

§ 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 is required. The Commission shall amend the rules as necessary to ensure that each condition listed on the Recommended Uniform Screening Panel developed by the Secretary of the United States Department of Health and Human Services and the Advisory Committee on Heritable Disorders of Newborns and Children (the RUSP) is included in the Newborn Screening Program within three years after being added to the RUSP, except that the Commission is exempt from rule making with respect to adding screening tests for Pompe disease, Mucopolysaccharidosis Type I (MPS I), and X-Linked Adrenoleukodystrophy (X-ALD). The Department of Health and Human Services shall provide a report to the Joint Legislative Oversight Committee on Health and Human Services 18 months after a condition is added to the RUSP. When a delay adding an RUSP-identified condition to the Newborn Screening Program exceeds three years, the Department shall provide a report on the status and reasons for the delay to the Joint Legislative Oversight Committee on Health and Human Services every six months following the three-year delay.

Screening is not 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 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 one hundred twenty-eight dollars (\$128.00) 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. The Commission may by rule, and in consultation with the Secretary, increase this fee by no more than the amount necessary to offset the cost of incorporating a condition listed on the RUSP into the Newborn Screening Program. The Commission shall by rule decrease this fee when it determines, in consultation with the Secretary, that current and anticipated fee receipts will exceed current and anticipated recurring operating costs of the Newborn Screening Program by more than ten percent (10%).

(d) The Newborn Screening Equipment Replacement and Acquisition Fund (Fund) is established as a nonreverting fund within the Department. Thirty-one dollars (\$31.00) of each fee collected pursuant to subsection (c) of this section shall be credited to this Fund and applied to the Newborn Screening Program to be used as directed in this subsection. The Department shall not use monies in this Fund for any purpose other than to purchase or replace laboratory instruments, equipment, and information technology systems used in the Newborn Screening Program. The Department shall notify and consult with the Joint Legislative Commission on Governmental Operations whenever the balance in the Fund exceeds the following threshold: the sum of (i) the actual cost of new equipment necessary to incorporate conditions listed on the RUSP into the Newborn Screening Program and (ii) one hundred percent (100%) of the replacement value of existing equipment used in the Newborn Screening Program. Any monies in the Fund in excess of this threshold shall be available for expenditure only upon an act of appropriation by the General Assembly.

(e) Annually on March 1, the Department shall report to the House Appropriations Committee on Health and Human Services, the Senate Appropriations Committee on Health and Human Services, and the Fiscal Research Division on the Newborn Screening Program. The report shall include all of the following information for the preceding fiscal year:

- (1) A description of the services funded by the Newborn Screening Program, including a description of the Department's activities with respect to each of the services listed in subsection (a) of this section.
- (2) A detailed budget and list of expenditures for the Newborn Screening Program, including all positions funded.
- (3) Fees and other receipts collected for the Newborn Screening Program.
- (4) Projected fees and other receipts for the Newborn Screening Program for the current and upcoming fiscal year.
- (5) Any condition the Department anticipates will be listed on the RUSP within the current or upcoming fiscal year and a description of the following:
 - a. Any laboratory instruments or equipment the Department will need to purchase in order to perform screening for that condition.
 - b. Any additional positions the Department will need to establish in order to perform screening for that condition.
- (6) The balance in the Newborn Screening Equipment Replacement and Acquisition Fund as of the preceding June 30.
- (7) Amounts credited to the Fund.
- (8) Amounts expended from the Fund and the purposes of the expenditures.
- (9) Proposed expenditures of the monies in the Fund for the current and upcoming fiscal year.
- (10) Any other information the Department deems relevant to maintaining the Newborn Screening Program as a fee-supported program. (1991, c. 661, s. 1; 1991 (Reg. Sess., 1992), c. 1039, s. 6; 1998-131, s. 13; 2000-67, s. 11.31(a); 2005-276, s. 41.1(a); 2007-182, s. 2; 2008-107, s. 29.4(a); 2013-45, s. 1;

2015-241, s. 12E.12(a); 2016-94, s. 12E.5(a); 2018-5, s. 11E.1(a); 2021-180,
s. 9G.6A(a.)