

**GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2013**

**SESSION LAW 2013-45
SENATE BILL 98**

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

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

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

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

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

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

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

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

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

The General Assembly of North Carolina enacts:

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

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

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

- (1) Development and distribution of educational materials regarding the availability and benefits of newborn screening.
- (2) Provision of laboratory testing.
- (3) Development of follow-up protocols to assure early treatment for identified children, and the provision of genetic counseling and support services for the families of identified children.
- (4) Provision of necessary dietary treatment products or medications for identified children as medically indicated and when not otherwise available.
- (5) For each newborn, provision of physiological screening in each ear for the presence of permanent hearing loss.
- (6) For each newborn, provision of pulse oximetry screening to detect congenital heart defects.

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



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

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

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

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

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

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

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

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

s/ Daniel J. Forest
President of the Senate

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

s/ Pat McCrory
Governor

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