Name of Commission: Commission for Public Health

Agency: Department of Health and Human Services, Division of Public Health

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Impact Summary: State Impact: Yes
Federal Impact: No
Local Impact: No
Substantial Impact No

Rule Title: 10A NCAC 43K - Newborn Screening for Critical Congenital Heart Defects, 0103 Reporting Requirements

Authority: Statutory Authority: G.S. 130A-125

I. Summary and Purpose

The proposed rule amendment (see Appendix A) affects the method by which hospitals and birthing centers report results of newborn screening for critical congenital heart defects (CCHD) in the first 24 to 48 hours of life based upon a national screening protocol. The current rule requires the reporting of information related to CCHD screening, evaluation and follow up for all medical facilities and health care providers who perform CCHD screening. The proposed rules will change the reporting system providers must use due to discontinued funding for the current system. The CCHD rules are the result of a 2013 legislative mandate: temporary rules were adopted in July 2014 and permanent rules were adopted in April 2015. Reporting is important to track both the process and outcomes of CCHD screening and to link the data to the NC Birth Defects Monitoring Program (BDMP).

II. Reason for Proposed Amendment

Report CCHD Screening Results Using Existing Newborn Screening Program Information and Reporting Systems

The current rule requires providers to report screening test results to a statewide CCHD database maintained by the Perinatal Quality Collaborative of North Carolina (PQCNC), which is partially funded by the NC legislature. In addition, providers are required to prepare separate quarterly reports summarizing the tests performed in the quarter. PQCNC in turn sends the screening results and quarterly reports to the NC DPH Birth Defects Monitor Monitory Program for follow up.

The Early Hearing Detection Intervention (EHDI) program has a reporting system called HearingLink, which in 2015 did not have the capabilities to accept results from the CCHD screening. Hospitals and birthing centers use this system to report all other NBS results, including those for auditory screening. At the time, the NC Division of Public Health did not have financial resources available to modify its existing newborn screening reporting system to receive CCHD screening results, which would have been the most direct and least impactful means for providers to report.
DPH provided some funding from the Maternal and Child Block Grant in seed money to PQNC to build out and support their CCHD reporting database. This funding was no longer available after 2015 and PQNC relied on state funding from their newborn quality improvement program to supplement the ongoing reporting database.

In recent legislative sessions, there had been discussion about adjusting the funding that PQNC receives. In anticipation of any funding reductions, NC DPH revisited modifying HearingLink and identified both software modifications and effort needed. Effective this current fiscal year, PQNC will no longer be able support CCHD reporting. DPH made the modifications necessary to receive CCHD results and completed pilot testing with plans to receive live screening results when PQNC is unable to.

III. Benefits from Proposed Rule Change

The purpose of the CCHD screening rules is to assure earlier detection and treatment of CCHD in all babies born in NC regardless of the location of the birth. Approximately 200 infants, or 1 in 585 births, are born with CCHD in NC per year. Data from the NC BDMP and reported in one study revealed that approximately 30% of infants with CCHD born in larger NC hospitals historically have been detected late (after discharge) when pulse oximetry screening was not used. The hospitals detected these infants with CCHD late because they had a normal prenatal ultrasound, no symptoms, and a normal clinical exam in the first days or weeks of life.

The use of a universal pulse oximetry screening for all infants born in NC, which follows the nationally recommended protocol, would significantly reduce late detection of CCHD. A national study has concluded that using a pulse oximetry screening for CCHD is a cost-effective measure.

DPH had estimated that mandated screening of all newborns in NC would reach an additional estimated 15% of newborns (currently 80% are screened based on NC Hospital Association estimates). The additional 15% of newborns screened would result in the early detection of 7 additional infants with CCHD, which would result in hospital cost savings resulting from fewer days spent in the hospital in the first year of life, as well as savings due to reduced missed days of work and costs to parents and improved quality of life for both the parents and children. In addition, DPH estimates the proposal would also potentially prevent one death associated with late detection of CCHD every 10 years. There would be an additional indirect benefit as some of the infants who are identified early with an abnormal screening result do have other medical conditions, such as other heart conditions, lung problems or infection, that can benefit from earlier detection and treatment.

Implementation of the proposed rules will better align the care related to screening for CCHD and the evaluation and follow up of positive CCHD screening results for all neonates and infants in NC with the national screening recommendations already mentioned. The rules will improve the standard and outcomes of care for all neonates and infants regardless of location of birth by:

1) Assuring that all hospitals, birthing centers, and attending health care providers of neonates and infants in NC are screening all neonates and infants based upon a nationally standardized, evidence-based, screening protocol for early detection of CCHD. This assures that providers use the most sensitive testing with the lowest false positive rate (i.e. that very few babies with an abnormal screen who do not have CCHD get unnecessary further testing);

2) Assuring that there is an evidence-based and standardized plan in place for evaluation and follow up of all newborns and infants with positive or abnormal CCHD screenings regardless of the location of the birth in NC. This assures early treatment for newborns diagnosed with CCHD;
3) Improving the essential function of a core public health mandate – surveillance of birth defects. The rule would improve the timeliness and completeness of case ascertainment, and therefore the data collection and monitoring of CCHD by the NC BDMP for public health surveillance purposes. The requirement for information reporting would also facilitate the evaluation of population level benefits of mandatory screening, including the impact on medical related costs, premature morbidity, mortality and developmental and educational outcomes. All of these activities fall within the mandate and mission of the NC BDMP.

To get a yearly baseline of the number of CCHD screenings that must be reported, DPH estimated that up to 60 reports would be needed for newborns with a false positive screening (based on the test’s 0.05% sensitivity and up to 95% of newborns being screened) and another about 200 reports for newborns with true positive CCHD screening. This number is assumed to grow with the rate of births in the state.

A conversation with newborn screening staff at one hospital revealed that the reporting of positive CCHD screening results each day would be logged at the same time newborn hearing screening results are entered. These reporting tasks are currently conducted in two separate systems. Under the proposed rules, all reporting would be completed in the modified HearingLink system, resulting in expected staff time savings. If we take a conservative estimate of the time for electronic reporting system entry to report positive results to one system, we estimate the time to report screening results will be reduced from 4.5 minutes of nursing time to 2.25 minutes. Based on salary and compensation data from the NC Department of Commerce, the hourly wage for a registered nurse in NC in 2017 was $30.08 on average. Given that employee benefits accounts for 33.6% of total compensation for registered nurses nationally, total hourly compensation is approximately $45.3 Therefore, the estimated cost per case reported will be reduced from $3.4 to $1.7, a savings of $1.70 per report. Assuming 260 reports are filed annually, that is an opportunity cost savings of nursing staff time of up to $442.

The proposed rule amendment also removes the required quarterly aggregate reports that facilities prepared. Given that the data for the quarterly reports will now be contained within HearingLink, DPH staff, with minimal effort, can generate the reports directly.

By eliminating the requirement for providers to compile and submit quarterly aggregate numbers the annual opportunity cost burden on providers will be reduced from $182,000 to $133,000 for births in-hospitals and from $1,700 to $900 for out-of-hospital births based on the most recent 2014 cost estimates. The expected savings amounts to approximately $49,800 annually in staff time.

State
Costs to the state included a one-time software upgrade opportunity cost of $2,236.65 in software development and testing time incurred in the 4th qtr of 2017 and 1st qtr of 2018. The opportunity cost for ongoing maintenance is minimal.

There are no additional costs for the NBS or BDMP staff resulting from the proposed rule amendment.

Table 4 provides a summary of the estimated costs and savings associated with reporting CCHD screening results directly to DPH.

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Table 1. Resources and impacts associated with the reporting CCHD Screening Results directly to DPH

<table>
<thead>
<tr>
<th>Resources</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Impact on State Agency</strong></td>
<td></td>
</tr>
<tr>
<td>Upgrades to Hearing Link to receive CCHD</td>
<td>$2,236.65 (one-time opportunity cost)</td>
</tr>
<tr>
<td>screening results</td>
<td></td>
</tr>
<tr>
<td>Maintenance cost</td>
<td>Minimal undefined opportunity cost</td>
</tr>
<tr>
<td>Total one-time cost to State Agency</td>
<td>2,236.65</td>
</tr>
<tr>
<td>Total annual cost to State Agency</td>
<td></td>
</tr>
<tr>
<td><strong>B. Impact on Local Agencies</strong></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>$0</td>
</tr>
<tr>
<td><strong>C. Impact on Private Sector</strong></td>
<td></td>
</tr>
<tr>
<td>Reduced staff time to report CCHD screening</td>
<td>$50,240. (existing staff time savings of (49,000. + $800 + 440.)</td>
</tr>
<tr>
<td>results</td>
<td></td>
</tr>
<tr>
<td><strong>Total Impact</strong></td>
<td></td>
</tr>
<tr>
<td>Total one-time cost</td>
<td>2,236.65</td>
</tr>
<tr>
<td>Total annual cost</td>
<td>NA</td>
</tr>
<tr>
<td>Total annual benefits</td>
<td>$50,240 staff time savings plus unquantified benefits from data availability</td>
</tr>
</tbody>
</table>
APPENDIX A

10A NAC 43K .0103 is proposed for amendment as follows:

10A NCAC 43K .0103 REPORTING REQUIREMENTS

(a) All medical facilities and attending providers of neonates or infants performing critical congenital heart defect (CCHD) screening shall report the information described below about positive failed screenings to a statewide CCHD database maintained by the Perinatal Quality Collaborative of North Carolina (PQCNC), the Division of Public Health. The following information must be reported by medical facilities and attending providers within seven days of all positive failed screenings:

1. Date and time of birth of the neonate or infant, gestational age, and the medical facility or birth location, and
2. Age in hours at time of screening; all pulse oximetry saturation values, including initial, subsequent, and final screening results; final diagnosis if known; any known interventions and treatment, and any need for transport or transfer; and the location of the transfer or transport if known.

(b) Within two weeks of receiving a positive screening, PQCNC shall report the above information from the CCHD database to the NC Birth Defects Monitoring Program using a unique identifier generated by the CCHD database for the neonate or infant. The unique identifier shall be retained by the source medical facility or attending provider for help with identification of the neonate or infant.

(c) All medical facilities and attending providers of neonates or infants performing critical congenital heart defect screening shall report aggregate information described in Subparagraphs (e)(1) through (e)(7) of this Rule quarterly and no later than 15 days after the end of each quarter of the state fiscal year to a statewide CCHD database maintained by the Perinatal Quality Collaborative of North Carolina (PQCNC), the Division of Public Health.

(d) PQCNC shall report the aggregate information described in Subparagraphs (e)(1) through (e)(7) to the NC Birth Defects Monitoring Program within 30 days after the end of each quarter of the state fiscal year.

(e) The required quarterly aggregate information from medical facilities and attending providers of neonates or infants reported to PQCNC and that PQCNC reports to the Division of the NC Birth Defects Monitoring Program shall include the total unduplicated counts of:

1. Live births;
2. Neonates and infants who were screened;
3. Negative screenings;
4. Positive screenings;
5. Neonates or infants whose parents or guardians objected to the critical congenital heart defect screenings;
6. Transfers into the medical facility, not previously screened; and
7. Neonates and infants not screened and the reasons if known which include a diagnostic echocardiogram being performed after birth and prior to discharge, transfer out of the medical facility before screening, or death.

History Note: Authority G.S. 130A-125;