10A NCA 43K .0101 is adopted with changes as published in 29:11 NCR 1298-1301 as follows:

CHAPTER 43 – PERSONAL HEALTH

SUBCHAPTER 43K – NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DEFECTS

10A NCAC 43K .0101 DEFINITIONS

As used in this Section:

(1) "Neonate" means any term infant less than 28 days of age or any preterm infant less than 28 days corrected age.

(2) "Infant" means a person who is less than 365 days of age.

(3) "Critical congenital heart defects" (CCHD) means heart conditions present at birth that are dependent on therapy to maintain patency of the ductus arteriosus for either adequate pulmonary or systemic blood flow and that require catheter or surgical intervention in the first year of life. Critical congenital heart defects are associated with significant morbidity and mortality and may include hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

(4) "Medical facility" means a free-standing birthing center, licensed hospital, or licensed ambulatory surgery center where scheduled or emergency births occur or where inpatient neonatal services are provided.

(5) "Pulse oximetry" means a non-invasive transcutaneous assessment of arterial oxygen saturation using near infrared spectroscopy. This screening test measures with high reliability and validity the percentage of hemoglobin that is oxygenated, also known as the blood oxygen saturation.

(6) "Positive screening" means the final result is a failed or abnormal pulse oximetry screening for critical congenital heart defects for a neonate or infant using a screening protocol based on the most current American Academy of Pediatrics and American Heart Association (AAP/AHA) recommendations. This includes neonates or infants who have not yet been confirmed to have critical congenital heart defects or have other conditions to explain abnormal pulse oximetry results. 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.

(7) "Negative screening" means the final result is a passed or normal pulse oximetry screening for critical congenital heart defects for a neonate or infant using a screening protocol based on the most current AAP/AHA recommendations.

(8) "Attending providers of the neonate or infant" means the health care providers, such as pediatricians, family physicians, physician assistants, midwives, nurse practitioners, neonatologists, and other specialty physicians, who perform neonatal and infant assessments and review positive and negative pulse oximetry screening results to perform an evaluation and to create a plan of care for the neonate or infant prior to discharge from the care of the health care provider. This includes health care providers who attend to neonates or infants in hospitals, free-standing birthing centers, homes, or other locations.

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

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 43K .0102

DEADLINE FOR RECEIPT: Friday, March 13, 2015

***NOTE WELL:* This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

In (a)(1), who is responsible for writing the protocols? Is it the hospital or birthing center? What about the homes or other locations?

In (a)(3), please make changes in accordance with 26 NCAC 02C .0108(7), which indicates that the "smallest unit of text to be struck through or underlined shall be an entire word…"

In (a)(3), I assume that by "stable", you mean "stable" in the opinion of the attending provider?

In (c)(2), is the "written process" the same referred to in (a)(1)? If so, please be consistent in your wording.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

Amber Cronk May
Commission Counsel
March 2, 2015

10A NCAC 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 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 based on the AAP/AHA recommendations as soon as the neonate or infant is stable 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 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 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.

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 43K .0103

DEADLINE FOR RECEIPT: Friday, March 13, 2015

***NOTE WELL:* This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

Did you intend on further listing out the items contained in (a)(2)? Based on the semi-colons, it appears as though you did. If you did, please do so and delete the "and" at the end of (a)(1). It does appear that further listing would make this more clear.

In (b), what is the process for providing a unique identifier? What do you mean by unique identifier? Are there any specific requirements for how the identifier shall be retained? Are there any rules or statutes that you can cross-reference?

In (c) and (d), what do you mean by "below"? The information contained in (c)(1) through (c)(7)? Please make this more clear.

Please correct your temporary effective date.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

Amber Cronk May
Commission Counsel
March 2, 2015

10A NCA 43K .0103 is adopted 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 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 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 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, 201;
Eff April 1. 2015.

10a NCAC 48B.0103 is amended as published in 29:11 NCR 1301-1304 as follows:

10A NCAC 48B .0103 ACCREDITATION REQUIREMENTS

(a) To receive an accreditation status of "accredited," a local health department must satisfy all of the accreditation standards contained in this Subchapter. In order to satisfy the accreditation standards, the local health department shall satisfy activities under the standards according to the following proportions:

(1) Standard 1. Agency core functions and essential services:

(A) The local health department must satisfy at least 26 of the 29 activities listed in the benchmarks contained in Sections .0200 and .0300 of this Subchapter;

(B) The local health department must satisfy at least 23 of the 26 activities listed in benchmarks contained in Sections .0400 through .0600 of this Subchapter;

(C) The local health department must satisfy at least 34 of 38 activities listed in the benchmarks contained in Sections .0700 through .1100 of this Subchapter;

(2) Standard 2. Facilities and administrative services: The local health department must satisfy at least 24 of the 27 activities listed in the benchmarks contained in Section .1200 of this Subchapter; and

(3) Standard 3. Board of health: The local health department must satisfy at least ~~25 of the 28~~ 24 of the 27 activities listed in the benchmarks contained in Section .1300 of this Subchapter.

(b) In order to satisfy an activity, the local health department must satisfy all of the requirements prescribed for that activity. Failure to complete any activity requirement associated with an activity means that the activity is not satisfied.

History Note: *Authority G.S. 130A-34.1;*
Temporary Adoption Eff. January 1, 2006;
Eff. October 1, 2006;
Amended Eff. April 1, 2015; February 1, 2013:

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 48B .1301

DEADLINE FOR RECEIPT: Friday, March 13, 2015

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The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

In (b)(1), what is the state law that you are referring? Is your regulated public familiar with this?

In (b)(2), what do you mean by "shall have access to"? Does legal counsel have to be on retainer or employed by the local board of health?

In (b)(5), is there any guidance that you can cross-reference with regard to how the local board of health shall determine the need for a local rule or ordinance? Is this done in the sole discretion of the local board of health? Is there a need to include the advisory committee or the director?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

Amber Cronk May
Commission Counsel
March 2, 2015

10A NCAC 43B.1301 is 0103 is amended as published in 29:11 NCR 1301-1304 as follows:

10A NCAC 48B .1301 BENCHMARK 34

(a) Benchmark: The local board of health shall exercise its authority to adopt and enforce rules necessary to protect and promote the public's health.

(b) Activities:

(1) The local board of health shall have operating procedures which shall comply with state law.

~~(2) The local board of health shall review its operating procedures annually.~~

(2)~~(3)~~ The local board of health shall have access to legal counsel.

(3)~~(4)~~ The local board of health shall follow the procedures for adopting rules in G.S. 130A-39.

(4)~~(5)~~ The local board of health shall evaluate the need for the adoption or amendment of local rules or ordinances.

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

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 48B .1304

DEADLINE FOR RECEIPT: Friday, March 13, 2015

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The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

Please be consistent in your use of the serial comma.

In (b)(2), did you intend to only provide the approval of policies to the local board of health, and not to the consolidated human services director? You have allowed the consolidated services director to approve policies in (b)(6).

Please check line 17. It seems to be misplaced.

In (b)(5), who is the supervisor? Also, is there any guidance in rule or statute for the annual performance review?

In (b)(5), did you mean "local health director"? Please be consistent in your wording.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

Amber Cronk May
Commission Counsel
March 2, 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 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.

The supervisor ~~local board of health or the consolidated human services 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.

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 48B .1305

DEADLINE FOR RECEIPT: Friday, March 13, 2015

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The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

In (b)(1), did you intend to only include the local board of health and not the advisory committee on health?

In (b)(2), what data are you referring to? Is there a cross-reference on the requirements of the data that you can provide?

In (b)(3), are there any minimum requirements in order to assure that the public has the opportunity to participate, such as public hearings? Is there a statute or rule that you can cross-reference to provide additional guidance?

Please update your history note to reflect the effective date.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

Amber Cronk May
Commission Counsel
March 2, 2015

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. October 1, 2006.

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 48B .1306

DEADLINE FOR RECEIPT: Friday, March 13, 2015

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The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

In (b)(2), (b)(3), and (b)(5), did you intend to only include the local board of health and not the advisory committee on health?

In (b)(1) and (b)(4), what do you mean by the board of health or the advisory committee shall communicate in support of local health departments' efforts and health programs and improvement process?

In (b)(2), what are "essential services"? Also, is your regulated public familiar with the referenced local, state, and federal requirements?

In (b)(3), I understand that the fees shall be in accordance with 130A-39(g); however, what will the approval of the budget be based on? Is this based on the requirement in (a)(5)?

In (a)(5), what is the "maintenance of effort requirement"? Should there be a "the" before "maintenance of effort requirement."

Please consider reorganizing this rule to make it more clear.

Please update your history note to reflect the effective date.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

Amber Cronk May
Commission Counsel
March 2, 2015

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. October 1, 2006.

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 48B .1307

DEADLINE FOR RECEIPT: Friday, March 13, 2015

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The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

In (b)(2), what sort of communication are you requiring? What do you mean by "communicate support"?

Please update your history note to reflect the effective date.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

Amber Cronk May
Commission Counsel
March 2, 2015

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. October 1, 2006.

10A NCAC 43B.1308 is amended as published in 29:11 NCR 1301-1304 as follows:

10A NCAC 48B .1308 BENCHMARK 41

(a) Benchmark: The local board of health or the advisory committee on health shall promote the development of public health partnerships.

(b) Activities:

(1) The local board of health or the advisory committee on health shall take actions to foster community input regarding public health issues.

(2) The local board of health or the advisory committee on health shall take actions to foster local health department partnership-building efforts and staff interactions with the community.

(3) The local board of health or the advisory committee on health shall take actions to foster the coordination of resources to enhance partnerships and collaboration to achieve public health objectives.

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