

### **10A NCAC 43K .0103 REPORTING REQUIREMENTS**

(a) All medical facilities and attending providers of neonates or infants performing critical congenital heart defect (CCHD) screening shall report the information described below about positive screenings to a statewide CCHD database maintained by the Perinatal Quality Collaborative of North Carolina (PQCNC). The following information must be reported by medical facilities and attending providers within 7 days of all positive screenings:

- (1) date and time of birth of the neonate or infant, gestational age, and the medical facility or birth location, and
- (2) age in hours at time of screening; all pulse oximetry saturation values, including initial, subsequent, and final screening results; final diagnosis if known; any known interventions and treatment, and any need for transport or transfer; and the location of the transfer or transport if known.

(b) Within two weeks of receiving a positive screening, PQCNC shall report the above information from the CCHD database to the NC Birth Defects Monitoring Program using a unique identifier generated by the CCHD database for the neonate or infant. The unique identifier shall be retained by the source medical facility or attending provider for help with identification of the neonate or infant.

(c) All medical facilities and attending providers of neonates or infants performing critical congenital heart defect screening shall report aggregate information described in Subparagraphs (e)(1) through (e)(7) of this Rule quarterly and no later than 15 days after the end of each quarter of the state fiscal year to a statewide CCHD database maintained by the Perinatal Quality Collaborative of North Carolina (PQCNC).

(d) PQCNC shall report the aggregate information described in Sub-paragraphs (e)(1) through (e)(7) to the NC Birth Defects Monitoring Program within 30 days after the end of each quarter of the state fiscal year.

(e) The required quarterly aggregate information from medical facilities and attending providers of neonates or infants reported to PQCNC and that PQCNC reports to the NC Birth Defects Monitoring Program shall include the total unduplicated counts of:

- (1) live births;
- (2) neonates and infants who were screened;
- (3) negative screenings;
- (4) positive screenings;
- (5) neonates or infants whose parents or guardians objected to the critical congenital heart defect screenings;
- (6) transfers into the medical facility, not previously screened; and
- (7) neonates and infants not screened and the reasons if known which include a diagnostic echocardiogram being performed after birth and prior to discharge, transfer out of the medical facility before screening, or death .

*History Note: Authority G.S. 130A-125;  
Temporary Adoption Eff. July 25, 2014;  
Eff. April 1, 2015.*