Fiscal Note
Screening for Critical Congenital Heart Defects

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 (impact to Medicaid included under state impact)
Local Impact: No
Substantial Impact: Yes

Rule Title: 10A NCAC 43K - Newborn Screening for Critical Congenital Heart Defects
.0101 Definitions
.0102 Screening Requirements
.0103 Reporting Requirements

Authority: Statutory Authority: G.S. 130A-125, S.L. 2013-45

I. Summary and Purpose

The proposed rules (see Appendix A) would require screening of every neonate and infant born in North Carolina (NC) for critical congenital heart defects (CCHD) in the first 24 to 48 hours of life based upon a national screening protocol. In addition, the rules require an evidence-based evaluation and follow-up plan for babies with positive CCHD screenings based on national recommendations.[1] Finally, the rules require 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 proposal is a result of a 2013 legislative mandate. Reporting is important in order to meet legislative requirement to track both the process and outcomes of CCHD screening and link the data to the NC Birth Defects Monitoring Program (BDMP).

The purpose of the 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.[2] 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.[3] The hospitals detected these infants with CCHD late because

[1] Kemper, A., Mahle, W., Martin, G., et al.. (2011). Strategies for Implementing Screening for Critical Congenital Heart Disease. *Pediatrics*, *128*(5), E1259-E1267. Retrieved June 1, 2013.

[2] Meyer, R. (2012). Running the Numbers: Critical Congenital Heart Defects in North Carolina. *NC Med J, 73*(6), 504-508. Retrieved June 1, 2013.

[3] Peterson, C., Ailes, E., Riehle-Colarusso, T, et al. (2014). Late Detection of Critical Congenital Heart Disease Among US Infants: Estimation of the Potential Impact of Proposed Universal Screening Using Pulse Oximetry. *JAMA Pediatrics, 168*(4), E1-E10. Retrieved February 11, 2014.

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.[4] DPH expects 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 as a result of less 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. 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.

The costs associated with the proposal related to the screening of an additional 15% of the newborn population, are anticipated to be a result of echocardiograms and additional costs related to follow-up exams of babies with positive results to the CCHD screening, and due to providers reporting CCHD cases and the state processing that information. Table 1 below provides a summary of estimated total costs and total savings that are quantifiable from implementation of the CCHD newborn screening rules over the next ten years. The net present value of quantified benefits is estimated to exceed the costs, mostly due to the estimate that one life would be saved over the next 10 years.

Table 1: Estimates of Total Costs and Total Savings from Implementation (in thousand $)

Item	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Costs										
State Gov't	$57	$7	$8	$8	$8	$8	$8	$9	$9	$9
Private Sector										
- Providers	$270	$335	$424	$437	$451	$465	$480	$497	$514	$531
- Payers	$3	$3	$3	$3	$4	$4	$4	$4	$4	$4
- PQCNC	$20	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Costs	**$350**	**$345**	**$435**	**$449**	**$463**	**$477**	**$493**	**$509**	**$526**	**$544**
NPV of Costs	**$3,140**									
Benefits										
State Gov't	$55	$70	$101	$104	$106	$109	$112	$115	$119	$122
Local Gov't	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Private Sector	$7,049	$63	$90	$93	$95	$97	$100	$103	$106	$109
Other Benefits										
Total Benefits	**$7,104**	**$133**	**$191**	**$196**	**$201**	**$206**	**$212**	**$218**	**$224**	**$231**
NPV of Benefits	**$7,841**									

[4] Peterson, C., Grosse, S., Oster, M., et al. (2013). Cost-Effectiveness of Routine Screening for Critical Congenital Heart Disease in US Newborns. *Pediatrics, 132*(3), E595-E603. Retrieved August 6, 2013.

II. Background

The agency is proposing these rules as a result of a recent statutory change. On May 8, 2014, Governor McCrory signed into law Senate Bill 98 (S.L. 2013-45), which expands the Newborn Screening Program, established in G.S. 130A-125 and administered by the NC Department of Health and Human Services, to include newborn screening for critical congenital heart defects (CCHD) using pulse oximetry (see statutory change in Appendix B). The statute requires that the Commission for Public Health adopt temporary and permanent rules to include pulse oximetry screening in the Newborn Screening Program, and address follow-up treatment plans of newborns diagnosed with CCHD and a tracking system for the screenings.

As of July 2014, 41 states have legislation enacted or regulatory additions to rules that require CCHD screening in newborns .[5] The first state to implement statewide screening for CCHD in newborns was New Jersey in 2011. The New Jersey experience showed that the vast majority of their babies with CCHD were not screened using pulse oximetry in their first year of implementation of screening but were detected later through their birth defects monitoring program.[6] NC rules have tried to anticipate reasons an infant might not get screened and has included requirements for screening of all birthing including screening of births occurring outside of hospitals and also in the NICU setting. DPH anticipates that the rules will allow us to capture more of the CCHD infants earlier via screening. These proposed rules would bring NC in line with standard of care delivered to neonates and infants in other states, including Virginia, South Carolina, Georgia and Tennessee. The rules would also require NC to follow current national recommendations from the US Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and the US Secretary of Health and Human Services, the American Heart Association, and the American Academy of Pediatrics to perform evidence based CCHD screening in newborns.[7] The Bright Futures Recommendations for Pediatric Preventive Health, which are national standards for age appropriate well child care for all infants, children and adolescents, were revised this year and also include CCHD screening of newborns.[8]

The American Academy of Pediatrics and American Heart Association only recently issued recommendations in 2011 for a screening protocol using a noninvasive test called pulse oximetry on newborns at 24 to 48 hours of life.[9] These national recommendations also included standards for an evaluation and follow-up of newborns and infants with a positive CCHD screening. An extensive literature review and a panel of experts were used to develop the national recommendations. The screening protocol alerts health care providers of low blood oxygen saturations in the blood of the newborns using pulse oximetry before they develop signs and symptoms of CCHD.

Babies with CCHD have heart conditions present at birth that require specialized care and treatment soon after birth to help keep the heart, lungs and body functioning properly. Babies with CCHD by definition

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[5] The Newborn Foundation Coalition. CCHD Screening Map. Accessed October 16, 2014. www.cchdscreeningmap.org

[6] Garg, L., Braun, K., Knapp, M., et al. (2013). Results From the New Jersey Statewide Critical Congenital Heart Defects Screening Program. *Pediatrics, 132*(2), E314-E323. Retrieved July 16, 2013.

[7] Kemper, A., Mahle, W., Martin, G., et al. (2011). Strategies for Implementing Screening for Critical Congenital Heart Disease. *Pediatrics*, *128*(5), E1259-E1267. Retrieved June 1, 2013.

[8] American Academy of Pediatrics. (2014). Recommendations for Pediatric Preventive Health Care. Retrieved March 30, 2014 from: http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity%20Schedule_FINAL.pdf

[9] Kemper, A., Mahle, W., Martin, G., et al. (2011). Strategies for Implementing Screening for Critical Congenital Heart Disease. *Pediatrics,* 128(5), E1259-E1267. Retrieved June 1, 2013

require catheter or surgical interventions in the first year of life in consultation with a pediatric cardiologist and/or cardiothoracic surgeon.[10] CCHD screening using pulse oximetry is important because it is used to detect infants earlier, before they have symptoms or an abnormal clinical exam. An infant with CCHD is subject to "profound, sudden worsening in clinical status in the first days or weeks of life."[11] An infant can go home and then come back emergently in shock, which can cause injury to the brain and other body systems. There are seven primary critical congenital heart defects and several other secondary congenital heart defects that the national pulse oximetry screening protocol targets for early detection.[12] The screening protocol using pulse oximetry has a high sensitivity of 77.5%,[13] which means that the screening test is abnormal or positive in about 77 babies out of 100 that actually have CCHD. Additionally, the protocol also has a very low false positive rate of 0.05%, i.e. very few babies will have an abnormal screen and not have CCHD.[14]

In order to meet the requirements of Session Law 2013-45, the agency developed temporary rules based on researching the requirements and outcomes of CCHD screening programs in other states. In addition, an Expert Panel of multiple stakeholders within NC was used to inform the rules, which included families of infants with CCHD, pediatricians, neonatologists, pediatric cardiologists, midwives, and representatives from the NC Hospital Association, Perinatal Quality Collaborative of NC, NC Board of Nursing, NC Association of Physician Assistants, NC Academy of Family Physicians, NC College of Obstetrics and Gynecology, and many others. The Commission for Public Health adopted the temporary rules on May 14, 2014 and the Rules Review Commission approved them on July 17, 2014. The rules became effective on July 25, 2014, and will remain in effect until April 21, 2015 or until the permanent rules become effective, whichever is earlier. The proposed language of the permanent rules is similar to that passed in the temporary rules with some changes in the Reporting Requirements. Medical facilities and birthing facilities started to increase the numbers of infants being screened for CCHD in anticipation of the legislation in 2013 and then in anticipation of rules in 2014.

III. Impact

Based on national experience with state mandates for hearing screening, we anticipate that the rules for CCHD screening will result in 95% CCHD screening rates, or 15% more of our newborns being screened within two years of the implementation of the rules.[15] According to the NC Hospital Association, NC

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[10] U.S. Department of Health and Human Services, Maternal and Child Health Bureau. ONLINE. 2010. Maternal and Child Health Bureau. Evidence Review: Critical Congenital Cyanotic Heart Disease. (Subcontract No. SC-07-028). Available: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nominatecondition/reviews/cyanoticheart.pdf

[11] Mahle, W.T., Newburger, J.W., Matherne, J.P., et al. (2009) Role of Pulse Oximetry in Examining Newborns for Congenital Heart Disease: A Scientific Statement from the AHA and AAP. *Pediatrics. 124*(183). 823-835. Retrieved October 14, 2014.

[12] Kemper, A., Mahle, W., Martin, G., et al. (2011). Strategies for Implementing Screening for Critical Congenital Heart Disease. *Pediatrics, 128*(5), E1259-E1267. Retrieved June 1, 2013.

[13] U.S. Department of Health and Human Services, Maternal and Child Health Bureau. (2010). Maternal and Child Health Bureau. Evidence Review: Critical Congenital Cyanotic Heart Disease. (Subcontract No. SC-07-028). Retrieved on October 16, 2014 from: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nominatecondition/reviews/cyanoticheart.pdf.

[14] Ibid.

[15] Green, D., Gaffney, M., Devine, O., & Grosse, S. (2007). Determining the Effect of Newborn Hearing Screening Legislation: An Analysis of State Hearing Screening Rates. *Public Health Reports, 122*(2), 198-205. Retrieved October 16, 2014.

providers were screening 80% of newborns for CCHD even before implementation of the temporary rules. Under G.S. 130A-125, parents have the legal right to opt out of any required newborn screening tests. Parental refusals of CCHD screening for their newborns, early discharge, unstable newborns, and having some infants who receive diagnostic echocardiograms instead of screening for CCHD will negatively impact the ability to achieve screening of 100% of newborns for CCHD. However, without the rules, screening rates would increase much more slowly and probably would never achieve 95% of newborns being screened for CCHD.[16]

Table 2 projects the estimated numbers of additional births screened in hospitals and other locations as a result of the proposed rules based on population projection data obtained from the NC Office of State Budget and Management. By the end of FY 2014-15, DPH estimates 88% of newborns born in hospitals would be getting screened, or an additional 8%, and 91% by the second year of screening. By the end of FY 2016-17, DPH estimates a total of 95% of newborns would be getting screened, or an additional 15%, and that percentage will be maintained through FY 2023-24.

Birthing center births will aim to screen 95% of the approximately 300 births within two years, the same as for in hospital births. There are only two main centers and the larger location is already screening, though using a modified protocol, so DPH estimates 80% of the births in birthing centers are already screened. DPH also assumed that the rate of births in birth centers would be constant at about 0.3% of total birth for the timespan analyzed.

Births that are planned for delivery in homes that are attended by midwives and other providers have been constant over the last five years according to the NC State Center for Health Statistics and are estimated to remain constant around 500 births. DPH anticipates that it would be a slower process to get more home births screened, and DPH estimates capturing 10% of home births per year up to a maximum 40% of home births being screened. Families who choose home births are often more likely to refuse hearing and metabolic screenings as well as other procedures for newborns and are at some increased risk to refuse CCHD screening. In addition, it is unclear the type and total number of all independent providers attending all home births, so the ability to do outreach to all of these different providers is more difficult.

Table 2: Estimated Number of Births and of Additional Births Screened for CCHD per Year

Item	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Newborns	116,316	117,101	117,911	118,654	119,421	120,260	121,149	122,097	123,067	124,045
Additional newborns screened	9,305	12,881	17,686	17,798	17,913	18,039	18,172	18,314	18,460	18,606
- In hospitals	9,231	12,747	17,487	17,547	17,661	17,784	17,916	18,056	18,199	18,344
- Out of hospitals	74	134	199	251	252	255	256	258	261	262
- *Birthing centers*	25	35	49	49	49	50	50	50	51	51
- *Home births*	49	99	150	202	203	205	206	208	210	211

[16] Ibid

This analysis includes the costs and benefits in FY 2014-15 associated with implementation of the temporary rules, which were effective July 25, 2014, as well as the costs and benefits for implementation of the proposed permanent rules, which would become effective in April 2015.

A. Cost-Effectiveness

The Peterson 2013 study showed the overall cost-effectiveness of universal screening in the inpatient setting. The study concluded that the cost-effectiveness of the screening per case identified was $20,862 and the cost-effectiveness per life-year gained was $40,385.[17] The analysis indicated a 52% chance the incremental cost of screening would be < $50,000 per life-year gained. These results indicate that the measure is cost-effective. As a rule of thumb, the literature has traditionally viewed measures that lead to cost effectiveness ratios under $50,000, or even under $100,000, as cost-effective.[18]

The World Health Organization (WHO) uses a threshold for gross domestic product (GDP) per capita and considers anything under the GDP per capita to be highly cost-effective. The effectiveness ratio from the Peterson 2013 study in 2014 dollars is less than $43,000. The 2013 GDP per capita in NC was close to $50,000 in 2014 dollars. Therefore, based on WHO criterion, universal screening for CCHD using pulse oximetry would be highly cost-effective.

B. Benefits

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.

[17] Peterson, C., Grosse, S., Oster, M., et al. (2013). Cost-Effectiveness of Routine Screening for Critical Congenital Heart Disease in US Newborns. *Pediatrics, 132*(3), E595-E603. Retrieved August 6, 2013.

[18] Centers for Disease Control and Prevention. HIV Cost-Effectiveness. http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/

In NC, approximately 200 infants are born with CCHD per year. Based on a national study, in the recent past, about 29.5% of babies with CCHD were not detected until late.[19] This would mean that health care providers detected CCHD late in about 59 babies per year who were born in NC's larger hospitals DPH conservatively estimates that the implementation of the proposed rules is expected to result in 15% less late detections. Although, it is likely that this percentage would be higher since late detections mostly occur in the absence of early screening, which is more likely to occur in rural hospitals. Based on this assumption and data that the screening protocol is able to detect 77.5% of CCHD cases, screening is expected to result in the early detection of 4 and 5 newborns with CCHD per year in the first two years of implementation, respectively, and 7 additional newborns per year afterwards. These infants would have been detected late in the absence of the rule.

Early detection of CCHD through screening of these 4 to 7 additional newborns in NC can be inferred to be associated with 52% less hospital admissions, 18% less hospitalized days, and 35% less estimated inpatient costs during the first year of life for each of these babies based on the Florida study.[20] In the cases of an earlier diagnosis, newborns spend more days in the hospital early on, but fewer hospital days later, and overall there are less hospital days and thus less hospital costs in the first year of life. The average length of hospital stay for an infant diagnosed with CCHD early vs. late who survives infancy is 7 days shorter. [21] Extrapolating from these results based on a conversation with a Centers for Disease Control health economist, this translates into $25,000 per infant in savings in hospital costs during the first year of life. This estimate is assumed to grow with the rate of inflation in healthcare related prices.[22] That is about $100,000 to $222,000 in savings in hospital costs per year for cases that will be detected early due to the pulse oximetry screening protocol. This saving will be incurred by mainly Medicaid and third party payers. Since Medicaid covers about 55% of newborns based on communication with the NC State Center for Health Statistics, DPH assumed that Medicaid would have the same share in the savings. While both the state and the federal government would incur the saving to Medicaid based on their share of funding in the program, for the purpose of this analysis, the agency considered the benefit as an impact on the state government alone.

There are no studies discussing the positive impact of the pulse oximetry screening on costs to parents of infants with CCHD from less missed days of work and costs to parents and improved quality of life for both the parents and infants. As mentioned above, the average length of hospital stay for an infant diagnosed with CCHD early versus late who survives infancy is 7 days shorter.[23] According to data from the Bureau of Labor statistics, in 2013 the median hourly wage for a North Carolinian worker was $15.46 and, nationally, workers were compensated about 20% in benefits.[24,25] Based on this data, DPH assumed

[19] Peterson, C., Ailes, E., Riehle-Colarusso, T, et al. (2014). Late Detection of Critical Congenital Heart Disease Among US Infants: Estimation of the Potential Impact of Proposed Universal Screening Using Pulse Oximetry. *JAMA Pediatrics, 168*(4), E1-E10. Retrieved February 11, 2014.

[20] Peterson, C., Dawson, A., Grosse, S., et al. (2013). Hospitalizations, costs, and mortality among infants with critical congenital heart disease: How important is timely detection? *Birth Defects Research (Part A): Clinical and Molecular Teratology, 97*, 664-672. Retrieved October 16, 2014.

[21] Ibid.

[22] IHS Global Insight U.S. Macro Database. Chained Price Index--Consumer Spending on Health Care, Pharmaceuticals And Medical Products, 30-year Baseline Forecast.

[24] Bureau of Labor Statistics. May 2013 State Occupational Employment and Wage Estimates: North Carolina. http://www.bls.gov/oes/current/oes_nc.htm

[25] Bureau of Labor Statistics. "Employment Cost Index Historical Listing – Volume III." July 2014. http://www.bls.gov/web/eci/echistrynaics.pdf

that the total value of an hour of a parent's time was about $19 and that this would increase at the rate of inflation.[26] That is an estimated savings of about $1,000 per parent, or $4,000 to $9,000 per year for the parents of the additional infants who would be detected earlier as a result of the proposed rule These estimates assume one parent per infant would be affected, which may be underestimating the savings, and 7 eight-hour days.

Additionally, the implementation of the rules is expected to result in the prevention of one infant death due to late detection of CCHD over the next 10 years. This estimate is based on 65 cases of newborns with CCHD that would be detected earlier over the next 10 years (see Table 3 below) and the Florida study that determined 1.8% of infants with late-detected CCHD have deaths in emergency settings that were potentially preventable if they had received a diagnosis during the birth hospitalization.[27] The federal Office of Management recommends that federal agencies use a value of statistical life of $6.3 million in 2008 dollars, which would be about $7 million in 2014 dollars, in estimating the impacts of regulations.[28] Therefore, the net present value of the benefit from the one averted death over the next 10 years is $7 million as a result of 15% more of NC newborns being screened for CCHD.

The proposal would lead to additional benefits that are difficult to quantify. There are infants who are also identified early for other medical conditions, such as other heart conditions, lung problems or infections, because of an abnormal pulse oximetry screening result. This suggests that these infants would also benefit from earlier detection and treatment. New Jersey's first nine months of universal implementation with screening over 73,000 infants showed that pulse oximetry screening resulted in about 33% of infants who would not have been evaluated were found to have some medical condition other than CCHD.[29] One study in Sweden found that 45% of the false positive screening results in infants was due to a medical condition other than CCHD.[30] The agency could infer that early detection of these other conditions would also result in less hospital days, less missed days of work and costs to parents, less costs to Medicaid and third party payers, and improved quality of life for both the parents and infants. However, there are no estimates of cost benefits in the literature due to earlier detection of these other conditions.

The proposed rules could actually reduce the overall current costs and anxiety related to a screening being falsely positive by requiring that the AAP/AHA recommendations for screening, evaluation and follow-up are used. Anecdotally, DPH knows that some hospitals and providers are using a different protocol that

[26] IHS Global Insight U.S. Regional Database. Consumer Price Index, North Carolina, 30-year State Forecast.

[27] Peterson, C., Dawson, A., Grosse, S., et al. (2013). Hospitalizations, costs, and mortality among infants with critical congenital heart disease: How important is timely detection? *Birth Defects Research (Part A): Clinical and Molecular Teratology*, *97*, 664-672. Retrieved October 16, 2014.

[28] Office of Management and Budget. Office of Information and Regulatory Affairs. "2013 Draft Report to Congress on The Benefits And Costs Of Federal Regulations And Agency Compliance With The Unfunded Mandates Reform Act." Footnote 16. Retrieved November 10, 2014 from: http://www.whitehouse.gov/sites/default/files/omb/inforeg/2013_cb/draft_2013_cost_benefit_report.pdf

[29] Garg, L., Braun, K., Knapp, M., et al. (2013). Results From the New Jersey Statewide Critical Congenital Heart Defects Screening Program. *Pediatrics*, *132*(2), E314-E323. Retrieved July 16, 2013.

[30] De Wahl, G.A., Wennergren, M, Sandberg, K., et al. (2009). Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish perspective screening study in 39,821 newborns. *BMJ 338*: a3037.

screens the babies earlier than 24 hours of life. A protocol which requires screening at 24 to 48 hours results in the lowest number of false positives.[31]

The saving estimates above do not include additional potential benefits from early detection related to avoiding complications, such as going into shock at home and being admitted on an emergency basis with increased risk for brain and body injury. One can infer that earlier diagnosis of CCHD using pulse oximetry screening should reduce the risk of brain injury and have improved neurological outcomes; however, there are no studies to demonstrate a causal relationship between delayed diagnosis and brain injury. Several studies report that children with CCHD experience more frequent delays and impairments in several developmental areas including motor, speech and language, visual-motor-perceptual function, and executive function, and use more special services such as early intervention and therapies.[32] Since children with CCHD have an increased rate of neurodevelopmental delays and disabilities overall, earlier detection of CCHD and monitoring is important.[33] If there is indeed a causal relationship between earlier detection and reduced risk of brain injury, it would lower societal costs due to reduced needs for early intervention services, specialized therapies, educational and other developmental services for children with CCHD. It would also improve the academic success and work productivity of children with CCHD due to reduced work limitations and disabilities. However, at this time there are no data on the impact of earlier screening and diagnosis of CCHD on neurodevelopmental outcomes in these children or on the lower societal costs due to reduced need for services over time.

It is important to note that DPH expects most of the benefits from the proposed rule change to be a result of additional screening for CCHD of the babies born in the smaller, rural hospitals in NC. Past correspondence with hospitals in NC by the NC Chapter of the American Heart Association and by DPH staff show that all of the major medical centers and larger hospitals and several of the smaller birthing hospitals are now performing CCHD screening. DPH had reports in August that at least two rural hospitals were still not screening for CCHD. Based on results from a Florida study,[34] babies born in rural locations may account for a large percentage of the babies who are detected late. According to a conversation with a CDC expert, this share could be as much as 25% of the late-detected infants, or 2 additional infants with CCHD per year who can be potentially detected earlier with the proposed screening.[35] Therefore, the cost-effectiveness of starting to screen for CCHD can be inferred to be higher for the smaller, rural hospitals that are not currently screening for CCHD.[36] Late detection is also likely to be higher with infants born in locations outside of the hospital setting such as birthing centers and homes where screening is not being performed using the national screening protocol.

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[31] U.S. Department of Health and Human Services, Maternal and Child Health Bureau. 2010. Maternal and Child Health Bureau. Evidence Review: Critical Congenital Cyanotic Heart Disease. (Subcontract No. SC-07-028). Available: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nominatecondition/reviews/cyanoticheart.pdf

[32] Mahle, W.T., Newburger, J.W., Matherne, J.P., et al. (2009) Role of Pulse Oximetry in Examining Newborns for Congenital Heart Disease: A Scientific Statement from the AHA and AAP. *Pediatrics. 124*(183). 823-835. Retrieved October 14, 2014.

[33] Marino, B.S., Lipkin, P.H., Newburger, J.W., et al. (2012). Neurodevelopmental Outcomes in Children with Congenital Heart Disease: Evaluation and Management. *Circulation. 126*: 1143-1172

[34] Dawson, A., Cassell, C., Riehle-Colarusso, T., et al. (2013). Factors Associated With Late Detection of Critical Congenital Heart Disease in Newborns. *Pediatrics, 132*(3), E604-E611. Retrieved October 16, 2014.

[35] Email and phone communications with Dr. Scott Grosse, August 2014. Research Economist, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention.

[36] Dawson, A., Cassell, C., Riehle-Colarusso, T., et al. (2013). Factors Associated With Late Detection of Critical Congenital Heart Disease in Newborns. *Pediatrics, 132*(3), E604-E611. Retrieved October 16, 2014.

The many benefits from the reporting of data related to CCHD screening were discussed at the beginning of this section. The rules incorporate the consensus recommendations from an expert panel of key stakeholders from across the country about data and data exchange for reporting of CCHD screening results.[37] Timely reporting of positive results improves timeliness and efficiency of reporting of birth defects and decreased time to ascertainment of a CCHD diagnosis by the NC BDMP. This could help public health potentially detect a cluster of cases, investigate if there were some environmental causes or other factors and allow the public health officials to be more responsive to the CCHD surveillance data. Typically, it takes up to two years for the NC BDMP to fully close a CCHD case. The timely reporting of other structural malformations that are not CCHD but that are secondary targets and non-cardiac birth defects found as a results of CCHD screening and the evaluation would also help with timeliness of the NC BDMP ascertainment of these birth defects. Timely reporting of positive CCHD screenings and results of the diagnostic evaluations when known would also help to monitor the follow-up of positive CCHD screenings. The reporting of quarterly aggregate data to the NC BDMP helps to determine if there are hospitals not reporting data and if there is a need to work with partners to do outreach to the hospitals about the issues they may be experiencing that are preventing them from screening for CCHD. Partners with public health could include the North Carolina Hospital Association, Perinatal Quality Collaborative of North Carolina (PQCNC), and provider associations such as the NC Pediatric Society, and the NC Academy of Family Physicians as well as the many other partners who worked with DPH on the Expert Panel to develop draft recommendations for the temporary rules.

Table 3 provides a summary of estimated earlier detections due to the rules and the related savings.

Table 3: Estimated Number of CCHD Cases Detected Earlier and Related Savings (in thousand $)[1]

Item	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Additional early detections	4	5	7	7	7	7	7	7	7	7
Hospital cost savings	$100	$128	$184	$188	$193	$198	$204	$210	$216	$222
- Medicaid share	*$55*	*$70*	*$101*	*$104*	*$106*	*$109*	*$112*	*$115*	*$119*	*$122*
- Private share	*$45*	*$58*	*$83*	*$85*	*$87*	*$89*	*$92*	*$94*	*$97*	*$100*
Parents' lost time savings	$4	$5	$8	$8	$8	$8	$8	$8	$9	$9
VLS of deaths averted [2]	$7,000									
Total Savings	**$7,104**	**$133**	**$191**	**$196**	**$201**	**$206**	**$212**	**$218**	**$224**	**$231**
NPV of Benefits [3]	**$7,841**									

[1] *The table does not include unquantified benefits related to earlier detection through CCHD screening of other conditions and improved neurodevelopmental outcomes of children.*
[2] *VSL stands for the value of statistical life.*
[3] *The figure represents the 10-year net present value (NPV) of benefits as of July 1, 2014 using a 7% discount rate.*

[37] Martin, G., Beekman, R., Mikula, E., et al. (2013). Implementing Recommended Screening for Critical Congenital Heart Disease. *Pediatrics, 132*(1), E185-E192. Retrieved March 25, 2014.

C. *Costs*

i. *Screening Costs*

All of the quantifiable costs from CCHD screening of newborns relate to the opportunity costs to the hospital, birthing facility, or provider if performing the screening outside of the hospital. The literature estimates that the opportunity cost for the actual screening in a hospital setting is $13.50 per newborn in 2011 dollars,[38] or about $14.5 in 2014 dollars.[39] This cost is based on the average US average hourly wage and benefits of a registered nurse, and the cost of the pulse oximetry machine, sensors and maintenance of the machine. The analysis assumes conservatively that this cost would increase at the rate of inflation in health care prices.[40]

The hospitals currently absorb the screening test cost since Medicaid and third party payers do not reimburse the hospitals specifically for the screening. The cost of the pulse oximetry screening for the hospital is considered part of the overall care provided for the newborn or infant that is reimbursed as a bundled payment to the hospital. It is unclear if hospitals will try to negotiate increasing the fee for the newborn hospital care package with Medicaid and other insurers to include this cost of the CCHD screening test. DPH conservatively estimates that all of the additional 15% of babies will be screened for CCHD. However, according to the rules those babies who are found to have CCHD will have neonatal echocardiograms done because of symptoms or known on prenatal ultrasound and will not have to be screened using the pulse oximetry protocol. The estimated annual impact on hospitals, based on the screening cost and the estimated additional newborns screened in hospitals (see Table 2), ranges from about $134,000 in FY 2014-15 to $337,000 by FY 2023-24.

According to staff at a NC birthing center, birthing centers typically discharge newborns at 6 to 8 hours of life and follow-up the newborns and their mothers in the home at 24 and 48 hours of life. A conversation with a nurse midwife who performs home births also revealed that there is also follow-up with the newborn and mother in the first two days after birth. This follow-up is an opportunity for the midwife to screen for CCHD in the home, and this currently occurs easily as part of follow-up care in at least a few other states across the country according to conversations with Wisconsin and Maryland midwives.

The cost of CCHD screening for the provider caring for the neonate and mother in the home is also considered part of the cost of the care of the neonate, so the CCHD screening cost is absorbed by the providers and is not separately billed to Medicaid or third party payers. If the mother's insurance does not cover a home delivery and newborn care, the provider could bill the mother for the costs. The exact cost for CCHD screening in the home setting has not been studied, but a conservative estimate based on professional judgment would be to double the cost of the hospital screening, or assume $29 for a screening for CCHD in the home. DPH assumed this cost would also increase at the rate of inflation in healthcare prices.[41] Based on the estimated number of additional screenings outside the hospital, the estimated annual cost to providers ranges between $2,000 and $10,000.

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[38] Peterson, C., Grosse, S., Oster, M., et al. (2013). Cost-Effectiveness of Routine Screening for Critical Congenital Heart Disease in US Newborns. *Pediatrics, 132*(3), E595-E603. Retrieved August 6, 2013.

[39] IHS Global Insight U.S. Regional Database. Consumer Price Index, North Carolina, 30-year State Forecast.

[40] IHS Global Insight U.S. Macro Database. Chained Price Index--Consumer Spending on Health Care, Pharmaceuticals And Medical Products, 30-year Baseline Forecast.

[41] Ibid.

ii. Evaluation and Follow-up Costs

There is an additional cost related to the diagnostic evaluation of a newborn with a positive CCHD screening. The proposed rules require providers to perform a diagnostic evaluation of a newborn to determine the medical reason or cause for a positive or abnormal CCHD screening in a newborn as per the AAP/AHA recommendations before discharge from care.[42] DPH has already estimated above that 7 additional newborns with CCHD will be picked up because of an abnormal pulse oximetry screening result; therefore, these newborns will require a diagnostic evaluation as a result of the proposed rules.

Due to the screening test's false positive rate, 0.05% of additional infants screened would also have a positive CCHD screening but not actually have a heart defect. Based on the estimated number of additional newborns screened (see Table 2), DPH estimated that 5 to 9 additional infants per year are expected to have a false positive screening. However, there is going to be a learning curve and an increased number of false positives initially for those medical facilities, birthing centers, and providers who are currently screening but not using the correct screening protocol and for those who will start screening as a result of the rules, . Therefore, the analysis assumes 9 false positive screenings per year for each of 10 years presented. In total, this would be an estimate of 13 to 16 babies per year with positive CCHD screenings that would need diagnostic evaluations as a result from implementation of the rules. New Jersey detected 30 infants (out of a total of 73,000 infants screened) who had a diagnostic evaluation done as a result of a positive or failed CCHD screening and found 3 of those infants with CCHD.[43] As mentioned above, some infants with CCHD would be picked up because of other reasons, such as a prenatal ultrasound, symptoms, etc.

Based on the Peterson 2013 cost-effectiveness study, a diagnostic evaluation entails the use of a neonatal echocardiogram, which includes a technician doing the echocardiogram and then consultation with a specially trained health care provider with expertise in reading such echocardiograms (ideally a pediatric cardiologist), in an inpatient or outpatient hospital setting, shortly after the positive CCHD screening result was obtained.[44] In addition, the Peterson study estimated that 43% of babies with positive CCHD screenings would also require transport for an echocardiogram or for treatment of the CCHD to a hospital setting. The cost of the evaluation (echocardiogram and transport in 43% of babies for an echocardiogram and/or treatment) in the Peterson study was then averaged across all newborns screened. That cost was estimated to be under $0.50 per infant screened according to a recent conversation with Dr. Scott Grosse, the expert from CDC and one of the authors to the study. This is a conservative estimate because in reality, several newborns with a positive CCHD screening will be found to have another cause for the positive screening and may not need an echocardiogram. In addition, the use of telemedicine was not explicitly addressed in the Peterson study, but it can be inferred that its use should decrease the use of transports and decrease costs.

To determine this per infant cost, the Peterson 2013 study used a cost estimate for an echocardiogram based on market scan commercial reimbursement rates from 2011 of $206 to $236, depending on whether there was a positive or negative diagnosis of CCHD. [45] These estimates adjusted to 2014 using inflation

[42] Kemper, A., Mahle, W., Martin, G., et al.. (2011). Strategies for Implementing Screening for Critical Congenital Heart Disease. *Pediatrics, 128*(5), E1259-E1267. Retrieved June 1, 2013.

[43] Ibid.

[44] Peterson, C., Grosse, S., Oster, M., et al. (2013). Cost-Effectiveness of Routine Screening for Critical Congenital Heart Disease in US Newborns. *Pediatrics, 132*(3), E595-E603. Retrieved August 6, 2013.

[45] Ibid.

in health care prices yielded $221 and $253 (the analysis assumes these costs would increase over the next 10 years with the rate of inflation in health care prices). Based on the 4 to 7 additional CCHD cases identified as a result of the rule change (see Table 3) and 9 additional false positive screenings, the estimated additional annual cost of evaluations is $3,000 to $5,000.

The study also used the market scan commercial reimbursement rate from 2011 to estimate the cost of transport to a facility for an echocardiogram or treatment, which was $439, [46] or $471 when inflated to 2014 (the analysis assumes this cost would increase over the next 10 years with the rate of inflation in health care prices). DPH also used the Peterson study estimate that 43% of the infants with a positive CCHD screening results to calculate that about 6 to 7 infants could require transport annually. That is an additional about $3,000 to $4,000 for transport costs. The total annual cost for echocardiograms and transport is estimated to be $6,000 to $9,000. This does not factor in that lower costs may results from the use of telemedicine. As stated earlier, the use of telemedicine was not explicitly addressed in the Peterson study but it can be inferred that its use should decrease the use of transports and decrease costs. The cost for the echocardiogram being performed, the professional consultation (even via telemedicine) usually with a pediatric cardiologist, and the transport are able to be billed to Medicaid and other third party payers and can be reimbursed back to hospitals and providers. DPH expects that about 55% of the total cost for the diagnostic evaluations (echocardiogram and transport if needed) would be paid by Medicaid, or $3,000 to $,000 (based on 2012 coverage data from the NC State Center for Health Statistics), and 45%, or $3,000 to $4,000, would be paid by other payers. We would estimate that the number of cases of CCHD is going to remain relatively constant based on the past data from the NC BDMP. This again shows that there is not a significant increase in costs related to the diagnostic costs of infants found to have a positive CCHD screening result using the national screening protocol required in the rules.

iii. Reporting Costs

There are also costs anticipated related to the reporting of data as a result of implementation of the proposed rules. The costs related to collecting and reporting data by medical facilities and health care providers is not recoverable and so these costs are also absorbed by the hospitals, birthing centers and health care providers who are involved in collecting the data related to screening, evaluation and follow-up of positive or abnormal pulse oximetry screenings. Since providers have not been reporting the results of screening and evaluating for the newborns they currently screen for CCHD (about 80% of newborns), the analysis below presents costs related to reporting for all screened newborns (up to 95% of the newborns).

DPH estimates that provides would have to report to the PQCNC detailed screening and evaluation information for up to 60 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 newborns with true positive CCHD screening (this number was assumed to grow with the rate of population growth).

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 into another system. The proposal would require hospitals, other facilities and providers to collect the data specified in the rule (i.e., pulse oximetry screening results, time of screening) about the positive CCHD screenings and then log onto a different online web based system from the metabolic or hearing screening systems to enter the data within seven days of obtaining the positive CCHD screening

[46] Ibid.

result. If we take a conservative estimate of the time for creating a paper log or electronic reporting system entry to report positive results, we can estimate this will take 4.5 minutes of nursing time (half of the time that was estimated to complete the full CCHD screening process in the Peterson 2013 study). Based on salary and compensation data from the Bureau of Labor Statistics, the hourly wage for a registered nurse in NC in 2013 was $28.5 on average, which inflated to 2014 and including benefits would result in a total hourly compensation of $34.85. [47,48] Therefore, the estimated cost per case reported is $2.6 and the analysis assumes this would increase at the rate of inflation.[49] That is an opportunity cost of nursing staff time of up to $850 per year to report the required additional positive CCHD screening data.

Providers would also have to compile quarterly aggregate numbers from EHR or paper logs created to record screening results, denials, and evaluation outcomes. A conservative professional estimate of the time required for all four reports would be 25% of the amount of time required by the nurse to complete the screening itself, or 2 minutes based on of the 9 minutes required for the whole CCHD screening as per the Peterson 2013 cost-effectiveness study. Based on the cost of the hourly compensation of a nurse (see above), this would cost about $1.3 per newborn screened in hospitals. DPH estimates that the cost would be double per newborn for the birthing centers and other providers involved with home deliveries for compiling these quarterly reports. Given that the quarterly reporting is a new requirement, it applies to all screenings, not just additional screening resulting from the rule change; therefore, the annual cost estimates associated with quarterly reports for births in hospitals would be $133,000 to $182,000 and for out of hospital births would be $900 to $1,700.

Within the next ten years, DPH anticipates that CCHD screening data will be able to be collected through the electronic birth certificate in addition to other forms of perinatal and birth data. This will make data collection and entry much easier for medical facilities and providers caring and screening newborns. As a result, this should reduce the burden of time and cost of reporting to medical facilities and providers screening newborns for CCHD as well as for other conditions.

There are also anticipated costs for incorporating this rule change into the NC BDMP surveillance. These would be minimal and would be considered opportunity costs, due to the use of existing staff time, since no additional staff will focus on data collection or analysis. Data collection on CCHD will be included the chart abstraction process which is carried out for all other birth defects, but there will be additional data collected on positive screening assured by required reporting.

The main cost for BDMP field staff will be with the additional time required to follow-up with hospital staff to obtain the infant's name and medical record number for each positive screen that is reported, and the time required to review any additional charts that are not already in the BDMP clinical database. The latter cost will be depend primarily on the false positive rate for pulse oximetry screening, as this would involve charts that most likely would not have been reviewed if no other evidence of a birth defect was found for those infants. Typically, it takes an average of about 15 minutes to review a medical record and rule out a birth defect diagnosis, and with an expected false positive rate of 0.05% this would add up to 270 charts to the 12,000 charts already reviewed annually by BDMP field staff, and result in an annual opportunity cost of staff time of up to $1,800, based on staff's hourly total compensation of about $26.

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[47] Bureau of Labor Statistics. May 2013 State Occupational Employment and Wage Estimates: North Carolina. http://www.bls.gov/oes/current/oes_nc.htm

[48] Bureau of Labor Statistics. "Employment Cost Index Historical Listing – Volume III." July 2014. http://www.bls.gov/web/eci/echistrynaics.pdf

[49] IHS Global Insight U.S. Regional Database. Consumer Price Index, North Carolina, 30-year State Forecast.

The other opportunity cost to the NC BDMP will be evaluating the screening program performance which includes reviewing quarterly reports which will require evaluation and compilation of true positives and false positives in order to determine screening sensitivity, specificity, and positive predictive value across the state. This will be done quarterly and annually, and should require no more that about 6-8 hours of a statistician's time to complete per year. This would result in an opportunity cost of $98/hour and up to a total of $800. There will be additional time of up to 14 hours of the NC BDMP director time to review quarterly reports, review the surveillance, and work with partners across the state to assess need for improved screening techniques due to high false positives and outreach to increase screening with hospitals and providers who are not submitting data, which is estimated to be another $1,370. Overall, DPH estimates that the annual opportunity cost related to NC BDMP staff time would be about $4,000.

Additionally, there are costs related to reporting related to the development of an online reporting system for the positive CCHD screening results and aggregate quarterly reports from medical facilities and providers caring for newborns and infants outside of medical facilities. PQCNC has developed an online CCHD database to collect data related to positive screenings, evaluations and follow-up information to report to the NC BDMP. PQCNC is also collecting online aggregate data reports from medical facilities and health care providers related to CCHD screening, evaluation and follow-up quarterly and making this information available to the NC BDMP by 30 days after the end of each quarter. DPH is providing $50,000 to assist with development and implementation of the online database for CCHD data during FY 2015. The Maternal and Child Health Block Grant funding is being used from DPH and this funding is not guaranteed to be available after FY 2015. As a result, the $50,000 is not included as part of the budget in subsequent years. As a result, PQCNC would provide in kind support for additional annual costs related to the maintenance of the system. DPH does not have information to estimate these costs.

There is also going to be cost related to efforts to help with outreach about screening and about improving the quality of screenings being done as a result of having these rules. The Perinatal Quality Collaborative of NC (PQCNC), a non-profit organization, is helping with outreach to hospitals and other providers who care for newborns about CCHD screening. PQCNC is providing an additional $20,000 in kind support to support a quality improvement learning collaborative during FY2015 with hospitals, birthing centers, and providers involved with births in other locations and to develop the web-based CCHD database. The quality improvement efforts will be offered free of charge to all medical facilities and providers involved with screening newborns for CCHD to help increase the numbers of newborns being screened and to improve the quality of CCHD screening, evaluation, follow-up and reporting. This funding from PQCNC is also not guaranteed to be available after FY2015. The one learning collaborative session may run into the very early part of FY 2016 since the collaborative is anticipated to begin in January and run for six months.

Table 4 provides a summary of the estimated costs related to screening additional newborns, evaluating and following up with those with positive screening results, and reporting of data.

Table 4. Estimated Costs (in thousand $)

Item	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Screening additional newborns	***$136***	***$193***	***$272***	***$282***	***$291***	***$301***	***$311***	***$323***	***$334***	***$347***
- Hospitals	$134	$189	$266	$274	$283	$292	$303	$314	$325	$337
- Other providers	$2	$4	$6	$8	$8	$8	$9	$9	$9	$10
Additional Diagnostic Evaluations	***$6***	***$6***	***$7***	***$8***	***$8***	***$8***	***$8***	***$8***	***$9***	***$9***
- Medicaid	$3	$3	$4	$4	$4	$4	$5	$5	$5	$5
- Other payers	$3	$3	$3	$3	$4	$4	$4	$4	$4	$4
Reporting Costs	***$208***	***$146***	***$155***	***$159***	***$164***	***$168***	***$173***	***$178***	***$183***	***$189***
- Providers	$134	$142	$152	$156	$160	$164	$169	$174	$179	$185
- State	$54	$4	$4	$4	$4	$4	$4	$4	$4	$4
- PQCNC	$20									
Total Costs	**$350**	**$345**	**$435**	**$449**	**$463**	**$477**	**$493**	**$509**	**$526**	**$544**
NPV of Costs*	**$3,140**									

** The figure represents the 10-year net present value (NPV) of costs as of July 1, 2014 using a 7% discount rate.*

IV. Assumptions and Uncertainties

DPH made several assumptions in the analysis that may affect the estimated costs and benefits if they were not to hold. One underlying assumption was that the proposed requirement would result in an additional 15% of newborns (or a total of 95% of all births) screened within two years as a result of the full implementation of the CCHD screening rules. If the rules would lead to a maximum of 8% additional newborns screened, then the 10-year NPV of costs would fall to about $2.2 million from $3.1 million and benefits would fall to $7.3 million from $7.8.

DPH also assumed that the 15% additional screening would ideally include births in freestanding birthing centers since there are mainly two birthing centers that are active in NC, and one is screening already. However, it is difficult to determine how quickly screening for CCHD would start for the approximately 500 births per year that have intentionally occurred in homes (2011 data from the NC State Center for Health Statistics) since many different providers across the state assist these births. The births in other locations outside of hospitals and birthing centers make up a very small percentage (a total of less than 1% according to the NC SCHS); therefore, it is unlikely that the assumptions regarding amount of screening of such births would vary the end estimates significantly. Nevertheless, the agency will continue to make all efforts to do outreach to these families and the providers who care for these infants in order to get as many infants screened for CCHD as possible.

The largest portion of the estimated benefits relates to the averting deaths due to earlier detection of CCHD. The analysis made a conservative assumption that the rules would only prevent one death. The estimated benefits would almost double if two cases were to be averted in the next 10 years. If the rule

would not result in any cases averted, however, the NPV of the estimated benefits would be as low as $1.3 million.

The analysis additionally assumed up to 7 cases per year would be detected earlier. This may be slightly underestimating the impact from the rules since the proposed procedures for evaluation and follow-up, which follow national recommendations, may themselves detect additional cases earlier. If up to 8 cases were detected earlier once screening reached 95% of the newborn population, the NPV of the estimated benefits could reach close to $8 million.

In the process of determining the cost of the diagnostic evaluation, the Peterson 2013 study determined that the market value cost of an echocardiogram would vary according to whether the diagnosis was CCHD or not CCHD. The Peterson study performed sensitivity analysis of a range of costs for the echocardiogram and for transportation. Table 5 below shows how the 10-year net present value estimated in this analysis would vary if the costs for the echocardiogram and transportation varied as use in the Petereson sensitivity analysis. Since the cost of the follow-up evaluation is a small percentage of the total estimated cost, there is little fluctuation in the total cost estimate as a result of changes to echocardiogram and transportation costs.

Table 5. Sensitivity of the 10-Year NPV of Costs Estimate to Changes in Evaluation Costs (thou. $)

		Transportation Cost					
		$16	*$200*	***$439***	*$800*	*$1,000*	*$1,582*
Echo-cardiogram Cost	*$65*	$3,094	$3,104	$3,118	$3,138	$3,149	$3,182
	$83	$3,096	$3,106	$3,120	$3,140	$3,152	$3,184
	$206	$3,112	$3,122	$3,136	$3,156	$3,167	$3,200
	$236	$3,116	$3,126	**$3,140**	$3,160	$3,171	$3,204
	$976	$3,211	$3,221	$3,235	$3,255	$3,266	$3,299
	$1,084	$3,225	$3,235	$3,249	$3,269	$3,280	$3,313

It is not clear whether the study factored in the use of telemedicine; that could change the total cost for the technical component of the echocardiogram and also lower the transportation costs due to not having to transport the infant to a facility capable of performing the evaluation. In addition, about 60 positive CCHD screenings are estimated to be false positives which will be found to have non-cardiac causes and not need an echocardiogram.

While telemedicine and infants with false positives not needing echocardiograms may drive down the estimate for evaluations, it is possible that the estimate may be underestimating the impact. Although not all providers currently use the evaluation protocol proposed in the rules, DPH did not include in this analysis the cost of evaluations due to positive results of the 80% of newborns who providers currently screened regardless of the proposed rule. If DPH were to include those evaluations in the impact of the rule change, the NPV of the cost would increase from $3.1 million to close to $4 million.

The cost estimated for quarterly data reporting may be overestimating the impact from the rules. DPH assumed conservatively that it would take 2 minutes per screening performed to compile the 4 quarterly reports. If it took only half that time, the NPV of costs would decrease from $3.1 million to $2.5 million. If however it took providers 1 minute per screening for each of the quarterly reports, or 4 minutes per screening, the costs would increase to $4 million.

There is a probability that the cost to state government for the NC BDMP staff would be reduced since several of the 270 infants with positive screening results would be already captured through reporting of birth defects by hospitals and providers.

There is a probability that the cost of reporting CCHD related data would also be lowered if it were to be reported on the electronic birth certificate. However, the ability for this to happen and the timeframe for it to occur is not known. Therefore, the agency assumed that reporting would occur as described in the section above.

It is unclear if there would be any impact on local governments as a result of this rule change. If for some reason the provider does not screen the newborn or there is no documentation for the screening, it is possible that local health departments may need to screen that infant, which would result in an additional opportunity cost for the health departments. Given all the uncertainties, it is impossible to estimate what that impact may be; however, the agency does not expect this to be significant.

V. Alternatives

Given the well-defined statutory mandate, the agency had little leeway in drafting the proposed rules, mostly limited to the screening and evaluation protocols and the methods of reporting the CCHD data. The agency considered the following alternative options for reporting of CCHD related data and a screening protocol but dismissed them because of the reasons described below.

1. **Report CCHD Screening Results Using Existing Newborn Screening Program Information and Reporting Systems**
   The Early Hearing Detection Intervention (EHDI) program has a reporting system called Hearing Link, which does not have the capabilities to take on the CCHD screening program. The addition of CCHD screening would require IT system changes that would take a significant amount of funds not available to DPH. In addition, the State Laboratory for Public Health has reporting information system about screening results called STAR Lims. This system also does not have the capabilities to add reporting for the CCHD screening program. The addition of reporting of CCHD screening would also require IT changes that would also take a significant amount of funds not available to DPH. No money has been appropriated for reporting related to CCHD screening to DPH. The Expert Panel recommended that medical facilities and health care providers have one way to submit CCHD data via an online CCHD database to submit positive CCHD screening results and quarterly aggregate data related to births and CCHD screenings.

2. **Use of a Different CCHD Screening Protocol**
   A CCHD screening protocol could have been developed that was specific to NC, which was done in many other states. The Expert Panel considered this and decided it would make the most sense to use the same screening protocol as the nationally recommended AAP/AHA protocol. A different or revised NC screening protocol would have caused confusion about medical facilities and health care providers who are already screening using the national protocol. It would also cost more time to retrain staff. In addition, when changes are made to the national protocol the NC rules allow the protocol to adjust as evidence-based processes are recommended for pulse oximetry screening.

In the absence of the mandate, the agency considered three other alternatives to the proposed rules but dismissed them based on the concerns discussed below:

1. No Rules for Screening for CCHD of Every Neonate Born in NC

One alternative to mandated screening is the status quo, in which large, metropolitan birthing hospitals are likely to practice screening while smaller hospitals, birthing centers and attending providers at in-home births and other locations are less likely to screen without a mandate. The adoption of screening for CCHD as a standard of care is voluntary, but the average time for adoption of a standard of care into clinical practice can be as long as 10 years. As a result, even though many hospitals and providers could be screening, it could take several more years before all of the babies born in hospitals, birthing centers, homes and other locations would be screened. In addition, without rules that require the AAP/AHA screening protocol, medical facilities and providers could perform screening that did not follow the recommended standardized protocol and would not be as effective at identifying those with CCHD.

Smaller rural hospitals face several barriers in screening all newborns such as having: the trained staff who can perform a neonatal echocardiogram (ECHO), having the proper equipment to do a pediatric ECHO, having telemedicine capabilities or another way to have a pediatric cardiologist read the ECHO, and having the ability to transfer infants so that a pediatric cardiologist can evaluate them based on the ECHO or not having the ECHO because of an abnormal screening. Small hospitals are unlikely to address these barriers adequately without the requirement for universal screening. We know that infants born in smaller, rural hospitals (without NICUs) are much more likely to have late diagnoses of CCHD. In NC, 38.6% of infants are delivered at a hospital with only a level I or II nursery based on a study the NC BDMP performed on infants with CCHD born between the years 2005-2009.[50] Consequently, the proposed rule change would have a higher cost-effectiveness than the current policy of hospitals self-selecting in rural areas. The implementation of the universal hearing screening has shown that it takes much longer for hospitals and other providers to get on board with screening without a legislative mandate.[51]

The status quo relies on a clinical exam after birth by a health care provider and on the results of a screening prenatal ultrasound, if one was performed. Neither is sensitive enough for screening for CCHD.[52] Prenatal ultrasound in NC detect an estimated 46% of cases of CCHD, based on unpublished data from Duke University communicated to DPH by Dr. Walsh, a pediatric cardiologist at Wake Forest University. In addition, mothers do not always choose to receive prenatal care. Among Medicaid births in 2009, 18.5% of mothers did not receive prenatal care and thus would not have received a prenatal ultrasound.[53]

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[50] Meyer, R. (2012). Running the Numbers: Critical Congenital Heart Defects in North Carolina. *NC Med J, 73*(6), 504-508. Retrieved June 1, 2013.

[51] Green, D., Gaffney, M., Devine, O., & Grosse, S. (2007). Determining the Effect of Newborn

Hearing Screening Legislation: An Analysis of State Hearing Screening Rates. *Public Health Reports, 122*(2), 198-205. Retrieved October 16, 2014.

[52] U.S. Department of Health and Human Services, Maternal and Child Health Bureau. ONLINE.

2010. Maternal and Child Health Bureau. Evidence Review: Critical Congenital Cyanotic Heart Disease. (Subcontract No. SC-07-028). Available: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/nominatecondition/reviews/cyanoticheart.pdf

[53] Community Care of NC. (2011). Module 15: The Pregnancy Medical Home Background: Medicaid coverage of perinatal care and North Carolina statistics. Retrieved on October 16, 2014 at: http://commonwealth.communitycarenc.org/toolkit/15/default.aspx#_ftn2

2. **Prenatal fetal echocardiogram**

As mentioned earlier, prenatal care is not delivered to 18.5% of women who receive Medicaid. In addition, not all women plan for their pregnancy, an estimated 43% of pregnancies are unplanned according to the 2011 NC PRAMS survey, which also contributes to women potentially not receiving prenatal care and hence a prenatal ultrasound. The 2014 NC Women's Health Report Card stated that only 80% of women receive prenatal care in the first trimester.

Even with a prenatal ultrasound, the unpublished Duke University study estimates that prenatal ultrasounds can only detect 46% of CCHD in a fetus. Part of that is because the prenatal ultrasound is done by an obstetric provider who only gets a four chamber view of the heart and that does not evaluate for many forms of CCHD. A fetal echocardiogram is much more detailed, sensitive and has a very high rate of finding CCHD in a fetus. However, fetal echocardiograms must be performed by specially trained providers, who are usually maternal fetal medicine providers. In addition, fetal echocardiograms are not indicated in every pregnancy and only in pregnancies that are high risk. The cost is also much more significant.

Therefore, fetal echocardiograms should not be used as a universal screening test due to limited access to trained providers, especially in the rural parts of our state, and because it is not considered standard of care. It would be a significant and unnecessary burden on the obstetric provider community to required fetal echocardiograms for all women and a significant cost burden to both Medicaid and private insurers. In addition, significantly more ore training would be required to be able to meet the demand for fetal echocardiograms.

3. **Neonatal Echocardiogram Required for Every Infant Born in NC**

A neonatal echocardiogram would also not be appropriate to require on every newborn. Neonatal echocardiograms should be based on clinical exams and history to determine risk. Requiring a neonatal echocardiogram on close to 120,000 infants per year would be a huge burden on the health care system. This option would have very little benefit and a great cost ranging from $200 to $1,000 per newborn.[54] According to the AAP/AHA scientific statement from 2009, "when used as a screening tool, echocardiography has a high frequency of either false positive results (usually related to the transitional circulation) or recognition of clinically benign diagnoses (e.g, small muscular ventricular septal defects). In addition, there may be an inadequate supply of trained personnel who can perform this screening with a reasonable degree of accuracy. Therefore, there is considerable interest in improving the detection of CCHD with novel diagnostic techniques."[55]

[54] Peterson, C., Grosse, S., Oster, M., et al. (2013). Cost-Effectiveness of Routine Screening for Critical Congenital Heart Disease in US Newborns. *Pediatrics, 132*(3), E595-E603. Retrieved August 6, 2013.

[55] Mahle, W.T., Newburger, J.W., Matherne, J.P., et al. (2009) Role of Pulse Oximetry in Examining Newborns for Congenital Heart Disease: A Scientific Statement from the AHA and AAP. *Pediatrics. 124*(183). 823-835. Retrieved October 14, 2014.

APPENDIX A

PROPOSED PERMANENT RULES

10A NCA 43K .0101 is proposed for adoption as follows:

CHAPTER 43 – PERSONAL HEALTH

SUBCHAPTER 43K – NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DEFECTS

10A NCAC 43K .0101 DEFINITIONS

As used in this Section:

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

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

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

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

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

(6) "Positive screening" means the final result is a failed or abnormal pulse oximetry screening for critical congenital heart defects for a neonate or infant using a screening protocol based on the most current American Academy of Pediatrics and American Heart Association (AAP/AHA) recommendations. This includes neonates or infants who have not yet been confirmed to have critical congenital heart defects or have other conditions to explain abnormal pulse oximetry results. A copy of the recommendations is available for inspection at the NC Division of Public Health, Women's and Children's Health Section, Children and Youth Branch, 5601 Six Forks Road, Raleigh, NC 27609. In addition, the recommendations can be accessed at the American Academy of Pediatrics website at:

http://pediatrics.aappublications.org/content/128/5/e1259.full.pdf+html?sid=85e81711-f9b8-43d1-a352-479168895a72.

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

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

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

10A NCA 43K .0102 is proposed for adoption as follows:

10A NCAC 43K .0102 SCREENING REQUIREMENTS

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

(1) Screening of every neonate for critical congenital heart defects (CCHD) using pulse oximetry shall be performed at 24 to 48 hours of age using a 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 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 approved pulse oximetry equipment is used and maintained to screen the neonate or infant for the presence of critical congenital heart defects.

(b) Parents or guardians may object to the critical congenital heart defects screening at any time before the screening is performed in accordance with G.S. 130A-125.

(c) All medical facilities and attending providers of the neonate or infant shall have and implement a written plan for evaluation and follow up of positive critical congenital heart defect screenings.

(1) Evaluation and follow up of a positive screening for all neonates shall be in accordance with the most current published recommendations from the American Academy of Pediatrics and American Heart Association (AAP/AHA) which is incorporated by reference including subsequent amendments and editions. A copy of the recommendations is available for inspection at the NC Division of Public Health, Women's and Children's Health Section, Children and Youth Branch, 5601 Six Forks Road, Raleigh, NC 27609. In addition, the recommendations can be accessed at the American Academy of Pediatrics website at: http://pediatrics.aappublications.org/content/128/5/e1259.full.pdf+html?sid=85e81711-f9b8-43d1-a352-479168895a72.

(2) For neonates with positive screenings who are born in a birthing facility, a home, or other location, the AAP/AHA recommended evaluation and follow up shall occur as soon as possible but no later than 24 hours after obtaining the positive screening result.

(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 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;*

10A NCA 43K .0103 is proposed for adoption as follows:

10A NCAC 43K .0103 REPORTING REQUIREMENTS

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

(1) date and time of birth of the neonate or infant, gestational age, and the medical facility or birth location, and

(2) age in hours at time of screening; all pulse oximetry saturation values, including initial, subsequent, and final screening results; final diagnosis if known; any known interventions and treatment, and any need for transport or transfer; and the location of the transfer or transport if known.

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

(c) All medical facilities and attending providers of neonates or infants performing critical congenital heart defect screening shall report aggregate information described below quarterly and no later than 15 days after the end of each quarter of the state fiscal year to the Perinatal Quality Collaborative of North Carolina (PQCNC).

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

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

(1) live births;

(2) neonates and infants who were screened;

(3) negative screenings;

(4) positive screenings;

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

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

(7) neonates and infants not screened and the reasons if known, which include a diagnostic echocardiogram being performed after birth and prior to discharge; transfer out of the medical facility before screening; or death.

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

APPENDIX B
SESSION LAW 2013-45

"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.**"**