

GENERAL ASSEMBLY OF NORTH CAROLINA  
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SENATE DRS75051-MG-13C\* (10/26)

Short Title: Require Pulse Oximetry Newborn Screening. (Public)

Sponsors: Senators Brock, Pate, and Stein (Primary Sponsors).

Referred to:

1 A BILL TO BE ENTITLED  
2 AN ACT TO EXPAND THE NEWBORN SCREENING PROGRAM ESTABLISHED BY  
3 THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO INCLUDE  
4 NEWBORN SCREENING FOR CONGENITAL HEART DISEASE UTILIZING PULSE  
5 OXIMETRY, AS RECOMMENDED BY THE NORTH CAROLINA CHILD FATALITY  
6 TASK FORCE.

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

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

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

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

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

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

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

22 Whereas, in September 2011, the Secretary of the United States Department of  
23 Health and Human Services approved adding screening for CCHDs to the Recommended  
24 Uniform Screening Panel upon the recommendation of the Secretary's Advisory Committee on  
25 Heritable Disorders in Newborns and Children; Now, therefore,  
26 The General Assembly of North Carolina enacts:

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

28 "**§ 130A-125. Screening of newborns for metabolic and other hereditary and congenital**  
29 **disorders.**

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

32 (1) Development and distribution of educational materials regarding the  
33 availability and benefits of newborn screening.

34 (2) Provision of laboratory testing.



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1 (3) Development of follow-up protocols to assure early treatment for identified  
2 children, and the provision of genetic counseling and support services for the  
3 families of identified children.

4 (4) Provision of necessary dietary treatment products or medications for  
5 identified children as medically indicated and when not otherwise available.

6 (5) For each newborn, provision of physiological screening in each ear for the  
7 presence of permanent hearing loss.

8 (6) For each newborn, provision of pulse oximetry screening to detect  
9 congenital heart defects.

10 (b) The Commission shall adopt rules necessary to implement the Newborn Screening  
11 Program. The rules shall include, but shall not be limited to, the conditions for which screening  
12 shall be required, provided that screening shall not be required when the parents or the guardian  
13 of the infant object to such screening. If the parents or guardian object to the screening, the  
14 objection shall be presented in writing to the physician or other person responsible for  
15 administering the test, who shall place the written objection in the infant's medical record.

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

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

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

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

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

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