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 should not grant the request for a waiver of the 210-day deadline for submission of the temporary rule in accordance with G.S. 150B-21.1(a2) by the Commission for Public Health to the Rules Review Commission.

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 the 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 counsel to object to the temporary rules and the waiver request 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 failed to meet the statutory requirements for temporary rulemaking. Pursuant to G.S. 150B-21.1(a2), Commission for Public Health has requested a waiver of the 210 days submission deadline. The waiver request is attached for your review and staff counsel has provided responses to the waiver request as set forth below:

[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.

Pursuant to G.S. 150B-21.1(a2), and upon written request of the agency, the Rules Review Commission may waive the 210-day submission deadline upon consideration of the following:

(1) degree of public benefit:

Staff's response: The welfare of infant children is a significant concern. However, "Attachment A" to Commission for Public Health's waiver request contains notations on August 2013 that may reflect that approximately 80 of 90 hospitals had some existing processes in place. The intent of the language in the fifth bullet point on page 7 is unclear. Staff counsel is without further opinion on this factor for the waiver request.

(2) whether the agency had control over the circumstances that required the requested waiver:

Staff's response: The waiver request combines this element with the "need for the waiver." Staff counsel will isolate Commission of Public Health's control to the third bullet point on page 3, in which the waiver states the following:

> The main reason for the length of time that was needed to develop temporary rules was because the Expert Panel needed the time to resolve several complex scientific issues and to reach consensus among all of the stakeholders.

While staff counsel acknowledges that the Rules Review Commission values the consensus of stakeholders in the rulemaking process, staff counsel has significant concerns that the inability to reach a consensus impeded the temporary rulemaking process for Commission of Public Health. Looking to the statute for guidance, G.S. 150B-21.1 begins with the following statement:

> 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…

It is staff counsel's opinion that the justification for an "immediate adoption" of a temporary rule that is necessary and would be contrary to the public interest mandates that an agency may not merely rest on its loins, but must act, even if the action is without the full consent of the external stakeholders. The goal of temporary rulemaking is to provide immediate rules that may expire without future rulemaking action and is not subject to a delayed effective date by the submission

of 10 letters. It is therefore staff counsel's opinion that the justification of needing to "reach consensus among all of the stakeholders" is not a sufficient justification for the waiver.

Further, staff counsel would like to reflect that the Commission for Public Health received the statutory mandate to make temporary and permanent rules. The majority of the timeline narrative of "Attachment A," pages 5 through 10, speaks to the actions of Dr. Gerri Mattson and the Expert Panel. The first action official taken by the rulemaking body in relation to the temporary rules process as set forth in G.S. 150B-21.1 was in May of 2014, as indicated on page 10. As noted in the RRC Staff Opinion for the June 2014 Rules Review Commission meeting, the May 14, 2014 meeting by the Commission for Public Health was 372 since the "recent act" of the General Assembly justifying the temporary rulemaking action and 162 days since the 210-day deadline for submission of the temporary rule in accordance with G.S. 150B-21.1(a2) by the Commission for Public Health to the Rules Review Commission. Staff counsel has significant concerns on the rulemaking body's failure to act and then justifying the failure to act on the need to "reach consensus among all of the stakeholders." The second factor to be considered by the Rules Review Commission in granting the waiver is "whether the agency had control over the circumstances that required the requested waiver" and it is staff counsel's opinion that the agency had control over the circumstances and merely failed to act until May of 2014, well after the statutory deadline.

(3) notice to and opposition by the public:

Staff's response: The waiver request by the Commission for Public Health does not speak to the notice to and opposition by the public to waive the 210-day deadline for submission of the temporary rule in accordance with G.S. 150B-21.1(a2) by the Commission for Public Health to the Rules Review Commission.

(4) the need for the waiver:

Staff's response: The waiver request combines this element with "whether the agency had control over the circumstances that required the requested waiver." Staff counsel will isolate the Commission for Public Health's need for the waiver to the fourth bullet point on page 2. Staff counsel, well sensitive to the implementation of new programs into existing agency structure, is concerned that this argument lacks merit. The Rules Review Commission has reviewed rules adopted by agencies for implementations of new programs within the temporary rulemaking timeline and without the necessity of a waiver. A recent set of rules involved the coordinated efforts of three state agencies, numerous meetings to discuss possible implementation options,

and logistics of record keeping for the purposes of litigation. Those rules for a new program were promulgated under the temporary rulemaking timeline with a buffer of extra days, should it have become necessary. It is therefore staff counsel's opinion that the justification of this program being "totally new" is not a sufficient justification for the waiver.

(5) previous requests for waivers submitted by the agency.

Staff's response: The waiver request indicates on page 4 that no prior waiver requests have been submitted to the Rules Review Commission. Staff counsel is without further opinion on this factor for the waiver request.

Staff counsel would like to remind the Commission that the standard for review of temporary rules is set forth in G.S. 150B-21.1(b) and states the following:

> 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.

It is staff counsel's opinion that the need for the waiver is based on the agency's failure to comply with Subsection (a) of G.S. 150B-21.1 and that G.S. 150B-21.9 states the following:

> (a) Standards. - The Commission must determine whether a rule meets all of the following criteria:
>
> (1) It is within the authority delegated to the agency by the General Assembly.
>
> (2) It is clear and unambiguous.
>
> (3) It is reasonably necessary to implement or interpret an enactment of the General Assembly, or of Congress, or a regulation of a federal agency. The Commission shall consider the cumulative effect of all rules adopted by the agency related to the specific purpose for which the rule is proposed.
>
> (4) It was adopted in accordance with Part 2 of this Article.
>
> The Commission shall not consider questions relating to the quality or efficacy of the rule but shall restrict its review to determination of the standards set forth in this subsection.

Staff counsel emphasizes for the Rules Review Commission that G.S. 150B-21.9 prohibits the Rules Review Commission from examining the quality or efficacy of a rule or set of rules.

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 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 was not within the statutory 210 day time period set forth in G.S. 150-21.1(a2). Pursuant to G.S. 150B-21.1(a2), Commission for Public Health has requested a waiver of the 210-day deadline.

Staff counsel has reviewed the request for a waiver of the 210-day deadline for submission of the temporary rule in accordance with G.S. 150B-21.1(a2) by the Commission for Public Health to the Rules Review Commission and opines that the Commission for Public Health lacks sufficient justification for the waiver request. Staff counsel realizes the ultimate determination is solely within the purview of the Rules Review Commission, but provides this Staff Opinion for the limited purpose of providing advice to the Rules Review Commission on the merits of the Commission for Public Health's waiver request.

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North Carolina Department of Health and Human Services
Division of Public Health

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Penelope Slade-Sawyer
Division Director

July 10, 1014

TO: Abigail Hammond, JD
Rules Review Commission

FROM: Felice Pete, Chair, Commission for Public Health
Chris Hoke, JD, DPH Rule-Making Coordinator, DHHS

SUBJECT: Administrative Rules Waiver Request

Per § 150B-21.1(a2), we hereby request a waiver from the 210 day limitation found in G.S. 150B-21.1(a1). The waiver request is for the following temporary rules:

SUBCHAPTER 43K – NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DEFECTS	
10A NCAC 43K .0101	DEFINITIONS
10A NCAC 43K .0102	SCREENING REQUIREMENTS
10A NCAC 43K .0103	REPORTING REQUIREMENTS

The following sections address the statutory requirements for requesting a waiver.

Degree of Public Benefit

- An estimate of at least 200 babies a year will be found with cardiac conditions and other medical conditions using a standardized screening protocol. This will save lives because health care providers will be able to detect these babies with these conditions early, before they go home from the hospital thereby allowing the appropriate diagnosis to be made, and life-saving interventions implemented while still in the hospital. This will prevent them from getting critically ill at home or even dying,

  To address this issue, the NC General Assembly passed SL 2013-45**,** 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. The law was effective May 8, 2013 and authorized the Commission for Public Health to

adopt permanent and temporary rules to implement the critical congenital heart defect newborn screening.

- This waiver is needed to allow the statute to be implemented as soon as possible in an evidence based manner and to assure that we are not missing neonates (newborns) with critical congenital heart disease. This also allows affected babies to receive early treatment to prevent or reduce morbidity and mortality.

- The temporary rules are the only way to assure in a timely manner 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 immediately 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. At this time we have anecdotal evidence that some hospitals are doing screening; however, we do not know all of the hospitals and providers conducting the screening. Public health staff also does not have access to conduct surveillance of the positive screening results nor does staff know the follow up procedures that should occur. It is only through state level public health data collection and surveillance, with assistance from the Perinatal Quality Collaborative of NC, can we monitor which medical facilities and attending providers are doing screening and how well they are doing the screening, evaluation and follow up.

Need for Waiver and Agency Control over Circumstances

- This is a totally new program that public health staff has no prior experience with because it is different from existing newborn screening conditions addressed by our existing state newborn screening programs. The program does not just require an adaptation of an existing protocol for a newborn condition. Our subject matter expert, a board-certified pediatrician is knowledgeable about newborn screening protocols; however, this was her first experience with the rule-making procedures.

- Staff within the Division of Public Health, which will be responsible for implementing this program, was not involved in the development of the legislation. The legislation was sponsored by the NC Child Fatality Task Force and was directly requested by numerous stakeholders in NC, including parents of infants and children affected by critical congenital heart disease, NC Chapter of the American Heart Association, the March of Dime North Carolina, numerous health care providers, and multiple medical associations.

- This is a complex scientific topic that required involvement of diverse group or multiple medical and health care and family experts. An Expert Panel was convened as soon as practical after legislation was passed. The Expert Panel consisted of numerous stakeholders, including families of children with critical congenital heart defects, pediatric cardiologists, primary care pediatricians, neonatologists, nurse practitioners, the NC Chapter of the American Heart Association, the NC Chapter of the March of Dimes, numerous public heath staff, the Perinatal Quality Collaborative of NC, the NC Board of Nursing, the NC Academy of Physician Assistants, and the NC Hospital Association. A working subgroup from this expert panel has been identified and has begun working on the fiscal impact analysis required for the permanent rule-making process. A meeting is being scheduled for mid-July with the state budget fiscal analyst to facilitate the preparation of the fiscal impact analysis.

- The main reason for the length of time that was needed to develop temporary rules was because the Expert Panel needed the time to resolve several complex scientific issues and to reach consensus among all of the stakeholders.

  Please see *Attachment A* for a complete timeline of all activities during the rule making process since the legislation was enacted in May 2013.

Notice to and Opposition by the Public

- As noted previously above in the list of Expert Panel participants, representatives from a wide variety of stakeholders were actively involved in the development of

these temporary rules. The Expert Panel met numerous times via face to face meetings, over conference calls, and through facilitated electronic collaboration.

Please refer to *Attachment B* for a complete list of the Expert Panel and whom they represent.

- The members of this panel are responsible for representing their colleagues in their respective medical fields and the membership of their respective organizations, informing all interested parties of the rules' content and ensuring that the language is vetted appropriately with interested parties they represent.

- The temporary rules adopted represent a true consensus. Also note that DPH did not receive any negative comments during the comment period, at the public hearing, or during the Commission for Public Health meeting when the rules were adopted.

Previous Waiver Requests Submitted by the Agency

The agency has not submitted waiver requests to the RRC since the statute was enacted.

Waiver Request
Attachment A:
Timeline and Narrative of Events and Activities Related to Newborn Screening for Critical Congenital Heart Defects (CCHD): May 2013 through June 2014

May 2013

- The NC state legislature passed Session Law 2013-45, Senate Bill 98, entitled 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.

- Law was enacted and became effective on May 8, 2013.

- Dr. Mattson began to develop a list of people for an Expert Panel on Newborn Pulse Oximetry Screening for Critical Congenital Heart Disease.

June 2013

- Dr. Mattson developed a list of members to participate on an Expert Panel on Newborn Pulse Oximetry Screening for Critical Congenital Heart Disease (CCHD) from a variety of stakeholders and invited them through email.
- Dr. Mattson began research on processes and tools used by other states related to follow up, tracking and monitoring.

July 2013

- The list of Expert Panel members was finalized with multiple stakeholders being represented. See the attached list of the multiple members.
- During July Dr. Mattson continued to research and compiled two sets of notebooks of screening tools for CCHD and follow up, tracking and monitoring outcomes from other several other states. This included literature review, website review and talking with staff in other states and across NC. Dr. Mattson was also able to get information from six hospitals in NC about their policies for screening for CCHD.
- The first meeting of Expert Panel was held on July 29, 2013 for three hours in Raleigh with 19 people in person, and five others who participated by phone. Six invited members were not able to attend.

  The agenda from the first meeting of the Expert Panel included: a perspective from a parent of a child with CCHD, a review of the newborn screening legislation and expert panel's charge, an overview of CCHD and newborn pulse oximetry overall, births and birthing hospitals data obtained from the NC State Center for Health Statistics and shared by Dr. Mattson, an overview of the NC Birth Defects Monitoring Program from the director of this program, an overview of the rulemaking process by DPH legal staff, a discussion about follow up processes when there are concerns about a diagnosis of CCHD by a pediatric cardiologist from Carolinas Medical Centers, information about NC and other states related to follow up tracking and monitoring processes and outcomes of newborn pulse

oximetry screening, and training and education needs discussion led by Dr. McCaffrey from the Perinatal Quality Collaborative of NC (PQCNC).

Action items from the meeting included**:**

- Dr. Mattson will contact someone in Georgia to determine the status of implementation of screening in GA birthing facilities.
- More discussion about rules for follow up of failed screening and for those with diagnosed or concerns for CCHD is needed by the group.
- The group expressed interest in getting feedback from rural hospitals about barriers to implementation. One suggestion was to survey birthing hospitals and other providers involved with delivering babies to get a sense of barriers to screening and also about who is doing pulse ox screening across the state, if the AAP/AHA standard protocol is being used or another protocol, and current infant/pediatric cardiology services capacity and processes.
- Dr. Mattson was asked to consider contacting Steve Shore of the NCPS, Dr. Greg Randolph at the NC Center for Public Health Quality, Dr. Earls with CCNC (who had to leave the meeting early via conference call), and Dr. Kemper, a pediatrician from Duke University and national expert on CCHD screening. to discuss possible training/education ideas for providers. Dr. McCaffrey from PQCNC suggested also contacting Carol Koeble at the NC Quality Center with the Carolinas Center for Medical Excellence.
- Dr. Mattson suggested that two subcommittees form to address creating recommendations for rules and recommendations to address other identified concerns. One subcommittee would focus on components of the follow up protocol to ensure early treatment for newborns diagnosed with CCHD (including use of telemedicine) that should be in rule. The other subcommittee would focus on recommendations for rules for a system for tracking the process and outcomes of newborn pulse ox screening with linkage to the NC Birth Defects Monitoring Program. This subcommittee would also recommend actions to help with information gathering about disposition and cardiology follow up. Each subcommittee would also be asked to think about recommendation related to training and education to help support efforts but that would not need to be in rule.
- Dr. Mattson asked Expert Panel members to let her know of their interest to serve on one or both of these subcommittees. She will have one or two conference calls for each subcommittee before the next Expert Panel meeting on August 28. Dr. Mattson will ask for Expert Panel member volunteer to participate on the two subcommittees.

- Dr. Mattson gave one of the sets of notebooks of her research of state practices and processes to the Perinatal Quality Collaborative of NC.

August 2013

- Dr. Mattson contacted staff from states bordering NC and did additional research to further define their processes. This included phone calls with folks from Georgia and Tennessee.
- Dr. Mattson helped staff and arrange phone meetings of two subcommittees of the Expert Panel with one to develop content for rules for follow up protocols to address early treatment of newborns found to have CCHD and the other to develop a system to track the processes and outcomes of screening with linkages to the NC BDMP. Each committee met at least once (one met twice). A pediatric cardiologist from Duke was the chair of the follow up protocol subcommittee and Dr. Kemper and a representative from the NC Hospital Association were chairs of the other subcommittee about a reporting system. Drafts of rules were developed and made available from the chairs of each committee with Dr. Mattson's assistance for the Expert Panel committee on August 28, 2013.
- Dr. Mattson presented to the Commission for Public Health about the work on the rules for screening for CCHD.
- Dr. Mattson took the list of birthing hospitals surveyed by the NC American Heart Association in December 2012 and their response about whether they were screening at the time and attempted to update the list. Dr. Mattson worked with pediatric cardiologists and other health care providers across the state to try to determine whether additional hospitals were doing screening. Dr. Mattson also asked the pediatric cardiologists to help her determine which cardiologist referral source each birthing hospital used. Dr. Mattson shared the list of where hospitals refer with the NC Hospital Association who mapped this out across the state by birthing hospital. There were about 10 birthing hospitals out of almost 90 that could not be mapped out.
- Dr. Mattson also worked with the NC Hospital Association on a draft of a survey to send out to birthing hospitals in NC based on surveys done by TN and GA. This draft was presented at the August Expert Panel meeting.
- Dr. Mattson also researched NICU issues related to CCHD screening in NC and also from other states.
- Dr. Mattson explored training opportunities related to CCHD screening.
- The Expert Panel met for the second time face to face on August 28 for three hours in Raleigh. 18 people attended in person. Three people attended by webinar.

  The agenda included the following: another perspective from a parent of a child with CCHD; follow up from the last meeting with Dr. Mattson and Ms. Erica Nelson with the NC Hospital Association (shared more information from neighboring states, shared information updated information obtained from several birthing hospitals, and information about how and where birthing hospitals refer for pediatric cardiology and ECHO reading, and draft of a survey from the NCHA to birthing hospitals); issues related to NICU, home births and birthing centers; draft language for rules for follow up and a system for reporting from the two subcommittees with discussion in groups to comment and give feedback and report out by the two groups; discussion about role for PQCNC in this process; example of local training and education and implementation for Carolinas Medical Center;

and discussion about next steps. The NCHA assembled a group of hospitals to give feedback on the draft of the rules for reporting and follow up that the subcommittee created and presented that to the Expert Panel.

There were several action items from this meeting. During the meeting it became clear that there was not consensus on how and to whom to report data related to screening for CCHD and that this was a complicated issue. There was also concern that QI efforts should not be offered through PQCNC. It was agreed that QI efforts would not be in rules but offered optionally. However, there remained strong concerns raised about the burden placed on hospitals for reporting and reporting to a third party other than public health. However, it was agreed that the Expert Panel would not need to meet face to face and would work to resolve the disagreements and finalize the details about the rules via email or conference call.

September, October, and November 2013

- The NC Hospital Association and Dr. Mattson based on feedback from Expert Panel members worked on the language for a survey of the hospitals related to CCHD screening. The survey was sent out to get a sense of what was going on in birthing hospitals across the state. This included follow up protocols, processes, and barriers including referral for cardiology evaluation. Expert Panel members felt strongly about having this information to help determine what is going on across the state to adequately represent rural hospitals. The NC Hospital Association sent out the survey in mid-October and then it took a few weeks to get responses back from hospitals; however, the survey was not completed by many hospitals.
- Drafts of language for the rules for follow up protocols and a system for reporting were modified by Dr. Mattson with feedback from the multiple Expert Panel members from the August meeting and asking again via several email communications to the whole Expert Panel and many emails to and from individual members. Additional interested parties/stakeholders were also included on the emails about the drafts of the rules.
- Consensus on the language for the rules could not be reached by the Expert Panel members related to a reporting system for the data which was complicated. There were still also concerns about which agency would be able to provide training and education related to CCHD screening using a quality improvement learning collaborative model.
- The NC Hospital Association (NCHA) decided in October that they wanted to pull a group of hospitals and other stakeholders to hold a meeting to discuss data collection and quality improvement opportunities but was not able to get a meeting date until December. Public health staff was invited to a meeting.
- Dr. Mattson attended a Mission hospital sponsored grand rounds for health care providers given by one of the pediatric cardiologists on the Expert Panel in October and gave an update on the status of the rules.

December 2013

- The NCHA held a meeting and discussed possible options was a data reporting system and quality improvement efforts. This meeting included PQCNC, NC BDMP, local hospitals and providers.
- As a result of the meeting, PQCNC and the NCHA and NC BDMP appeared to have a plan to move forward with a reporting system and potentially for QI work. However, subsequent communications resulted in confusion and consensus could not be reached on how to move forward.
- Dr. Mattson called a meeting of the Expert Panel on Newborn Pulse Oximetry Screening for CCHD via conference call in mid-December at the recommendations of public health management. This was done since consensus was not able to be reached on a reporting system and process. The goal of the meeting was to have a discussion about next steps to develop rules. A draft of rules was provided for the Expert Panel to discuss. That meeting resulted in Dr. Mattson needing to try to work with PQCNC and NCHA to try to determine if consensus could be reached on reporting system for tracking and monitoring issue. Dr. Mattson was not able to meet with Dr. McCaffrey from PQCNC until January.

January 2014

- Dr. Mattson met with Dr. McCaffrey from PQCNC to clarify potential options for reporting and a QI project. Dr. Mattson also communicated with the NCHA to try to determine their concerns and acceptable options for reporting and QI work.
- Dr. Mattson sent a version of draft rules to the Expert Panel for additional feedback but consensus could not be reached.
- Dr. Mattson tried again to engage the birthing centers and nurse midwives at the recommendation of the Expert Panel members to try to get their feedback and perspective on the draft rules. Providers involved in home births were contacted.

February 2014

- Since consensus could still not be reached between the NCHA and PQCNC, Dr. Mattson formally asked PQCNC and NCHA to work to come up with a consensus by a set date or each agency should separately submit a plan or reporting data, how it would link to the NC BDMP and QI opportunities that could be offered.
- Dr. Mattson attended a national meeting of states with a focus on CCHD screening and brought back a wealth of information and contacts back to help with the process.
- NCHA and PQCNC could not achieve consensus in the end and two proposals were submitted.

March 2014

- The Expert Panel voting members (not including DPH staff) were given a week to vote on the two proposals provided by PQCNC and NCHA. Three voting members abstained. The overwhelming majority voted for the proposal from PQCNC (14 for PQCNC and 2 for NCHA.)

- The Expert Panel was notified of the results of the vote and was asked for feedback on another version of the draft rules. A final version was sent to the Expert Panel on March 26 before submitting the rules to OAH for posting for public comment and minimal feedback was received. No opposition from PQCNC or NCHA was received. Expert Panel members and other interested stakeholders were notified on March 28, 2014 that rules would be posted on OAH site for public comment.
- Dr. Mattson consulted with contacts she had made from a couple of states from the national meeting on CCHD screening for thoughts about NC's draft of CCHD screening rules.

March/April 2014

- Draft rules were submitted for posting on OAH site on March 31, 2014 and subsequently posted on the OAH and agency websites on April 7, 2014.
- A public hearing was held on April 21, 2014 and there were only positive comments in support of the draft rules. No opposition was raised, and representatives from the Expert Panel voiced their support for the temporary rules.

May 2014

- A Commission for Public Health meeting was held on May 14, 2014. A few comments and some slight changes were suggested, which were agreeable to public health staff.
- Representation from the NC American Heart Association, the March of Dime North Carolina, Duke pediatric cardiology and primary care, and a parent of a child with CCHD spoke favorably about the rules at this meeting. No opposition was provided.
- Dr. Mattson consulted with staff from Wisconsin and New Jersey related to cost of pulse oximetry equipment.

June 2014

- Temporary rules were submitted to the Rules Review Commission in June
- Feedback was obtained from RRC staff counsel advising that they would recommend objecting to the rules on June 11, 2014.
- RRC meeting was held on June 17, 2014. Public health staff attended with staff from the NC Chapter of the American Heart Association.

Waiver Request
Attachment B
Expert Panel for Screening for Critical Congenital Heart Defects (CCHD) Recommendations for Rules

NC Chapter of American Heart Association: Betsy Vetter
NC March of Dimes: Tiffany Gladney and Peg O'Connell
Parents of children with CCHD:
Valerie King – Mended Little Hearts Tinman Group, Winston Salem
Joye Mullis – Mended Little Hearts, Triangle
Pediatric Cardiologists from the Major Academic Medical Centers and Other Pediatric Cardiology Providers from Other Health Systems

- Levine Children's Hospital (Carolinas Medical Center): **Dr. David Drossner**
- Mission Children's Hospital: **Dr. Aaron Pulver**
- East Carolina University: **Dr. Charlie Sang**
- University of North Carolina : **Dr. John Cotton**
- Wake Forest University: **Dr. Derek Williams**
- Womack Army Medical Center: **Dr. Flanagan**
- Novant/Presbyterian Health: **Dr. David Ohmstede**
- Duke University: **Dr. Angelo Milazzo**

Neonatalogists:

- **Dr. Marty McCaffrey** (University of North Carolina or UNC Neonatalogist and Director of Perinatal Quality Collaborative of NC also known as PQCNC)
- **Keith Cochran, Tara Bristol and Tammy Haithcox** also from PQCNC
- **Ricky Goldstein**, Duke Neonatalogist

Community Primary Care Providers:

- Practicing pediatrician to representing the NC Pediatric Society, **Dr. Larry Mann**
- Community Care of NC/Children's Health Insurance Program Reauthorization Action (CHIPRA): **Dr. Marian Earls**
- Duke Primary Care Pediatrics and national expert on CCHD screening, **Dr. Alex Kemper**

NC Hospital Association: Erika Nelson
NC Academy of Physician Assistants: **Donald Metzger**
NC Board of Nursing: Crystal Harris (also represents pediatric nurse practitioners)
Hi Risk Obstetric/Gynecology and Maternal Fetal Medicine (MFM) and Representative of the NC Obstetric Society:
Dr. Piers Barker (Duke MFM and Pediatric Cardiology)

Additional stakeholders not on the official Expert Panel but copied on emails to the Expert Panel:
NC Medical Society: **Connor Brockett**
Pediatric Nurse Practitioner from UNC: **Jamie Hausholter**
NC Child Fatality Task Force: **Elizabeth Hudgins**
NC OB/GYN Society: **Alan Skipper, exec director**
NC Pediatric Society: **Steve Shore, exec director**
Mission Neonatalogy: **Dr. Dillard**

NC Academy of Family Physicians: **Greg Griggs,** exec director was on email list and only was able to attend one meeting but was not considered an official member of the Expert Panel
UNC Neonatalogy: **Dr. Carl Seashore**
Eastern Carolina University/Vidant Health Primary Care: **Dr. Cotten**
Regional genetic counselor from Children and Youth Branch in Division of Public Health: **Ginny Vickery**
Nurse Midwives:
Maureen Darcey, certified nurse midwife (CNM) at Women's Birth and Wellness Center
Ami Goldstein, CNM, FNP (family nurse practitioner) at University of NC Family Medicine reviewed and commented on the draft rules.
Nancy Harman, CNM - a homebirth CNM out of Chatham County has had drafts of rules sent to her

NC Division of Public Health staff:

Chris Hoke, Chief Office of Regulatory and Legal Affairs\
Bob Martin, Public Health Program Manager,

WCH Section
Dr. Kevin Ryan, WCH Section Chief
Belinda Pettiford, Women's Health Branch Head
Dr. Isa Cheren, medical consultant for Women's Health
Carol Tant, Branch Head Children and Youth Branch
Gerlene Ross, Unit Manager of Genetics and Newborn Screening in the Children and Youth Branch
Dr, Gerri Mattson, pediatric medical consultant in the Children and Youth Branch
NC State Center for Health Statistics
Bob Meyer, Director of the NC Birth Defects Monitoring Program

From:	Mattson, Gerri
To:	dewillia@wakehealth.edu; Sang, Charlie; jcotton@ad.unc.edu; Drossner, David (David.Drossner@carolinashealthcare.org); Aaron Pulver, MD (Aaron.Pulver@avlcard.com); Angelo Milazzo, M.D. (angelo.milazzo@duke.edu); enelson@ncha.org; McCaffrey, Martin J (mjmccaff@email.unc.edu); dpohmstede@novanthealth.org; Alex Kemper, M.D. (alex.kemper@duke.edu); ryan.p.flanagan2.mil@mail.mil; Larry D. Mann (LMann@jeffersandmann.com); Betsy Vetter (Betsy.Vetter@heart.org); vjking1998@gmail.com; joyemullis@gmail.com; Ricki Goldstein, M.D. (ricki.goldstein@duke.edu); donatc63@aol.com; Marian Earls (mearls@n3cn.org); charris@ncbon.com; piers.barker@duke.edu
Cc:	elman_frantz@med.unc.edu; OLSSONJ@ecu.edu; Meyer, Robert; Hoke, Chris; Cheren, Isa; Seashore, Carl J (cseashor@med.unc.edu); Allen Ligon (allenligon@gmail.com); jennifer.li@dm.duke.edu; Pettiford, Belinda; Greg Griggs (ggriggs@ncafp.com); askipper@ncmedsoc.org; Ross, Gerlene; Tyson, Carol; Tant, Carol; Sanderson, Michael; Ryan, Kevin; Martin, Bob; Vickery, Ginny; Peg OConnell <poconnell@fuquaysolutions.com> (poconnell@fuquaysolutions.com); keith_cochran@med.unc.edu; tammy.haithcox@pqcnc.org Haithcox (tammy.haithcox@pqcnc.org); Tara Bristol (tara.bristol@pqcnc.org); "Shore, Steve" (ssncps@attglobal.net); CBrockett@ncmedsoc.org; Goldstein, Ami L (ami_goldstein@med.unc.edu); nwharman@gmail.com
Subject:	Draft of Expert Panel Recommendations for Newborn Screening for Critical Congenital Heart Defects
Date:	Wednesday, March 26, 2014 12:05:12 PM
Attachments:	2014 March 26 Expert Panel Draft of Recommendations for Rules 10ANCAC43K Newborn Screening for Critical Congenital Heart Defects.docx Session Law 2013-45.pdf
Importance:	High

Expert Panel Members and other interested partners,

I have attached the most recent revised draft of the full recommendations for rules from the Expert Panel about newborn screening for critical congenital heart defects. The revisions are based on feedback from Expert Panel members. The Commission is required to adopt temporary and permanent rules to include pulse oximetry screening in the Newborn Screening Program as stated in the legislation passed in NC in May 2013. The legislation further states that the Commission's rules for pulse oximetry 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.
(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.

I have attached the legislation with this email for your reference.

If you have comments about the attached draft of the recommendations for rules, please send them to me via email no later than 12 noon on Friday, March 28, 2014. I apologize for the short timeframe for review. I have included several comments in the body of the document to try to highlight and explain some of the changes.

I do want to include some information about a few of the comments in this email. Three additional definitions have been added to the first section on .0101 Definitions. The terms include definitions for "infant", "positive screenings" and "negative screenings". These definitions were added because infants (who are older than 28 days and no longer

considered neonates) will also be screened at times especially in the NICU setting. The definition of the "attending providers of the neonate" has also been modified to include infants and is now called "attending providers of the neonate or infant". The final sentence of the definition also has been added to include locations for births outside of hospitals and birthing centers such as homes. In addition, after discussion with legal and HIPAA experts at the NC Division of Public Health, it was determined that it was necessary to have positive screenings (failed or abnormal screenings) and the individual information about the neonate or infant with the positive screening reported directly to public health through the NC Birth Defects Monitoring Program by medical facilities and attending providers of the neonate or infant. This is reflected in the new language in the draft in the section on Reporting Requirements .0103 (a). I have also included more specific new language about the minimum data elements based on the July 2013 article in *Pediatrics* entitled, *Implementing Recommended Screening for Critical Congenital Heart Disease.* This is in place of the vague language used before which stated "the screening results of each positive CCHD screening" in the section on Reporting Requirements .0103 (a) (2). The new language about the reporting of aggregate information from medical facilities and attending providers of neonates or infants to PQCNC is found in the section on Reporting Requirements .0103 (b).

The plan is to finalize the final text of the rules and have the rules posted on the Office of Administrative Hearings early next week. This will allow for the required 30 business days for public comment before the next Commission for Public Health meeting in May. I will share the link to the web site once the rules are posted. You will have an opportunity to provide additional feedback on the rules during the public comment period.

The plan is to present the recommendations from the Expert Panel to the Commission for Public Health during the May 14, 2014 meeting for adoption as temporary rules for newborn screening for critical congenital heart defects.
Please note that the Commission has the ultimate authority to make all decisions on the content of the rules.

Again, if you have comments about the attached draft of the recommendations for rules, please send them to me via email no later than 12 noon on Friday, March 28, 2014. However, please remember that you will have an opportunity to provide additional feedback on these rules during the public comment period. I will share the link to the site where the rules will be posted.

Thanks again for your ongoing interest and participation in this important work.

Thanks as always for all that you do,

Gerri L. Mattson, MD, MSPH, FAAP

N.C. Department of Health and Human Services
Pediatric Medical Consultant, Children and Youth Branch - NC Division of Public Health
5601 Six Forks Road
Raleigh, NC 27609
(Office) 919-707-5622
(Fax) 919-870-4881
gerri.mattson@dhhs.nc.gov
www.ncdhhs.gov/dph

From:	Martin, Bob
To:	Martin, Bob
Subject:	FW: Final Draft of Expert Panel Recommendations for Newborn Screening for Critical Congenital Heart Defects
Date:	Thursday, July 10, 2014 10:47:59 AM
Attachments:	2014 Final Draft March 28 Expert Panel Draft of Recommendations for Rules 10ANCAC43K Newborn Screening for Critical Congenital Heart Defects.docx
Importance:	High

From: Mattson, Gerri
Sent: Friday, March 28, 2014 4:21 PM
To: dewillia@wakehealth.edu; Sang, Charlie; jcotton@ad.unc.edu; Drossner, David (David.Drossner@carolinashealthcare.org); Aaron Pulver, MD (Aaron.Pulver@avlcard.com); Angelo Milazzo, M.D. (angelo.milazzo@duke.edu); enelson@ncha.org; McCaffrey, Martin J (mjmccaff@email.unc.edu); dpohmstede@novanthealth.org; Alex Kemper, M.D. (alex.kemper@duke.edu); ryan.p.flanagan2.mil@mail.mil; Larry D. Mann (LMann@jeffersandmann.com); Betsy Vetter (Betsy.Vetter@heart.org); vjking1998@gmail.com; joyemullis@gmail.com; Ricki Goldstein, M.D. (ricki.goldstein@duke.edu); donatc63@aol.com; Marian Earls (mearls@n3cn.org); charris@ncbon.com; piers.barker@duke.edu
Cc: elman_frantz@med.unc.edu; OLSSONJ@ecu.edu; Meyer, Robert; Hoke, Chris; Cheren, Isa; Seashore, Carl J (cseashor@med.unc.edu); Allen Ligon (allenligon@gmail.com); jennifer.li@dm.duke.edu; Pettiford, Belinda; Greg Griggs (ggriggs@ncafp.com); askipper@ncmedsoc.org; Ross, Gerlene; Tyson, Carol; Tant, Carol; Sanderson, Michael; Ryan, Kevin; Martin, Bob; Vickery, Ginny; Peg OConnell <poconnell@fuquaysolutions.com> (poconnell@fuquaysolutions.com); keith_cochran@med.unc.edu; tammy.haithcox@pqcnc.org Haithcox (tammy.haithcox@pqcnc.org); Tara Bristol (tara.bristol@pqcnc.org); 'Shore, Steve' (ssncps@attglobal.net); CBrockett@ncmedsoc.org; Goldstein, Ami L (ami_goldstein@med.unc.edu); nwharman@gmail.com; Hudgins, Elizabeth S
Subject: Final Draft of Expert Panel Recommendations for Newborn Screening for Critical Congenital Heart Defects
Importance: High

Expert Panel Members and other interested partners,

Thank you again for reviewing and providing feedback on the full recommendations for rules from the Expert Panel about newborn screening for critical congenital heart defects to the Commission for Public Health. I received only a few comments about how to access the AAP/AHA recommendations which resulted in only minor revisions.

I have attached the final draft of the recommendations with this email which I anticipate will be posted for public comment early next week. I will share the link to the site when that information is available. You will have an opportunity to provide additional feedback on these rules during the public comment period.

Thanks again for your ongoing interest and participation in this important work.

Thanks as always for all that you do,

Gerri L. Mattson, MD, MSPH, FAAP

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From: Mattson, Gerri
Sent: Wednesday, March 26, 2014 12:05 PM
To: dewillia@wakehealth.edu; 'Sang, Charlie'; jcotton@ad.unc.edu; Drossner, David (David.Drossner@carolinashealthcare.org); Aaron Pulver, MD (Aaron.Pulver@avlcard.com); Angelo Milazzo, M.D. (angelo.milazzo@duke.edu); enelson@ncha.org; McCaffrey, Martin J (mjmccaff@email.unc.edu); 'dpohmstede@novanthealth.org'; Alex Kemper, M.D. (alex.kemper@duke.edu); 'ryan.p.flanagan2.mil@mail.mil'; Larry D. Mann (LMann@jeffersandmann.com); Betsy Vetter (Betsy.Vetter@heart.org); 'vjking1998@gmail.com'; 'joyemullis@gmail.com'; Ricki Goldstein, M.D. (ricki.goldstein@duke.edu); donatc63@aol.com; Marian Earls (mearls@n3cn.org); charris@ncbon.com; piers.barker@duke.edu
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Subject: Draft of Expert Panel Recommendations for Newborn Screening for Critical Congenital Heart Defects
Importance: High

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newborn screening for critical congenital heart defects.
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Thanks again for your ongoing interest and participation in this important work.

Thanks as always for all that you do,

Gerri L. Mattson, MD, MSPH, FAAP
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STATE OF NORTH CAROLINA
OFFICE OF ADMINISTRATIVE HEARINGS

Mailing address:
6714 Mail Service Center
Raleigh, NC 27699-6714

Street address:
1711 New Hope Church Rd
Raleigh, NC 27609-6285

June 19, 2014

Via Email and U.S. Mail: f.pete@me.com
Felice Pete, Chairperson
North Carolina Commission for Public Health
1627 St. Marys Street
Raleigh, North Carolina 27608

Re: 10A NCAC 43K .0101; .0102; .0103

Dear Chairperson Pete:

At the ~~July~~ June 18, 2014 meeting of the Rules Review Commission, the Commission reviewed the three temporary rules filed by the North Carolina Commission for Public Health. The Findings of Need forms filed indicates that the reason for the temporary rulemaking action is pursuant to a recent act of the General Assembly. The Commission declined to approve the above-captioned temporary rules based on the failure to comply with the Administrative Procedure Act (APA) in accordance with G.S. 150B-21.1(a) and 150B-21.9.

Please respond to this letter in accordance with the provisions of G.S. 150B-21.1(b1) or (b2). If you have any questions regarding the Commission's action, please do not hesitate to contact me.

Sincerely,

Abigail M. Hammond
Commission Counsel

Enclosure: Filing for 10A NCAC 43K .0101; .0102; .0103

cc: Chris Hoke, Rule-making Coordinator – chris.hoke@dhhs.nc.gov

Cpr 1 of 2
7/10/14

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): 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.

   ☐ 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 …

Original 7/10/14

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required? *20

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:

OBJECTED JUN 18 2014

☐ Date returned to agency:

Submitted for RRC Review:

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013

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

~~CHAPTER 43 – PERSONAL HEALTH~~

SUBCHAPTER 43K – NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DEFECTS

10A NCA 43K.0101 is adopted with changes 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~~ Critical congenital 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~~ 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 [(i.e.] such as pediatricians, family physicians, physician assistants, midwives, nurse practitioners, neonatologists neonatologists; and other specialty physicians) physicians who perform neonatal and infant assessments and review positive and negative pulse oximetry screening results to perform [determine] an appropriate 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, birthing centers, homes homes; or other locations.

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

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TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY
VOLUME:
ISSUE:

7/10/14

1. Rule-Making Agency: Commission for Public Health

2. RULE CITATION & NAME: 10A NCAC 43K .0102 SCREENING REQUIREMENTS

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): 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:

FILED
2014 JUL 10 PM 4:51
OFFICE OF ADMIN HEARINGS

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 ...

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

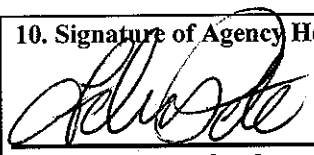
E-Mail: Chris.hoke@dhhs.nc.gov

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:

OBJECTED JUN 18 2014

☐ Date returned to agency:

Submitted for RRC Review:

Original 6/13/14

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

10A NCAC 43K .0102 SCREENING REQUIREMENTS

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

(1) Screening of every neonate for critical congenital heart defects (CCHD) using pulse oximetry shall ~~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 shall ~~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) Only U.S. Food and Drug Administration ~~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 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 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~~ home, or other location, the AAP/AHA recommended evaluation and follow up ~~should~~ shall 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 written process for evaluation and follow up of positive screenings in place at their medical facility.

(4) Options for neonatal or infant echocardiograms may ~~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.

ORIGINAL 7/10/14

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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 .0103 REPORTING REQUIREMENTS

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): 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:

FILED
2014 JUL 10 PM 4:51
OFFICE OF ADMIN HEARINGS

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 8, 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 ...

On 12 w/ 7/10/14

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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.

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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: OBJECTED JUN 18 2014 ☐ Date returned to agency:	Submitted for RRC Review:

10A NCA 43K.0103 is adopted with changes 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, 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; infant; and~~

(2) ~~age Age~~ in hours at time of ~~screening; screening;~~ all pulse oximetry saturation values, ~~which include~~ including initial, ~~subsequent~~ subsequent, and final screening ~~results; results;~~ final diagnosis if ~~known; known;~~ any known interventions and ~~treatment treatment;~~ ~~and~~ any need for transport or ~~transfer; 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~~ reports to the NC Birth Defects Monitoring Program shall include the total unduplicated counts of:

(1) ~~live Live births births;~~

(2) ~~neonates Neonates~~ and infants who were ~~screened~~ screened;

(3) ~~negative Negative screenings~~ screening;

(4) ~~positive Positive screenings~~ screening;

(5) ~~neonates Neonates~~ or infants whose parents or guardians objected to the critical congenital heart defect ~~screenings~~ screening;

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

(7) ~~neonates 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~~ death or other reasons.

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