10A NCAC .0102 is adopted with changes as published in 29:11 NCR 1298-1301 as follows:

10A NCAC 43K .0102 SCREENING REQUIREMENTS

(a) All medical facilities and attending providers of a neonate or infant shall assure the following:

(1) Screening of every neonate for critical congenital heart defects (CCHD) using pulse oximetry shall be performed at 24 to 48 hours of age using a written protocol developed by the provider based upon and in accordance with the most current recommendations from the American Academy of Pediatrics and American Heart Association (AAP/AHA) which are incorporated by reference including subsequent amendments and editions, unless a diagnostic neonatal echocardiogram has been performed. A copy of the recommendations is available for inspection at the NC Division of Public Health, Women's and Children's Health Section, Children and Youth Branch, 5601 Six Forks Road, Raleigh, NC 27609. In addition, the recommendations can be accessed at the American Academy of Pediatrics website at: http://pediatrics.aappublications.org/content/128/5/e1259.full.pdf+html?sid=85e81711-f9b8-43d1-a352-479168895a72.

(2) Screening of a neonate for CCHD who is born in a free-standing birthing center or home may occur as early as 6 hours of age but shall not occur later than 48 hours of age using the AAP/AHA recommendations.

(3)~~(2)~~ Screening of neonates and infants in neonatal intensive care units for critical congenital heart defects using pulse oximetry screening shall be performed using a written protocol ~~protocol~~ based on the AAP/AHA recommendations as soon as the neonate or infant is ~~stable~~ stable, as determined by the attending provider, and off oxygen and before discharge unless a diagnostic echocardiogram is performed on the neonate or infant after birth and prior to discharge from the medical facility.

(4)~~(3)~~ Only U.S. Food and Drug Administration approved pulse oximetry equipment is used and maintained to screen the neonate or infant for the presence of critical congenital heart defects.

(b) Parents or guardians may object to the critical congenital heart defects screening at any time before the screening is performed in accordance with G.S. 130A-125.

(c) All medical facilities and attending providers of the neonate or infant shall have and implement a written protocol developed by the provider ~~plan~~ for evaluation and follow up of positive critical congenital heart defect screenings.

(1) Evaluation and follow up of a positive screening for all neonates shall occur as soon as possible but no later than 24 hours of obtaining a positive screening result. Evaluation and follow-up shall be in accordance with the most current published recommendations from the American Academy of Pediatrics and American Heart Association (AAP/AHA) which is incorporated by reference including subsequent amendments and editions. A copy of the recommendations is available for inspection at the NC Division of Public Health, Women's and Children's Health Section, Children

and Youth Branch, 5601 Six Forks Road, Raleigh, NC 27609. In addition, the recommendations can be accessed at the American Academy of Pediatrics website at: http://pediatrics.aappublications.org/content/128/5/e1259.full.pdf+html?sid=85e81711-f9b8-43d1-a352-479168895a72.

~~(2) For neonates with positive screenings who are born in a birthing facility, a home, or other location, the AAP/AHA recommended evaluation and follow up shall occur as soon as possible but no later than 24 hours after obtaining the positive screening result.~~

(2) ~~(3)~~ Attending providers of neonates and infants in neonatal intensive care units must have a written protocol developed by the provider ~~process~~ for evaluation and follow up of positive screenings in place at their medical facility.

(3) ~~(4)~~ Options for neonatal or infant echocardiograms may include on-site, telemedicine, or by transfer or referral to an appropriate medical facility with the capacity to perform and interpret a neonatal or infant echocardiogram. Echocardiograms must be interpreted as recommended by the most current recommendations from the AAP/AHA, which are incorporated by reference including subsequent amendments and editions. A copy of the recommendations is available for inspection at the NC Division of Public Health, Women's and Children's Health Section, Children and Youth Branch, 5601 Six Forks Road, Raleigh, NC 27609. In addition, the recommendations can be accessed at the American Academy of Pediatrics website at: http://pediatrics.aappublications.org/content/128/5/e1259.full.pdf+html?sid=85e81711-f9b8-43d1-a352-479168895a72.

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

10A NCA 43K .0103 is adopted with changes as published in 29:11 NCR 1298-1301 as follows:

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 seven 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 process that provides~~ 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 Sub-paragraphs (e)(1) through (e)(7) ~~below~~ 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) ~~below~~ 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.

10A NCAC 43B.1304 is amended with changes as published in 29:11 NCR 1301-1304 as follows:

10A NCAC 48B .1304 BENCHMARK 37

(a) Benchmark: The local board of health shall assure the development, ~~implementation~~ implementation, and evaluation of local health services and programs to protect and promote the public's health.

(b) Activities:

(1) The local board of health or the consolidated human services director shall assure that a qualified local health ~~director,~~ director has been appointed in accordance with G.S. 130A-40 or ~~40.1, is in place to lead the agency.~~ 40.1

(2) The local board of health shall approve policies for the administration of local public health programs.

(3) The local board of health or the consolidated human services director shall describe and define the knowledge, skills, and abilities that must be met by the local health director, consistent with the requirements in G.S. 130A-40.

(4) The local board of health or the consolidated human services director shall review and approve the job description of the local health director.

(5) The supervisor ~~local board of health [or the consolidated human services director]~~ shall conduct an annual performance review of the health director.

(6) The local board of health or the consolidated human services director shall approve policies for the recruitment, retention and workforce development for agency staff.

History Note: *Authority G.S. 130A-34.1;*
Temporary Adoption Eff. January 1, 2006;
Eff. April 1, 2015; October 1, 2006.

10A NCAC 43B.1305 is amended as published in 29:11 NCR 1301-1304 as follows:

10A NCAC 48B .1305 BENCHMARK 38

(a) Benchmark: The local board of health shall participate in the establishment of public health goals and objectives.

(b) Activities:

(1) The local board of health shall annually review reports provided by the local health department on the community's health.

(2) The local board of health or the advisory committee on health shall review community health assessment data and citizen input used to plan and monitor progress toward health-related goals.

(3) The local board of health or the advisory committee on health shall assure that individuals, agencies, and organizations have the opportunity to participate in the development of goals, objectives and strategies for community health improvement.

History Note: *Authority G.S. 130A-34.1;*
Temporary Adoption Eff. January 1, 2006;
Eff. April 1, 2015; October 1, 2006.

10A NCAC 43B.1306 is amended as published in 29:11 NCR 1301-1304 as follows:

10A NCAC 48B .1306 BENCHMARK 39

(a) Benchmark: The local board of health shall assure the availability of resources to implement the essential services described in G.S. 130A-34.1(e)(2).

(b) Activities:

(1) The local board of health or the advisory committee on health shall communicate with the board of county commissioners, units of government and private foundations in support of local health department efforts to secure national, state and local financial resources.

(2) The local board of health shall review fiscal reports to assure essential services of public health are being provided in accordance with local, state and federal requirements.

(3) The local board of health shall annually review and approve the local health department budget and approve fees in accordance with G.S. 130A-39(g).

(4) The local board of health or the advisory committee on health shall communicate with the board of county commissioners, units of government and private foundations in support of the development, implementation and evaluation of public health programs and a community health improvement process.

(5) The local board of health shall assure that the proposed budget for the local health department meets maintenance of effort requirement in the consolidated agreement between the Division of Public Health and local health department.

History Note: *Authority G.S. 130A-34.1;*
Temporary Adoption Eff. January 1, 2006;
Eff. April 1, 2015; October 1, 2006.

10A NCAC 43B.1307 is amended as published in 29:11 NCR 1301-1304 as follows:

10A NCAC 48B .1307 BENCHMARK 40

(a) Benchmark: The local board of health or the advisory committee on health shall advocate in the community on behalf of public health.

(b) Activities:

(1) The local board of health or the advisory committee on health shall inform elected officials and community boards about community health issues.

(2) The local board of health or the advisory committee on health shall communicate support for the enactment and retention of laws and rules and the development of public health interventions that protect health and ensure safety.

History Note: *Authority G.S. 130A-34.1;*
Temporary Adoption Eff. January 1, 2006;
Eff. April 1, 2015; October 1, 2006.