RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 43K .0101; .0102; .0103

RECOMMENDED ACTION:

Approve**,** but note staff's comment

X Object, based on:

Lack of statutory authority

Unclear or ambiguous

Unnecessary

X Failure to comply with the APA

Extend the period of review

COMMENT:

It is staff's recommendation that the Rules Review Commission object to the temporary rules filed by the Commission for Public Health, as the Commission for Public Health failed to comply with G.S. 150B-21.1.

Failure to comply with G.S. 150B-21.1(a2):

The Commission for Public Health completed the Temporary Rule-Making Findings of Need forms for all three rules in box 6 by indicating that the reason for the action was "[t]he effective date of a recent act of the General Assembly or of the U.S. Congress." The recent act of the General Assembly cited by the Commission for Public Health is Session Law 2013-45, also known as Senate Bill 98. Session Law 2013-45 was ratified on May 2, 2013, signed by the Governor on May 8, 2013, and became effective on May 8, 2013.

G.S. 150B-21.1(a) authorizes an agency to "adopt a temporary rule when it finds that adherence to the notice and hearings requirements of G.S. 150B-21.2 would be contrary to the public interest and

that the immediate adoption of the rule is required by…the effective date of a recent act of the General Assembly." G.S. 150B-21.1(a2) defines a term "recent" as follows:

> A recent act, change, regulation, or order as used in subdivisions (2) through (5) of subsection (a) of this section means an act, change, regulation, or order occurring or made effective no more than 210 days prior to the submission of a temporary rule to the Rules Review Commission.

The following timeline is significant to establish the recommendation of staff to object to the temporary rules filed by the Commission for Public Health:

Date of Action	Action Taken	Days since the "recent act" of the General Assembly
May 8, 2013	Recent act of the General Assembly became effective.	0
December 4, 2013	210th day since recent act of the General Assembly became effective	210
March 31, 2014	Proposed temporary rules submitted to OAH for publication on website	328 (118 days since December 4, 2013)
May 14, 2014	Proposed temporary rules adopted by the Commission for Public Health	372 (162 days since December 4, 2013)
June 4, 2014[1]	Adopted temporary rules submitted to the Rules Review Commission	392 (183 days since December 4, 2013)

The timeline clearly establishes that the Commission for Public Health submitted the temporary rules to the Rules Review Commission outside the 210 days allowed by G.S. 150-21.1(a2), and therefore fails to meet the statutory requirements for temporary rulemaking.

Summary:

The Commission for Public Health has submitted three temporary rules for review by the Rules Review Commission, 10A NCAC 43K .0101; .0102; .0103. The Commission for Public Health indicated on the Findings of Need that the reason for the rulemaking action was a recent act of the General

[1] Please note that staff of the Commission for Public Health came to the Office of Administrative Hearings on Tuesday, May 20, 2014, in order to submit the temporary rules for review by the Rules Review Commission on that date. Based upon G.S. 150B-21.1(b) and the mandate for the Rules Review Commission to act within 15 business days after receiving temporary rules, staff counsel requested that the Commission for Public Health not submit the temporary rules prior to Wednesday, May 28, 2014 to avoid the necessity of calling a special set meeting. Please note that a submission on May 20, 2014 would have still been 277 days since the "recent act" of the General Assembly.

Assembly. The recent act of the General Assembly occurred 392 days prior to the submission of the adopted temporary rules by the Commission for Public Health, and is not within the statutory 210 day time period set forth in G.S. 150-21.1(a2).

Staff is concerned that should the Rules Review Commission review and approve the temporary rules adopted by the Commission for Public Health, that the Rules Review Commission would be violating the plain language of G.S. 150-21.1(a2). It is staff's opinion that the temporary rules filed by the Commission for Public Health should be objected to by the Rules Review Commission for failure to comply with the Administrative Procedure Act.

ORIGINAL 6/04/14

TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: Commission for Public Health

2. RULE CITATION & NAME: 10A NCAC 43K .0101 DEFINITIONS

3. Action: ☒ Adoption ☐ Amendment ☐ Repeal

4. Was this an Emergency Rule: ☐ Yes ☒ No Effective date:

5. Provide dates for the following actions as applicable:

a. Proposed Temporary Rule submitted to OAH: March 31, 2014

b. Proposed Temporary Rule published on the OAH website: April 7, 2014

c. Public Hearing date: April 21, 2014

d. Comment Period: April 7 – May 2, 2014

e. Notice pursuant to G.S. 150B-21.1(a3)(2):

f. Adoption by agency on: May 14, 2014

g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: July 1, 2014

h. Rule approved by RRC as a permanent rule:

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

☐ A serious and unforeseen threat to the public health, safety or welfare.
☒ The effective date of a recent act of the General Assembly or of the U.S. Congress.
Cite: SL 2013-45
Effective date: May 2, 2013
☐ A recent change in federal or state budgetary policy.
Effective date of change:
☐ A recent federal regulation.
Cite:
Effective date:
☐ A recent court order.
Cite order:
☐ State Medical Facilities Plan.
☐ Other:

FILED
2014 JUN -4 PM 4:11
OFFICE OF ADMIN HEARINGS

Explain:

...
TO EXPAND THE NEWBORN SCREENING PROGRAM ESTABLISHED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO INCLUDE NEWBORN SCREENING FOR CONGENITAL HEART DISEASE UTILIZING PULSE OXIMETRY, AS RECOMMENDED BY THE NORTH CAROLINA CHILD FATALITY TASK FORCE, THE COMMISSION FOR PUBLIC HEALTH SHALL ADOPT TEMPORARY AND PERMANENT RULES TO INCLUDE NEWBORN HEARING SCREENING AND PULSE OXIMETRY SCREENING IN THE NEWBORN SCREENING PROGRAM ...

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Immediate adoption of a temporary rule while the permanent rule is in process provides expedited implementation of screening for congenital heart disease, which potentially affects up to 200 newborns each year in North Carolina. Timely diagnosis can prevent major disease complications if gone undetected.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

9. Rule-making Coordinator: Chris Hoke, JD

Phone: 919 707-5006

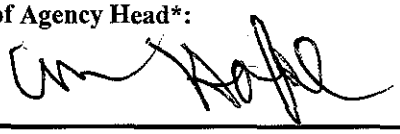
E-Mail: Chris.hoke@dhhs.nc.gov

Agency contact, if any: Bob Martin

Phone: 919 707-5179

E-Mail: bob.martin@dhhs.nc.gov

10. Signature of Agency Head*:



*** If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**
Typed Name: Chris Hoke, JD

Title: Chief, Legal and Regulatory Affairs

RULES REVIEW COMMISSION USE ONLY	
Action taken: ☐ Date returned to agency:	Submitted for RRC Review:

FULL VERSION

<< S97

Senate Bill 98 / S.L. 2013-45 (= H105)

S99 >>

Require Pulse Oximetry Newborn Screening.

2013-2014 Session

Bill Text	Fiscal Note
Filed [HTML]	
Edition 1 [HTML]	SFN0098v1r1
Edition 2 [HTML]	
Ratified [HTML]	
SL2013-45 [HTML]	

Last Action:	Ch. SL 2013-45 on 05/08/2013
Sponsors:	Andrew C. Brock; Louis Pate; Josh Stein; (Primary) Chad Barefoot; Don Davis; Ralph Hise; Gene McLaurin; Wesley Meredith;
Attributes:	Public; Text has changed;
Counties:	*No counties specifically cited*
Statutes:	130A (Chapter); 130A-125 (Section)
Keywords:	CHAPTERED, COMMISSIONS, DHHS, MINORS, NEWBORNS & INFANTS, PRESENTED, PUBLIC, PUBLIC HEALTH, PUBLIC HEALTH COMN., RATIFIED, TESTING

Vote History

Date	Subject	RCS #	Aye	No	N/V	Exc. Abs.	Exc. Vote	Total	Result
04/11/2013 10:23AM	Second Reading	[S] - 156	46	0	0	4	0	46	PASS
05/01/2013 3:18PM	Second Reading	[H] - 425	114	0	3	3	0	114	PASS

Viewing Last 2 Vote(s) ***View All Votes***

History RSS

Date	Chamber	Action	Documents	Vote
02/18/2013	Senate	Filed	DRS75051-MG-13C	
02/19/2013	Senate	Passed 1st Reading		
02/19/2013	Senate	Ref To Com On Health Care		
04/10/2013	Senate	Reptd Fav		
04/11/2013	Senate	Amend Adopted A1	**A1:** S98-ATK-11-V-1	PASS
04/11/2013	Senate	Passed 2nd Reading		PASS
04/11/2013	Senate	Passed 3rd Reading		
04/11/2013		Engrossed		
04/15/2013	House	Rec From Senate		
04/16/2013	House	Passed 1st Reading		
04/16/2013	House	Ref To Com On Health and Human Services		
04/30/2013	House	Reptd Fav		
04/30/2013	House	Cal Pursuant Rule 36(b)		
04/30/2013	House	Placed On Cal For 05/01/2013		
05/01/2013	House	Passed 2nd Reading		PASS: 114-0
05/01/2013	House	Passed 3rd Reading		
05/01/2013	House	Ordered Enrolled		
05/02/2013		Ratified		
05/02/2013		Pres. To Gov. 05/03/2013		
05/08/2013		Signed by Gov. 5/8/2013		
05/08/2013		Ch. SL 2013-45		

Note: a bill listed on this website is not law until passed by the House and the Senate, ratified, and, if required, signed by the Governor.

2013-2014 Session

Bill Number: enter bill # (i.e., S253) Look-Up

SESSION LAW 2013-45
SENATE BILL 98

AN ACT TO EXPAND THE NEWBORN SCREENING PROGRAM ESTABLISHED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO INCLUDE NEWBORN SCREENING FOR CONGENITAL HEART DISEASE UTILIZING PULSE OXIMETRY, AS RECOMMENDED BY THE NORTH CAROLINA CHILD FATALITY TASK FORCE.

Whereas, in 2010, approximately 122,300 babies were born to North Carolina residents; and

Whereas, congenital heart defects account for 24% of infant deaths due to birth defects; and

Whereas, more than 1,400 babies with congenital heart defects do not live to celebrate their first birthday; and

Whereas, in the United States, approximately 4,800 babies born every year have one of seven critical congenital heart defects (CCHDs); and

Whereas, infants with one of these CCHDs are at significant risk for death or disability if not diagnosed and treated soon after birth; and

Whereas, newborn screening using pulse oximetry, which is a noninvasive test to determine the amount of oxygen in the blood and the pulse rate, can identify some CCHDs before infants even show signs of the condition; and

Whereas, once identified, infants with CCHDs can receive specialized care and treatment by a cardiologist that could prevent death or disability early in life; and

Whereas, in September 2011, the Secretary of the United States Department of Health and Human Services approved adding screening for CCHDs to the Recommended Uniform Screening Panel upon the recommendation of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Now, therefore,

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 130A-125 reads as rewritten:

"**§ 130A-125. Screening of newborns for metabolic and other hereditary and congenital disorders.**

(a) The Department shall establish and administer a Newborn Screening Program. The program shall include, but shall not be limited to:

(1) Development and distribution of educational materials regarding the availability and benefits of newborn screening.

(2) Provision of laboratory testing.

(3) Development of follow-up protocols to assure early treatment for identified children, and the provision of genetic counseling and support services for the families of identified children.

(4) Provision of necessary dietary treatment products or medications for identified children as medically indicated and when not otherwise available.

(5) For each newborn, provision of physiological screening in each ear for the presence of permanent hearing loss.

(6) For each newborn, provision of pulse oximetry screening to detect congenital heart defects.

(b) The Commission shall adopt rules necessary to implement the Newborn Screening Program. The rules shall include, but shall not be limited to, the conditions for which screening shall be required, provided that screening shall not be required when the parents or the guardian of the infant object to such screening. If the parents or guardian object to the screening, the

objection shall be presented in writing to the physician or other person responsible for administering the test, who shall place the written objection in the infant's medical record.

(b1) The Commission ~~for Public Health~~ shall adopt temporary and permanent rules to include newborn hearing screening and pulse oximetry screening in the Newborn Screening Program established under this section.

(b2) The Commission's rules for pulse oximetry screening shall address at least all of the following:

(1) Follow-up protocols to ensure early treatment for newborn infants diagnosed with a congenital heart defect, including by means of telemedicine. As used in this subsection, "telemedicine" is the use of audio and video between places of lesser and greater medical capability or expertise to provide and support health care when distance separates participants who are in different geographical locations.

(2) A system for tracking both the process and outcomes of newborn screening utilizing pulse oximetry, with linkage to the Birth Defects Monitoring Program established pursuant to G.S. 130A-131.16.

(c) A fee of nineteen dollars ($19.00) applies to a laboratory test performed by the State Laboratory of Public Health pursuant to this section. The fee for a laboratory test is a departmental receipt of the Department and shall be used to offset the cost of the Newborn Screening Program."

SECTION 2. This act is effective when it becomes law.

In the General Assembly read three times and ratified this the 2nd day of May, 2013.

s/ Daniel J. Forest
President of the Senate

s/ Paul Stam
Speaker Pro Tempore of the House of Representatives

s/ Pat McCrory
Governor

Approved 4:51 p.m. this 8th day of May, 2013

Part 2. Adoption of Rules.

§ 150B-21.1. Procedure for adopting a temporary rule.

(a) Adoption. - An agency may adopt a temporary rule when it finds that adherence to the notice and hearing requirements of G.S. 150B-21.2 would be contrary to the public interest and that the immediate adoption of the rule is required by one or more of the following:

(1) A serious and unforeseen threat to the public health, safety, or welfare.

(2) The effective date of a recent act of the General Assembly or the United States Congress.

(3) A recent change in federal or State budgetary policy.

(4) A recent federal regulation.

(5) A recent court order.

(6) The need for a rule establishing review criteria as authorized by G.S. 131E-183(b) to complement or be made consistent with the State Medical Facilities Plan approved by the Governor, if the rule addresses a matter included in the State Medical Facilities Plan, and the proposed rule and a notice of public hearing is submitted to the Codifier of Rules prior to the effective date of the Plan.

(7) The need for the Wildlife Resources Commission to establish any of the following:

a. No wake zones.

b. Hunting or fishing seasons, including provisions for manner of take or any other conditions required for the implementation of such season.

c. Hunting or fishing bag limits.

d. Management of public game lands as defined in G.S. 113-129(8a).

(8) The need for the Secretary of State to implement the certification technology provisions of Article 11A of Chapter 66 of the General Statutes, to adopt uniform Statements of Policy that have been officially adopted by the North American Securities Administrators Association, Inc., for the purpose of promoting uniformity of state securities regulation, and to adopt rules governing the conduct of hearings pursuant to this Chapter.

(9) The need for the Commissioner of Insurance to implement the provisions of G.S. 58-2-205.

(10) The need for the Chief Information Officer to implement the information technology procurement provisions of Article 3D of Chapter 147 of the General Statutes.

(11) The need for the State Board of Elections to adopt a temporary rule after prior notice or hearing or upon any abbreviated notice or hearing the agency finds practical for one or more of the following:

a. In accordance with the provisions of G.S. 163-22.2.

b. To implement any provisions of state or federal law for which the State Board of Elections has been authorized to adopt rules.

c. The need for the rule to become effective immediately in order to preserve the integrity of upcoming elections and the elections process.

(12) The need for an agency to adopt a temporary rule to implement the provisions of any of the following acts until all rules necessary to implement the provisions of the act have become effective as either temporary or permanent rules:

a. Repealed by Session Laws 2000-148, s. 5, effective July 1, 2002.

b. Repealed by Session Laws 2000-69, s. 5, effective July 1, 2003.

(13), (14) Reserved.

(15) Expired pursuant to Session Laws 2002-164, s. 5, effective October 1, 2004.

(16) Expired pursuant to Session Laws 2003-184, s. 3, effective July 1, 2005.

(17) To maximize receipt of federal funds for the Medicaid or NC Health Choice programs within existing State appropriations, to reduce Medicaid or NC Health Choice expenditures, and to reduce Medicaid and NC Health Choice fraud and abuse.

(a1) Recodified as subdivision (a)(16) of this section by Session Laws 2004-156, s. 1.

(a2) A recent act, change, regulation, or order as used in subdivisions (2) through (5) of subsection (a) of this section means an act, change, regulation, or order occurring or made effective no more than 210 days prior to the submission of a temporary rule to the Rules Review Commission. Upon written request of the agency, the Commission may waive the 210-day requirement upon consideration of the degree of public benefit, whether the agency had control over the circumstances that required the requested waiver, notice to and opposition by the public, the need for the waiver, and previous requests for waivers submitted by the agency.

(a3) Unless otherwise provided by law, the agency shall:

(1) At least 30 business days prior to adopting a temporary rule, submit the rule and a notice of public hearing to the Codifier of Rules, and the Codifier of Rules shall publish the proposed temporary rule and the notice of public hearing on the Internet to be posted within five business days.

(2) At least 30 business days prior to adopting a temporary rule, notify persons on the mailing list maintained pursuant to G.S. 150B-21.2(d) and any other interested parties of its intent to adopt a temporary rule and of the public hearing.

(3) Accept written comments on the proposed temporary rule for at least 15 business days prior to adoption of the temporary rule.

(4) Hold at least one public hearing on the proposed temporary rule no less than five days after the rule and notice have been published.

(a4) An agency must also prepare a written statement of its findings of need for a temporary rule stating why adherence to the notice and hearing requirements in G.S. 150B-21.2 would be contrary to the public interest and why the immediate adoption of the rule is required. If the temporary rule establishes a new fee or increases an existing fee, the agency shall include in the written statement that it has complied with the requirements of G.S. 12-3.1. The statement must be signed by the head of the agency adopting the temporary rule.

(b) Review. - When an agency adopts a temporary rule it must submit the rule and the agency's written statement of its findings of the need for the rule to the Rules Review Commission. Within 15 business days after receiving the proposed temporary rule, the Commission shall review the agency's written statement of findings of need for the rule and the rule to determine whether the statement meets the criteria listed in subsection (a) of this section and the rule meets the standards in G.S. 150B-21.9. The Commission shall direct a member of its staff who is an attorney licensed to practice law in North Carolina to review the statement of findings of need and the rule. The staff member shall make a recommendation to the Commission, which must be approved by the Commission or its designee. The Commission's designee shall be a panel of at least three members of the Commission. In reviewing the statement, the Commission or its designee may consider any information submitted by the agency or another person. If the Commission or its designee finds that the statement meets the criteria listed in subsection (a) of this section and the rule meets the standards in G.S. 150B-21.9, the Commission or its designee must approve the temporary rule and deliver the rule to the Codifier of Rules within two business days of approval. The Codifier of Rules must enter the rule into the North Carolina Administrative Code on the sixth business day following receipt from the Commission or its designee.

(b1) If the Commission or its designee finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency. The agency may supplement its statement of need

with additional findings or submit a new statement. If the agency provides additional findings or submits a new statement, the Commission or its designee must review the additional findings or new statement within five business days after the agency submits the additional findings or new statement. If the Commission or its designee again finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency and return the rule to the agency.

(b2) If an agency decides not to provide additional findings or submit a new statement when notified by the Commission or its designee that the agency's findings of need for a rule do not meet the required criteria or that the rule does not meet the required standards, the agency must notify the Commission or its designee of its decision. The Commission or its designee shall then return the rule to the agency. When the Commission returns a rule to an agency in accordance with this subsection, the agency may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes.

(b3) Notwithstanding any other provision of this subsection, if the agency has not complied with the provisions of G.S. 12-3.1, the Codifier of Rules shall not enter the rule into the Code.

(c) Standing. - A person aggrieved by a temporary rule adopted by an agency may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes. In the action, the court shall determine whether the agency's written statement of findings of need for the rule meets the criteria listed in subsection (a) of this section and whether the rule meets the standards in G.S. 150B-21.9. The court shall not grant an ex parte temporary restraining order.

(c1) Filing a petition for rule making or a request for a declaratory ruling with the agency that adopted the rule is not a prerequisite to filing an action under this subsection. A person who files an action for declaratory judgment under this subsection must serve a copy of the complaint on the agency that adopted the rule being contested, the Codifier of Rules, and the Commission.

(d) Effective Date and Expiration. - A temporary rule becomes effective on the date specified in G.S. 150B-21.3. A temporary rule expires on the earliest of the following dates:

(1) The date specified in the rule.

(2) The effective date of the permanent rule adopted to replace the temporary rule, if the Commission approves the permanent rule.

(3) The date the Commission returns to an agency a permanent rule the agency adopted to replace the temporary rule.

(4) The effective date of an act of the General Assembly that specifically disapproves a permanent rule adopted to replace the temporary rule.

(5) 270 days from the date the temporary rule was published in the North Carolina Register, unless the permanent rule adopted to replace the temporary rule has been submitted to the Commission.

(e) Publication. - When the Codifier of Rules enters a temporary rule in the North Carolina Administrative Code, the Codifier must publish the rule in the North Carolina Register. (1973, c. 1331, s. 1; 1981, c. 688, s. 12; 1981 (Reg. Sess., 1982), c. 1232, s. 1; 1983, c. 857; c. 927, ss. 4, 8; 1985, c. 746, s. 1; 1985 (Reg. Sess., 1986), c. 1022, s. 1(1), 1(8); 1987, c. 285, ss. 10-12; 1991, c. 418, s. 1; 1991 (Reg. Sess., 1992), c. 900, s. 149; 1993, c. 553, s. 54; 1995, c. 507, s. 27.8(c); 1996, 2nd Ex. Sess., c. 18, ss. 7.10(c), (d); 1997-403, ss. 1-3; 1998-127, s. 2; 1998-212, s. 26B(h); 1999-434, s. 16; 1999-453, s. 5(a); 2000-69, ss. 3, 5; 2000-148, ss. 4, 5; 2001-126, s. 12; 2001-421, ss. 2.3, 5.3; 2001-424, ss. 27.17(b), (c), 27.22(a), (b); 2001-487, s. 21(g); 2002-97, ss. 2, 3; 2002-164, s. 4.6; 2003-184, s. 3; 2003-229, s. 2; 2003-413, ss. 27, 29; 2004-156, s. 1; 2011-398, s. 4; 2013-360, s. 12H.9(d); 2013-413, s. 39.)

timeanddate.com

Date calculator: Add to or subtract from a date

This service enables you to add or subtract days, months and years to a date to calculate a past or future date.

Design changes: What is new and why?

From **Wednesday, May 8, 2013**
Added 210 days

Result: Wednesday, December 4, 2013

timeanddate.com

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: All rules

DEADLINE FOR RECEIPT: Monday, June 16, 2014

***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. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

> *On the Temporary Rule-Making Findings of Need, line "e:" in box 5 is incomplete. Please provide the date and proof of the notice pursuant to G.S. 150B-21.1(a3)(2).*

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, June 11, 2014

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 43K .0101

DEADLINE FOR RECEIPT: Monday, June 16, 2014

***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. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 15, replace "These heart defects" with "Critical congenital heart defects"

Lines 15 thru 16, delete "but are not limited to"

Line 23, add a comma after "oxygenated"

Lines 26 and 32 reference "AAP/AHA recommendations" but there is not information on where these recommendations are located. Provide incorporation language in accordance with G.S. 150B-21.6.

Line 33, "(i.e.,) is both underlined and crossed out, reflecting both an addition and deletion of the text. Please clarify.

Line 35, add a comma after "neonatologists"

Line 35, delete the closing of the parentheses after "physicians"

Lines 36 thru 37, define or delete the phrase "an appropriate evaluation" If the term is deleted, then also delete the "and" before "plan"

Page 2, line 2, add a comma after "homes"

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, June 11, 2014

ORIGINAL
6/04/14

CHAPTER 43 – PERSONAL HEALTH

SUBCHAPTER 43K – NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DEFECTS

10A NCA 43K.0101 is adopted under temporary procedures as follows:

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. These heart defects are associated with significant morbidity and mortality and may include but are not limited to 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 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.

(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 ~~(i.e.,~~ 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 determine an appropriate evaluation and 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, birthing centers, homes or other locations.

History Note: *Authority G.S. 130A-125.*
Eff. July 1, 2014

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 43K .0102

DEADLINE FOR RECEIPT: Monday, June 16, 2014

***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. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Lines 4 and 24, replace "the" with "a" before "neonate"

Line 4, add "the following" after "assure"

Lines 6 and 16; page 2, lines 1 and 5, replace "must" with "shall"

Lines 12 and 31; page 2, line 9, replace "can" with "may"

Line 18, add a comma after "discharge"

Line 20, spell out "FDA" the first time it is used in this Subchapter

Lines 20 thru 21, what does this clause mean? It seems unclear. Please clarify. Consider replacing "is" with "shall be".

Lines 22 thru 23, are there time constraints for objecting? If so, please clarify and provide the necessary information.

Line 35, add a comma after "home"

Line 36, replace "should" with "shall"

Page 2, lines 1 thru 2, is the "process" required to be in writing? Is the "process" subject to review by someone outside the care units? If so, please clarify and provide the necessary information.

Page 2, line 3, replace "can" with "may"

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, June 11, 2014

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, June 11, 2014

ORIGINAL
8/1/14

10A NCA 43K.0102 is adopted under temporary procedures as follows:

10A NCAC 43K .0102 SCREENING REQUIREMENTS

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

(1) Screening of every neonate for critical congenital heart defects (CCHD) using pulse oximetry must be performed at 24 to 48 hours of age using a 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 neonates and infants in neonatal intensive care units for critical congenital heart defects using pulse oximetry screening must be performed using a 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.

(3) FDA 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 in accordance with G.S. 130A-125.

(c) All medical facilities and attending providers of the neonate or infant shall have and implement a 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 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 should occur as soon as possible but no later than 24 hours after obtaining the positive screening result.

(3) Attending providers of neonates and infants in neonatal intensive care units must have a process for evaluation and follow up of positive screenings in place at their medical facility.

(4) Options for neonatal or infant echocardiograms can 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: *Authority G.S. 130A-125;*
Eff. July 1, 2014.

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Commission for Public Health

RULE CITATION: 10A NCAC 43K .0103

DEADLINE FOR RECEIPT: Monday, June 16, 2014

***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. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Lines 7, 9, and 21 thru 28 contains lists and should begin with lowercase letters

Line 8, add "and" after the semicolon

Line 9, replace "which include" with "including"

Lines 9 thru 11, replace the commas with semicolons after "screening" "results" "known" and "transfer"

Line 10, add a comma after "subsequent"

Line 11, add a semicolon after "treatment"

Line 11, delete "and" after "treatment"

Line 15 references a web-based system, but there is not information on where this system or standards are located. Provide incorporation language in accordance with G.S. 150B-21.6.

Line 19, replace "must report" with "reports"

Lines 21 thru 26, add semicolons after the list item

Line 27, replace the comma with a semicolon after "screened"

Line 29, add a comma after "death"

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, June 11, 2014

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, June 11, 2014

ORIG: MTZ
6/04/14

10A NCA 43K.0103 is adopted under temporary procedures as follows:

10A NCAC 43K .0103 REPORTING REQUIREMENTS

(a) All medical facilities and attending providers of neonates or infants performing critical congenital heart defect screening shall report to the NC Birth Defects Monitoring Program the following information within seven days of all positive screenings:

(1) Name, date and time of birth of the neonate or infant, the medical facility or birth location, and the medical record number of the neonate or infant;

(2) Age in hours at time of screening, all pulse oximetry saturation values, which include 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) All medical facilities and attending providers of neonates or infants performing critical congenital heart defect screening shall report aggregate information related to critical congenital heart defect screenings quarterly using a web-based system to the Perinatal Quality Collaborative of North Carolina (PQCNC).

(c) PQCNC shall report aggregate information to the NC Birth Defects Monitoring Program within 30 days after the end of each quarter during a calendar year.

(d) The required quarterly aggregate information from medical facilities and attending providers of neonates or infants reported to PQCNC and that PQCNC must report 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 screening

(6) Transfers into the medical facility, not previously screened, and

(7) Neonates and infants not screened due to diagnostic echocardiograms being performed after birth and prior to discharge, transfer out of the medical facility, missed screening, death or other reasons.

History: *Authority G.S. 130A-125;*
Eff. July 1, 2014.