NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

October 2, 2019
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level B
301 Centennial Mall South, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 181, Chapter 10 of the Nebraska Administrative Code (NAC) – *Screening of Newborns for Critical Congenital Heart Disease.* The proposed regulations remove any repeat of statutory language from the regulations and update formatting. There are no substantive changes to the regulations.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title: 181	Prepared by:Julie Luedtke
Chapter: 10	Date prepared: 4.25.2019
Subject: Screening of Newborns for Critical Congenital Heart Disease	Telephone: 402 471-6733

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☒)	(☒)	(☒)
Increased Costs	(☐)	(☐)	(☐)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☐)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

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 arteriosis 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: Hospitals 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 a Neonatal Intensive Care Unit

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

10-003.04B For any newborn in a 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 a 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 10-003.3A, B and C.

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 10 SCREENING OF NEWBORNS FOR CRITICAL CONGENITAL HEART DISEASE

001. SCOPE. These regulations implement the law governing screening of newborns for critical congenital heart disease set out in Nebraska Revised Stats.(Neb. Rev. Stats.) §§ 71-553 through 71-557.

002. DEFINITIONS. Definitions set out Neb. Rev. Stats. §§ 71-553 through 71-557 and the following apply to this chapter.

002.01 CRITICAL CONGENITAL HEART DISEASE (CCHD). 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.

002.02 ECHOCARDIOGRAM. 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.

002.03 HOSPITAL. Any facility defined under Neb. Rev. Stat. § 71-419.

002.04 HYPOPLASTIC LEFT HEART SYNDROME. 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.

002.05 INCONCLUSIVE SCREEN RESULT. 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.

002.06 NEGATIVE SCREEN RESULT. 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.

002.07 NEONATAL INTENSIVE CARE UNIT (NICU). A hospital unit staffed and equipped to provide intensive care to premature, low birthweight and seriously ill newborns.

002.08 PHYSICIAN. A person licensed to practice medicine and surgery or osteopathic medicine and surgery.

002.09 POSITIVE SCREEN RESULT. 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.

002.010 PRENATAL CARE PROVIDER. A licensed health care professional providing care to pregnant women before delivery of the newborn.

002.011 PULMONARY ATRESIA. 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.

002.012 PULSE OXIMETRY. A non-invasive method of measuring the percent oxygen saturation of hemoglobin in the arterial blood.

002.013 TETRALOGY OF FALLOT. 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.

002.014 TOTAL ANOMALOUS PULMONARY VENOUS RETURN. 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.

002.015 TRANSPOSITION OF THE GREAT OF ARTERIES. A birth defect in which the two main arteries going out of the heart, the pulmonary artery and the aorta, are switched in position.

002.016 TRICUSPID ATRESIA. A structural birth defect in which the tricuspid heart valve is either missing or abnormally developed.

002.017 TRUNCUS ARTERIOSIS. 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.

003. HOSPITAL AND BIRTHING FACILITY RESPONSIBILITIES. All hospital and birthing facilities must:

(A) Have and implement policies and procedures consistent with this chapter to screen all newborns for critical congenital heart disease. 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.

(B) Document that it notified the receiving hospital of the critical congenital heart disease screening results for every newborn transferred. If no results were available, the

transferring facility must document it notified the receiving facility that the critical congenital heart disease screen needs to be completed.

(C) Complete screening for critical congenital heart disease 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, so negative screening results must not delay referral for pediatric cardiology evaluation of an infant otherwise suspected of having critical congenital heart disease. The results of all screening must be recorded in the newborn's medical record.

(D) Consider newborns 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 as having passed the screen.

(E) Consider 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 as an inconclusive result. The newborn must 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. The hospital or birthing facility must immediately notify the newborn's physician of the failed screen for critical congenital heart disease.

(F) Consider oxygen saturation percentages less than 90 percent on any screen, initial or rescreen, as a failed screen. This is an indication of possible critical congenital heart disease. The hospital or birthing facility must immediately notify the newborn's physician of this failed screen.

(G) Screen all newborns admitted to a neonatal intensive care unit for critical congenital heart disease. Screening of any newborn admitted to a neonatal intensive care unit for less than 8 days must follow the protocol set out in this chapter. For any newborn in a neonatal intensive care unit longer than 7 days, the screening requirement may be met by the level of care the newborn otherwise routinely receives in the unit, which may include including prolonged pulse oximetry monitoring, chest x-rays and echocardiogram, ~~and~~ continuous intensive monitoring and repeated physician exams.

(H) Maintain a method of verifying every newborn in its care received a screen for critical congenital heart disease. For any newborn discharged without such a screen, the hospital or birthing facility must notify the newborn's physician and parents or legal guardian, and must reschedule an appointment to complete the screen.

(I) Monitor quality indicators which must include at a minimum the number and percent of newborns with failed screens, newborns transferred without a screen, newborns referred for a pediatric echocardiogram, and the age at screening for all newborns who failed a screen.

004. PHYSICIAN DUTIES. All physicians and prenatal care providers must:

(A) Provide information to expecting parents about newborn screening for critical congenital heart disease. The information must include the importance of screening for critical congenital heart disease, how it is done and that all newborns must have the test whether they are born in a hospital or birthing facility or not.

(B) If he or she is a newborn's attending physician, the physician must verify the newborn screen for critical congenital heart disease has been completed and ensure the results are documented in the newborn's medical record including any discharge summaries prior to discharge. Upon notification of a failed screen, the attending physician shall

assess the infant, obtain or refer for echocardiogram and neonatal intensive care unit or cardiology evaluation.

(C) If a transfer to another facility is made, the attending physician must ensure the results of all screening, tests, and evaluations for critical congenital heart disease are provided to the receiving facility and physician.

005. BIRTHS OCCURRING OUTSIDE A HOSPITAL OR BIRTHING FACILITY. The parent or person registering the birth of a newborn not born in a hospital or birthing facility must ensure that all required screening for critical congenital heart disease occurs not sooner than 24 hours of life and prior to 48 hours in accordance with procedures specified in this chapter.