

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 counsel'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 on June 13, 2014 pursuant to an inquiry from staff counsel. On line (e), the Commission for Public Health indicated that the notice was provided pursuant to G.S. 150B-21.1(a3)(2) on April 7, 2014. G.S. 150B-21.1(a3) states the following:

- (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.

Abigail M. Hammond
Commission Counsel

- (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.

Staff counsel also has a print out from the N.C. Department of Health and Human Services dated June 19, 2014 that confirms an announcement date of April 7, 2014. The time frame from April 7, 2014 to adopt a temporary rule by the rulemaking body, May 14, 2014, is only 28 business days. Therefore, the Commission for Public Health failed to comply with the Administrative Procedure Act to provide at least 30 business days' notice to interested persons prior to adopting a temporary rule.

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 notice provided pursuant to G.S. 150B-21.1(a3)(2) was made on April 7, 2014. The notice was only 28 business days and not the minimum 30 business days required by the Administrative Procedure Act. 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.¹

¹ Please note that several forms were filed by the Commission of Public Health. A set filed on June 4, 2014 contained no date for the notice to interested parties. Upon request of staff counsel to the Rules Review Commission, a second set of forms were filed on June 13, 2014, indicating a date of April 7, 2014. A third set of forms were filed on July 10, 2014. However, the date on those form reflect a March 28, 2014. It is staff counsel's belief that the date on the July 10, 2014 forms is incorrect based upon conversations with the Commission for Public Health and the representations set forth on <http://cph.publichealth.nc.gov/home/PendingRules.htm> under

Rule	Notice	Adopted
<u>10A NCAC 43K .0101, .0102, .0103 – Newborn Screening for Critical Congenital Heart Defects</u>	04/07/2014	05/14/2014

Information and Instructions for Making Technical Changes

This document is requesting technical changes from your agency for the rules pending Commission review.

If the technical corrections require you to rewrite and resubmit the rule, the rewritten rule is due on the date specified in this document.

In order to properly submit rewritten rules, please refer to the following rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

1. You must submit three hard copies of the rewritten rule and one copy via email. The electronic copy must be saved as the official rule name (XX NCAC XXXX) and sent to oah.rules@oah.nc.gov.
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
 - Wrong: “aAssociation”
 - Right: “~~association~~ Association”
6. Treat punctuation as part of a word. For example:
 - Wrong: “day;; and”
 - Right: “~~day,~~ day, and”
7. Formatting instructions and examples may be found at:
www.ncoah.com/rules/examples.html

If you have any questions regarding proper formatting of technical changes after reviewing the rules and examples, please contact the reviewing attorney.

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



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

ORIGINAL 6/10/14
2014 JUNE 10 PM 4:11
OFFICE OF
ADMIN HEARINGS
VOLUME:
ISSUE:

1. Rule-Making Agency: Commission for Public Health
2. RULE CITATION & NAME: 10A NCAC 43K .0101 DEFINITIONS
3. Action: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input type="checkbox"/> Yes Effective date: <input checked="" type="checkbox"/> No
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. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> 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 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other: 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 ...

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

7. Why is ^{2nd staff opinion} ~~an emergency~~ 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

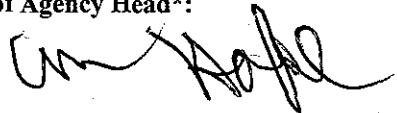
E-Mail: Chris.hoke@dhhs.nc.gov

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:

OBJECTED JUN 18 2014

☐ Date returned to agency:

Submitted for RRC Review:



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY
2nd Staff Opinion

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): April 7, 2014
- 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:

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 ...

2014 JUN 13 PM 4:02
OFFICE OF
ADMIN HEARINGS

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7. Why is ~~an immediate~~ ^{and staff opinion} 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:

OBJECTED JUN 18 2014

☐ Date returned to agency:

Submitted for RRC Review:



N.C. Department of Health and Human Services

North Carolina Commission for Public Health

The Commission for Public Health is the public health rulemaking body for North Carolina. The Commission is authorized and directed by the N.C. General Assembly to adopt rules to protect and promote the health of the public and to adopt rules necessary to implement public health programs administered by the Division of Public Health. The Commission for Public Health was first established by the N.C. General Assembly in 1877 as the State Board of Health. It was renamed the Commission for Health Services in 1973 and became the Commission for Public Health in 2007. The Division of Public Health is staff to the Commission.

History of the North Carolina Commission for Public Health

Announcements

April 7, 2014

Proposed Temporary Rules:

10A NCAC 43K .0101, .0102, .0103 – Newborn Screening for Critical Congenital Heart Defects

March 17, 2014

Proposed for Amendment:

10A NCAC 41A .0101 – Reportable Diseases and Conditions

January 14, 2014

Proposed for Amendment:

10A NCAC 41A .0401 – Dosage and Age Requirements for Immunization

March 15, 2012

Proposed for Repeal:

15A NCAC 18A .2600.01 - .2645 – Food Protection and Sanitation of Food Establishment

Proposed for Adoption:

15A NCAC 18A .2650-2676 – Food Protection and Sanitation of Food Establishment

Dec 13, 2011

The North Carolina Rules Review Commission approved two temporary rules at their November 17, 2011 meeting.

10A NCAC 41A .0106 Reporting of Health-Care- Associated Infections was adopted as a temporary rule to address the following:

On June 27, 2011, Governor Purdue signed into law House Bill 809 (G.S. 130A-150) which requires the Department of Health and Human Services, in collaboration with the state Healthcare-Associated Infections Advisory Group, to implement a mandatory statewide surveillance system for healthcare-associated infections by December 31, 2011. The statute also requires that the Public Health Commission adopt rules for the implementation of this system. Temporary Adoption Eff. November 30, 2011

10A NCAC 41A .0106 Reporting of Health-Care- Associated Infections ☐

Dec 13, 2011

15A NCAC 18A .2528 FENCES was amended under temporary procedures to address the following:

S.L. 2011-39 requires the Rule .2528 FENCES be amended to relieve owners of public swimming pools of the potential expense of upgrading existing pool fences to meet current safety standards. Temporary Amendment Eff. November 30, 2011.

Business Days Calculator – Count Workdays

Calculate the number of days between two dates, including or excluding weekends and/or public holidays.

From and including: **Monday, April 7, 2014**
 To and including: **Wednesday, May 14, 2014**
 Excluding Weekends and public holidays
 in United States. Change Country

Result: 28 days

38 calendar days – 10 days skipped:

Excluded 5 Saturdays

Excluded 5 Sundays

April 2014						
18 days included						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

May 2014						
10 days included						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31



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: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal	
4. Was this an Emergency Rule: <input type="checkbox"/> Yes Effective date: <input checked="" type="checkbox"/> No	
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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): March 28, 2014	
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.	
<input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> 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 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> Other:	
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 ...	

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 2014 JUL 10 PM 4:51
 OFFICE OF
 ADMIN HEARINGS

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

Adoption of the temporary rules while the permanent rule is in process provides expedited implementation of screening for critical congenital heart disease, which potentially affects up to 200 newborns each year in North Carolina. Timely diagnosis can prevent major disease complications and death which are possible outcomes if critical congenital heart diseases are not detected.

Temporary rules allow the statute to be implemented as soon as possible in an evidence based manner and to assure that we are not missing neonates with critical congenital heart disease

The temporary rules are the only way to assure that all medical facilities and attending providers of neonates and infants in NC (as defined in the rules) are using a consistent screening protocol based on national standards. The temporary rules also are the only means to assure that all medical facilities and attending providers of neonates and infants have a consistent and standardized plan for evaluation and follow up of positive critical congenital heart defect screenings.

These temporary rules are also the only way to allow data collection and monitoring of screening for critical congenital heart disease by attending providers across the state in medical facilities and other locations of where newborns are born.

An expert panel representing interested parties participated actively through the temporary rule making processes and reached consensus on the rule content and implementation. Please see attached for a list of the expert panel members and other interested parties.

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: Felice Pete

Title: Chair, Commission for Public Health

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

☐ Date returned to agency: