

Chapter 552

(Senate Bill 786)

AN ACT concerning

Health – Newborn Screening Program – Critical Congenital Heart Disease

FOR the purpose of requiring ~~that the Department of Health and Mental Hygiene's Newborn Screening Program include screening for critical congenital heart disease~~ the Department of Health and Mental Hygiene to adopt certain federal recommendations on critical congenital heart disease screening in newborns under certain circumstances; requiring the State Advisory Council on Hereditary and Congenital Disorders to develop certain recommendations for critical congenital heart disease screening of newborns in the State; requiring the Advisory Council to convene certain experts to provide certain information; requiring the Advisory Council to examine the impact of implementing mandatory critical congenital heart disease screening; requiring the Advisory Council to review certain studies and literature; requiring the Advisory Council to submit a certain report to certain committees of the General Assembly on or before a certain date; and generally relating to the State Advisory Council on Hereditary and Congenital Disorders and newborn screening for critical congenital heart disease.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 13–111
Annotated Code of Maryland
(2009 Replacement Volume and 2010 Supplement)

Preamble

WHEREAS, Congenital heart disease is the most common birth defect and affects approximately eight out of every 1,000 infants each year; and

WHEREAS, More than 36,000 infants are born with congenital heart disease each year in the United States; and

WHEREAS, Congenital heart disease is the leading cause of death for infants born with a birth defect despite survival rates now approaching 96% for all affected children; and

WHEREAS, A major cause of infant mortality as a result of congenital heart disease is that a significant number of children affected are not detected as having heart disease in the newborn nursery; and

WHEREAS, An effective newborn screening mechanism for congenital heart disease before newborns leave the nursery can reduce infant mortality; and

WHEREAS, Pulse oximetry has been shown to be an effective screening test to detect congenital heart disease before infants leave the newborn nursery; and

WHEREAS, Children's National Medical Center has worked with Holy Cross Hospital to become leaders in the implementation of pulse oximetry screening in community nurseries; and

WHEREAS, The Secretary of Health and Human Services' Advisory Committee for Heritable Disorders in Newborns and Children recommended the addition of screening for critical cyanotic congenital heart disease to the core panel for universal screening of all newborns in the United States; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

13–111.

(a) The Department shall establish a coordinated statewide system for screening all newborn infants in the State for certain hereditary and congenital disorders associated with severe problems of health or development, except when the parent or guardian of the newborn infant objects.

(b) Except as provided in § 13–112 of this subtitle, the Department's public health laboratory is the sole laboratory authorized to perform tests on specimens from newborn infants collected to screen for hereditary and congenital disorders as determined under subsection (d)(2) of this section.

(c) The system for newborn screening shall include:

(1) Laboratory testing and the reporting of test results; ~~and~~

(2) Follow-up activities to facilitate the rapid identification and treatment of an affected child; ~~AND~~

~~(3) SCREENING FOR CRITICAL CONGENITAL HEART DISEASE.~~

(d) In consultation with the State Advisory Council on Hereditary and Congenital Disorders, the Department shall:

- (1) Establish protocols for a health care provider to obtain and deliver test specimens to the Department's public health laboratory;
- (2) Determine the screening tests that the Department's public health laboratory is required to perform;
- (3) Maintain a coordinated statewide system for newborn screening that carries out the purpose described in subsection (c) of this section that includes:
 - (i) Communicating the results of screening tests to the health care provider of the newborn infant;
 - (ii) Locating newborn infants with abnormal test results;
 - (iii) Sharing newborn screening information between hospitals, health care providers, treatment centers, and laboratory personnel; and
 - (iv) Delivering needed clinical, diagnostic, and treatment information to health care providers, parents, and caregivers; and
- (4) Adopt regulations that set forth the standards and requirements for newborn screening for hereditary and congenital disorders that are required under this subtitle, including:
 - (i) Performing newborn screening tests;
 - (ii) Coordinating the reporting, follow-up, and treatment activities with parents, caregivers, and health care providers; and
 - (iii) Establishing fees for newborn screening that do not exceed an amount sufficient to cover the administrative, laboratory, and follow-up costs associated with the performance of screening tests under this subtitle.

(E) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, IF THE SECRETARY OF HEALTH AND HUMAN SERVICES ISSUES FEDERAL RECOMMENDATIONS ON CRITICAL CONGENITAL HEART DISEASE SCREENING OF NEWBORNS, THE DEPARTMENT SHALL ADOPT THE FEDERAL SCREENING RECOMMENDATIONS.

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The State Advisory Council on Hereditary and Congenital Disorders shall develop recommendations on the implementation of critical congenital heart disease screening of newborns in the State in accordance with this section.

(b) The Advisory Council shall:

(1) convene experts from the State's academic medical centers and any other hospital that the Advisory Council considers appropriate, as well as other State organizations and professional groups, to provide information for the development of recommendations for critical congenital heart disease screening of newborns in the State;

(2) examine the impact of implementing mandatory critical congenital heart disease screening, including an examination of costs, insurance reimbursement, necessary medical equipment and staff training, screening protocols and quality oversight, and risk of harm; and

(3) review medical and public health studies and literature across a broad range of newborn delivery systems with respect to critical congenital heart disease screening of newborns.

(c) On or before December 31, 2011, the Advisory Council shall submit its findings and recommendations on the implementation of critical congenital heart disease screening of newborns in a report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2-1246 of the State Government Article.

(d) Notwithstanding any recommendation developed by the Advisory Council under this section, if the Secretary of Health and Human Services issues federal recommendations on critical congenital heart disease screening of newborns, the Department shall adopt the federal screening recommendations in accordance with § 13-111(e) of the Health – General Article as enacted by this Act.

SECTION ~~2~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2011.

Approved by the Governor, May 19, 2011.