.04A All newborns admitted to the neonatal intensive care unit must be screened.

10-003.04B For any newborn in the NICU less than 8 days, screen using the standard protocol as described in 10-003.3A B and C.

10-003.04C For any newborn in the NICU longer than 7 days the screening requirement may be met by the level of care they receive often including prolonged pulse oximetry monitoring, possibly chest x-rays and echocardiogram, and continuous intensive monitoring and repeated physician exams.

10-003.05 Verifying every newborn in census is screened: The hospital or birthing facility must maintain a method of verifying every newborn in their census received a valid screen. For those who were transferred without a screen, the transferring hospital must document that the receiving hospital was notified during the newborn's transfer that screening for CCHD needs to be done. For any newborn discharged without a screen, the hospital must notify the newborn's physician and parents or legal guardian, and must reschedule an appointment to complete the screen.

10-003.06 Quality Monitoring The hospital or birthing facility must monitor quality indicators such as the number and percent of newborns with failed screens, newborns transferred without a screen, newborns referred for pediatric echocardiogram, age at screen for all newborns who failed the screen.

10-004 PHYSICIAN DUTIES

10-004.01 Prenatal care provider duties
Prenatal care providers must provide information to expecting parents about newborn screening for CCHD. Information must explain the importance of screening for CCHD, how it is done and that all newborns must have the test whether they are born in a hospital or birthing facility or not.

10-004.02 Attending physician duties
The newborn's attending physician or his/her designee must verify the newborn screen for CCHD has been completed and results documented in the newborn's medical record including any discharge summaries prior to discharge.

10-004.03 Failed Screen, follow-up Upon notification of a failed screen, the attending physician shall assess the infant, obtain or refer for echocardiogram and NICU/Cardiology evaluation.

10-004.04 Transfer to another facility If transfer to another facility is made, the attending physician or his/her designee shall ensure the results of all testing and evaluation are provided to the receiving facility and physician.

10-005 BIRTHS OCCURRING OUTSIDE A HOSPITAL OR BIRTHING FACILITY

10-005.01 The parent or person registering the birth of a newborn not born in a hospital or birthing facility must ensure the screen for critical congenital heart disease occurs not sooner than 24 hours of life and prior to 48 hours in accordance with procedures specified at 10-003.3 A B and C.