

Department of Legislative Services
Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 827

(Delegate O'Donnell)

Health and Government Operations

Finance

Newborn Infant Screening - Testing by Nonpublic Laboratories - Notification

This bill requires the Department of Health and Mental Hygiene's (DHMH's) Newborn Screening Program to notify parents and guardians of newborn infants that laboratories – other than DHMH's public health laboratory – are authorized to perform postscreening confirmatory or diagnostic tests on newborn infants for hereditary and congenital disorders.

Fiscal Summary

State Effect: DHMH can provide the required notice with existing budgeted resources and staff. Revenues are not affected.

Local Effect: None.

Small Business Effect: Potential minimal to the extent testing opportunities for commercial or private laboratories in the State that are small businesses increase.

Analysis

Current Law/Background: DHMH's Newborn Screening Program is a statewide system for screening all newborn infants in Maryland for certain hereditary and congenital disorders associated with severe problems of health or development (except when the parent or guardian of the newborn objects). The program was codified and centralized by Chapter 256 of 2008, which established the DHMH public health laboratory as the sole laboratory in Maryland allowed to perform the screening tests. The system for newborn screening includes laboratory testing, reporting of test results, and follow-up activities to facilitate the rapid identification and treatment of an affected child. The laboratory is required to screen for 53 first-tier metabolic hereditary disorders on all screening

specimens collected. These disorders are listed in the Code of Maryland Regulations (10.10.13.12). Second-tier tests can only be performed when requested by an individual authorized to request a medical laboratory test.

A laboratory other than the public health laboratory may perform postscreening confirmatory or diagnostic tests on newborn infants for hereditary and congenital disorders if the laboratory obtains and maintains a license and meets all the standards and requirements for a laboratory to perform such tests as established by the Secretary of Health and Mental Hygiene.

The Laboratories Administration has regulatory authority under § 13-111 of the Health-General Article to establish fees for newborn screening that do not exceed the administrative, laboratory, and follow-up costs associated with newborn screening testing in the State.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, Department of Legislative Services

Fiscal Note History: First Reader - February 21, 2016
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