

1 10A NCAC 43K.0101 is proposed as a temporary rule as follows:

2 **SUBCHAPTER 43K – NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DEFECTS**

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4 **10A NCAC 43K .0101 DEFINITIONS**

5 As used in this Section:

- 6 (1) “Neonate” means any term infant less than 28 days of age or any preterm infant less than 28 days
7 corrected age.
- 8 (2) “Infant” means a person who is less than 365 days of age.
- 9 (3) “Critical congenital heart defects” (CCHD) means heart conditions present at birth that are
10 dependent on therapy to maintain patency of the ductus arteriosus for either adequate pulmonary or
11 systemic blood flow and that require catheter or surgical intervention in the first year of life. These
12 heart defects are associated with significant morbidity and mortality and may include but are not
13 limited to hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous
14 pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus
15 arteriosus.
- 16 (4) “Medical facility” means a birthing center, licensed hospital, or licensed ambulatory surgery center
17 where scheduled or emergency births occur or where inpatient neonatal services are provided.
- 18 (5) “Pulse oximetry” means a non-invasive transcutaneous assessment of arterial oxygen saturation
19 using near infrared spectroscopy. This screening test measures with high reliability and validity
20 the percentage of hemoglobin that is oxygenated also known as the blood oxygen saturation.
- 21 (6) “Positive screening” means the final result is a failed or abnormal pulse oximetry screening for
22 critical congenital heart defects for a neonate or infant using a screening protocol based on the
23 most current American Academy of Pediatrics and American Heart Association (AAP/AHA)
24 recommendations. This includes neonates or infants who have not yet been confirmed to have
25 critical congenital heart defects or have other conditions to explain abnormal pulse oximetry
26 results.
- 27 (7) “Negative screening” means the final result is a passed or normal pulse oximetry screening for
28 critical congenital heart defects for a neonate or infant using a screening protocol based on the
29 most current AAP/AHA recommendations.
- 30 (8) “Attending providers of the neonate or infant” means the health care providers (i.e., pediatricians,
31 family physicians, physician assistants, midwives, nurse practitioners, neonatologists and other
32 specialty physicians) who perform neonatal and infant assessments and review positive and
33 negative pulse oximetry screening results to determine an appropriate evaluation and plan of care
34 for the neonate or infant prior to discharge from the care of the health care provider. This includes
35 health care providers who attend to births, neonates or infants in hospitals, birthing centers, homes
36 or other locations.

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2 *History Note: Authority G.S. 130A-125*