This bill requires the Maryland Department of Health (MDH) to authorize a person who is qualified to offer or perform laboratory testing in the State, as determined by MDH, to offer and perform laboratory testing for detecting sickle cell disease (SCD) at a “community-based health fair.” A person authorized to perform testing may provide information on and resources for living with SCD while performing testing at a community-based health fair. MDH must adopt regulations to carry out the bill.

Fiscal Summary

State Effect: MDH can adopt regulations using existing budgeted resources. To the extent MDH is required to perform the laboratory testing for SCD that results from community-based health fairs, general fund expenditures increase beginning in FY 2023 for staff and materials, as discussed below. Revenues are not affected.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: “Community-based health fair” means an event that offers health care services to an individual for free or using a sliding fee scale that is sponsored by (1) the federal government, the State, or a local government; (2) a nonprofit organization that is exempt from taxation; or (3) a nonprofit community organization that has the stated purpose of providing public health services to low-income individuals.
**Current Law:** In Maryland, all newborn babies are screened for SCD. MDH advises that the Laboratories Administration, Newborn & Childhood Screening Division provides congenital and hereditary screening for approximately 58 known serious medical disorders. The screening includes sickle cell trait and disease testing and identifies newborns that are “at risk” for potential disorders. Information is also provided on whether additional diagnostic testing is required.

MDH further advises that the Newborn & Childhood Screening Division historically provided testing services for SCD in adults. However, testing for adults ended in December 2018, as the laboratory only received approximately one sample per quarter, and it was no longer cost-effective to continue screening for sickle cell in adults.

Under Maryland regulations (COMAR 10.10.06.12), a person may perform a “health awareness test” at a temporary laboratory (located at a temporary testing site for fewer than 30 days in 12 consecutive months) or mobile laboratory (located in a moveable vehicle) at the request of an examinee. Staff who perform the tests must have training and experience to perform testing that includes (1) operation of the analyzers per manufacturer’s recommendations; (2) evaluation of the results of quality controls; (3) interpretation of the test results; and (4) counseling to the individual whose specimen is tested.

A “health awareness test” means a test approved by the Secretary of Health to be performed at a temporary or mobile laboratory, such as a health fair in a shopping mall, limited to tests that (1) are performed solely for the purpose of screening for certain medical conditions and are not to be used for diagnostic or management of health care conditions; (2) are performed on a specified waived testing device; and (3) measure glucose, lipids, or other clinical values which the Secretary has concluded are in the interest of public health to be measured at a health awareness event.

**State Expenditures:** Under the bill, MDH must authorize a specified person to offer and perform laboratory testing for detecting SCD at a community-based health fair. MDH can adopt regulations to carry out the bill using existing budgeted resources.

MDH is generally the main laboratory to test for SCD in the State; however, private laboratories can test for SCD, and at least one major laboratory provider currently performs such tests. To the extent that MDH must perform the laboratory testing for SCD resulting from community-based health fairs, MDH general fund expenditures increase by an estimated $189,100 in fiscal 2023 to hire one public health laboratory scientist, and by an additional $130,000 for lab equipment, reagents, and supplies.
Additional Information

Prior Introductions: None.

Designated Cross File: SB 883 (Senator Watson) - Finance.

Information Source(s): Maryland Association of County Health Officers; Maryland Municipal League; Department of Budget and Management; Maryland Department of Health; Department of Legislative Services

Fiscal Note History: First Reader - March 4, 2022

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