HB 399

Department of Legislative Services

Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 399 (Delegate Afzali, *et al.*)
Health and Government Operations Finance

Lyme Disease - Laboratory Test - Required Notice

This bill requires a health care provider who draws a patient's blood for a Lyme disease laboratory test or a medical laboratory that performs a Lyme disease test to provide a specified written notice to the patient at the time blood is drawn. The required notice includes disclaimers regarding the accuracy of tests for Lyme disease. A health care provider's or medical laboratory's provision of the required notice may not be the sole basis for a cause of action. The Department of Health and Mental Hygiene (DHMH) may adopt regulations that change the notice's content if DHMH finds significant differences between the notice's content and current medical evidence on Lyme disease testing. DHMH must provide written notice to the Senate Finance Committee and the House Health and Government Operations Committee before submitting any proposed regulations for publication.

Fiscal Summary

State Effect: DHMH can handle the bill's requirements with existing resources. Revenues are not affected.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Current Law/Background: State law currently does not require a health care provider to provide any disclaimers or warnings about laboratory tests for Lyme disease.

DHMH's website advises that Lyme disease is caused by a bacterium transmitted by the bite of an infected tick; not every tick bite causes Lyme disease. Symptoms usually develop from between 3 and 30 days after a tick bite and include a rash, fever, headache, and fatigue. If left untreated, the disease can cause more serious symptoms such as shooting pains and heart palpitations; in up to 5% of untreated cases, individuals may experience neurological symptoms such as problems with concentration and short-term memory. Most cases of Lyme disease are curable with antibiotics.

The University of Maryland Medical Center and Mayo Clinic websites advise that a Lyme disease diagnosis may be confirmed with a blood test, in which a laboratory specialist looks for Lyme disease antibodies in a patient's blood sample. Two such tests are available: ELISA for Lyme disease and Western blot for Lyme disease; these tests are most reliable a few weeks after an infection – after the body has had time to develop antibodies. If the ELISA test (which is used most often to detect Lyme disease) is negative, indicating a "normal" blood sample, then no or only a few antibodies were present in the blood sample and *usually* no other testing is needed. However, what are considered "normal" value ranges vary among different laboratories. Though a positive result on the ELISA test is "abnormal" – meaning antibodies are detected in the sample, it does not *confirm* a diagnosis of Lyme disease; such a diagnosis must be confirmed with the Western blot test (which detects antibodies to several proteins of the bacteria). For some individuals, the ELISA test may still be positive even after undergoing treatment for Lyme disease and the disappearance of symptoms; a positive ELISA test may also occur with certain diseases, such as rheumatoid arthritis.

In 2013, Virginia enacted legislation (Chapter 215 of 2013) that requires every physician who orders a laboratory test for Lyme disease to provide the patient or the patient's legal representative with written information nearly identical to the notice required under the bill.

Additional Information

Prior Introductions: None.

Cross File: SB 926 (Senator Young, *et al.*) - Finance.

Information Source(s): Department of Health and Mental Hygiene, University of Maryland Medical Center, Mayo Clinic, Department of Legislative Services

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Analysis by: Sasika Subramaniam

Direct Inquiries to:
(410) 946-5510
(301) 970-5510