

Chapter 124

(House Bill 827)

AN ACT concerning

**Newborn Infant Screening – Testing by Nonpublic Laboratories – ~~Authorization~~
Notification**

FOR the purpose of ~~authorizing certain laboratories to perform certain screening tests for hereditary and congenital disorders under certain circumstances; authorizing a parent or guardian of a newborn infant to request that a certain laboratory perform certain initial tests to screen for hereditary and congenital disorders; requiring a health care provider to obtain and deliver certain test specimens to screen for hereditary and congenital disorders to certain laboratories under certain circumstances; requiring the Department of Health and Mental Hygiene, in consultation with a certain council, to establish protocols for health care providers to obtain and deliver certain test specimens to certain laboratories; requiring that the coordinated statewide system for newborn screening that the Department of Health and Mental Hygiene is required to maintain include notifying parents and guardians of newborn infants that laboratories other than the Department's public health laboratory are authorized to perform postscreening confirmatory or diagnostic tests on newborn infants for hereditary and congenital disorders; and generally relating to newborn infant screening for hereditary and congenital disorders.~~

BY repealing and reenacting, without amendments,

Article – Health – General
Section 13–111(a) through (c)
Annotated Code of Maryland
(2015 Replacement Volume)

BY repealing and reenacting, with amendments,

Article – Health – General
Section 13–111(d) ~~and 13–112~~
Annotated Code of Maryland
(2015 Replacement Volume)

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.

(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~~

~~(I) THE Department’s public health laboratory; AND~~

~~(II) OTHER LABORATORIES AUTHORIZED TO PERFORM INITIAL TESTS ON SPECIMENS UNDER § 13–112(B)(1) OF THIS SUBTITLE;~~

(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

(V) NOTIFYING PARENTS AND GUARDIANS OF NEWBORN INFANTS THAT LABORATORIES OTHER THAN THE DEPARTMENT’S PUBLIC HEALTH

LABORATORY ARE AUTHORIZED TO PERFORM POSTSCREENING CONFIRMATORY OR DIAGNOSTIC TESTS ON NEWBORN INFANTS FOR HEREDITARY AND CONGENITAL DISORDERS; 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.

~~13-112.~~

~~(a) The Secretary may contract or delegate the screening required under § 13-111 of this subtitle to another entity with the approval of the State Advisory Council on Hereditary and Congenital Disorders.~~

~~(b) Subject to subsection (e) of this section, a laboratory other than the Department's public health laboratory may [perform].~~

~~(1) AT THE REQUEST OF THE PARENT OR GUARDIAN OF A NEWBORN INFANT, PERFORM THE INITIAL TESTS ON SPECIMENS COLLECTED TO SCREEN FOR HEREDITARY AND CONGENITAL DISORDERS, INCLUDING THE TESTS THE DEPARTMENT'S PUBLIC HEALTH LABORATORY OTHERWISE WOULD PERFORM UNDER § 13-111 OF THIS SUBTITLE; AND~~

~~(2) PERFORM postscreening confirmatory or diagnostic tests on newborn infants for hereditary and congenital disorders.~~

~~(c) Before offering or performing a SCREENING OR postscreening test on a newborn infant for hereditary and congenital disorders under subsection (b) of this section, a laboratory shall:~~

~~(1) Obtain and maintain a license issued by the Secretary as required by Title 17 of this article; and~~

~~(2) Meet all the standards and requirements for a laboratory to perform tests on newborn infants for hereditary and congenital disorders that are established by the Secretary.~~

~~(D) (1) A PARENT OR GUARDIAN OF A NEWBORN INFANT MAY REQUEST THAT A LABORATORY OTHER THAN THE DEPARTMENT'S PUBLIC HEALTH LABORATORY PERFORM THE INITIAL TESTS ON SPECIMENS COLLECTED TO SCREEN FOR HEREDITARY AND CONGENITAL DISORDERS, INCLUDING THE TESTS THE DEPARTMENT'S PUBLIC HEALTH LABORATORY OTHERWISE WOULD PERFORM UNDER § 13-111 OF THIS SUBTITLE.~~

~~(2) AT THE REQUEST OF THE PARENT OR GUARDIAN OF A NEWBORN INFANT, A HEALTH CARE PROVIDER SHALL OBTAIN AND DELIVER TEST SPECIMENS COLLECTED FROM THE NEWBORN INFANT TO SCREEN FOR HEREDITARY AND CONGENITAL DISORDERS TO A LABORATORY:~~

~~(I) AUTHORIZED TO PERFORM INITIAL SCREENING TESTS UNDER SUBSECTION (B)(1) OF THIS SECTION; AND~~

~~(II) SELECTED BY THE PARENT OR GUARDIAN TO PERFORM THE SCREENING TESTS.~~

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2016.

Approved by the Governor, April 12, 2016.