

Department of Legislative Services
Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 827 (Delegate O'Donnell)
Health and Government Operations

Newborn Infant Screening - Testing by Nonpublic Laboratories - Authorization

This bill authorizes a qualified laboratory, at the request of the parent or guardian of a newborn, to perform the initial tests on specimens collected to screen for hereditary and congenital disorders that would otherwise be performed by the Department of Health and Mental Hygiene's (DHMH's) public health laboratory. A parent or guardian may request that a laboratory other than the public health laboratory perform these tests. Thus, at the parent or guardian's request, a health care provider must obtain and deliver test specimens collected from the newborn infant to screen for hereditary and congenital disorders to the authorized laboratory that is selected by the parent or guardian.

Fiscal Summary

State Effect: Significant operational impact on DHMH's Laboratories Administration. Special fund revenues to the Newborn Screening Fund within DHMH decline by an indeterminate amount beginning in FY 2017, while special fund expenditures are maintained for some screening tests that are performed without charge, as discussed below.

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.

State Fiscal Effect:

Significant Operational Impact: Prior to 2008, commercial and private clinical laboratories were authorized to perform hereditary and congenital screening for newborn infants in the State. DHMH advises that this caused confusion and miscommunication, and resulted in unnecessary testing of specimens that were sent to the Laboratories Administration instead of intended private laboratories. Additionally, use of public and private laboratories complicated follow-up care. The Laboratories Administration anticipates that similar issues may arise under the bill's provisions.

Potential Decrease in Special Fund Revenues: Special fund revenues to the Newborn Screening Fund decline beginning in fiscal 2017, by an indeterminate amount. The Laboratories Administration advises that it currently charges birthing hospitals for both screening and follow-up hereditary and congenital disorder tests at the time of the birth. The Laboratories Administration has a record of the number of samples sent per hospital and charges the hospitals based on this number. The fee, which is set at \$106, covers both the initial screening and follow-up testing. When a newborn goes to a pediatrician's office for the first checkup after birth, the pediatrician sends the follow-up blood sample to the Laboratories Administration and the laboratory processes the specimen free of charge.

The Laboratories Administration cross-checks its records to see whether the specimen is for an initial screening or a follow-up based on whether the laboratory has processed any prior samples for that newborn. Occasionally, a physician sends a specimen for a newborn that did not receive an initial screening from the Laboratories Administration because the newborn was born out-of-state or outside of a birthing hospital. The Laboratories Administration then performs an initial and follow-up screening for that newborn free of charge. Under this process, the Laboratories Administration does perform a small number of tests free of charge. However, since the vast majority of births in the State occur in birthing hospitals, uncompensated tests represent a minimal amount of overall tests.

If the public health laboratory detects an abnormal result, it sometimes retests the sample, which is also performed free of charge. If a conclusive abnormal test result is detected, the Laboratories Administration refers the case for follow-up care.

DHMH anticipates that physicians' offices will continue sending the follow-up testing specimens to the Laboratories Administration, as under current practice, even if the initial screening was performed by a private laboratory. DHMH also anticipates that it will continue to perform these tests without payment. Further, if the Laboratories Administration did not perform the initial screening for the newborn, it will provide both the initial screening and the follow-up test free of charge. The initial screening is a more extensive test than the follow-up test. Thus, DHMH anticipates that it may be required to absorb and conduct a higher number of tests free of charge, which would result in a decrease in special fund revenues for the Newborn Screening Fund. The magnitude of any such decrease depends on the number of parents that choose to utilize a laboratory other than the Laboratories Administration public health laboratory to perform initial and follow-up screening tests. There are approximately 67,000 births in Maryland annually.

Additional Information

Prior Introductions: None.

Cross File: None.

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

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