

Department of Legislative Services
 Maryland General Assembly
 2014 Session

FISCAL AND POLICY NOTE

Senate Bill 594 (Senator Astle)
 Finance

Hepatitis C - Opportunity for Testing and Follow-Up Health Care

This bill requires a hospital or health care practitioner to offer (in a culturally and linguistically appropriate manner) a qualifying individual a Hepatitis C screening test or diagnostic test unless certain exceptions apply. If a qualifying individual accepts an offer for a screening test and the screening test is positive, the hospital or health care practitioner must offer follow-up care or refer the individual to a health care provider who can provide follow-up care. Annually, on or before October 1, the Department of Health and Mental Hygiene (DHMH) must report to specified committees on required information.

Fiscal Summary

State Effect: General fund expenditures increase by approximately \$225,000 beginning in FY 2015 for DHMH’s Laboratories Administration and Prevention and Health Promotion Administration (PHPA) to conduct additional laboratory testing and to collect, analyze, and report on the bill’s impact. The estimate includes the cost to hire one full-time epidemiologist and two part-time public health laboratory scientists. Future year expenditures increase to reflect annual increases and employee turnover as well as annual increases in ongoing operating expenses. Since the Laboratories Administration cannot bill patients for the type of tests required in the bill, State revenues are not affected.

(in dollars)	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	255,000	368,600	378,000	387,700	397,800
Net Effect	(\$255,000)	(\$368,600)	(\$378,000)	(\$387,700)	(\$397,800)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: To the extent that local health departments (LHDs) must provide additional testing or follow-up care for patients, costs for LHDs may increase significantly. Revenue is not expected to be materially affected because any additional testing and follow-up care is likely to be heavily subsidized.

Small Business Effect: Minimal.

Analysis

Bill Summary: A qualifying individual includes (1) someone born between the years of 1945 and 1965; (2) a current or former user of an injection drug; (3) the recipient of a blood transfusion, blood product, or organ transplant before 1992; (4) a recipient of a blood clotting product before 1987; (5) an individual who has liver disease or who has had abnormal liver test results; (6) a hemodialysis patient; (7) a health care worker who may be exposed to needle sticks; and (8) an individual who is infected with HIV.

If a qualifying individual accepts an offer of a screening test and the test result is positive, the hospital or health care provider must offer follow-up health care – which must include a diagnostic test. A “Hepatitis C diagnostic test” means a viral RNA laboratory test and allows a health care provider to conclude more specifically whether a person in fact has Hepatitis C.

A hospital or health care provider does not have to offer a qualifying individual a Hepatitis C screening or diagnostic test if the qualifying individual is being treated for a life-threatening emergency, has already been offered or received a screening test, or lacks capacity to consent to the test.

DHMH must collect and analyze information on positive screenings and the number of individuals who have accessed care following a positive report. This information must be included in the required annual report.

Current Law: The Code of Maryland Regulations requires that specific individuals report cases of Hepatitis C. The directors of medical laboratories must report positive evidence of Hepatitis C, including demographic information about the patient, the health care provider or facility ordering the test, and the test performed. However, Maryland laboratories are not currently required to report negative diagnostic test results.

DHMH currently directs facilities operated by the Behavioral Health Administration, the Developmental Disabilities Administration, and the former Family Health Administration, which includes hospital inpatient units, nursing home units, residential treatment centers, State residential centers, and secured evaluation therapeutic treatment

units, to conduct Hepatitis B and C screening for those individuals who have a “history of at-risk behaviors” upon admission and annually thereafter.

Background: According to the U.S. Centers for Disease Control and Prevention (CDC), Hepatitis C is a virus that infects the liver. Today, most people are infected by sharing needles and other equipment to inject drugs. However, prior to 1992 when widespread blood-supply screening was not as prevalent, the virus was spread through blood transfusions and organ transplants. Hepatitis C can result in long-term health problems and even fatalities. CDC states that there is no vaccine, so avoiding behavior that can spread the disease is the best way to prevent infection.

State Expenditures: General fund expenditures increase by \$254,999 in fiscal 2015, which accounts for the bill’s October 1, 2014 effective date. This estimate reflects the cost of hiring one permanent full-time epidemiologist to collect and analyze data on the effect of the bill, ensure accuracy of reports, conduct ongoing queries on data received, and comply with the bill’s reporting requirements. The estimate also reflects the cost of hiring two permanent part-time public health laboratory scientists to perform pre-analytical activities, to conduct the initial Hepatitis C screening and follow-up Hepatitis C RNA diagnostic testing, and to fulfill reporting requirements. Diagnostic tests are more complicated and costly than the initial screening test. Additionally, the estimate includes expenses for laboratory reagents, supplies, and expedited courier services to transfer Hepatitis C RNA samples to the lab within six hours. The estimate includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses. The information and assumptions used in calculating the estimate are stated below:

Laboratory Testing at DHMH’s Laboratories Administration

- The administration provides testing to detect viral markers for Hepatitis C for LHDs and the Health Department for Baltimore City. The administration does not have a mechanism for charging individuals for testing; therefore, these costs result in increased general fund expenditures.
- The administration anticipates that it will receive an additional 10,210 specimens per year for Hepatitis C antibody screening and that evaluating these specimens will cost approximately \$8 per test for reagents and supplies at a cost of approximately \$81,680 annually. These types of samples are tested in the Virology and Immunology Lab, which is currently staffed by three full-time employees. The additional samples resulting from the bill represent an approximate 20% increase in the lab’s workload. Thus, the administration requires an additional permanent part-time employee in this lab.
- The Laboratories Administration anticipates that it will receive an additional 1,021 specimens per year for Hepatitis C RNA diagnostic testing and that

evaluating these specimens will cost approximately \$92 per test at a cost of approximately \$93,932 annually. These types of samples are tested in the Molecular Disease Assessment Laboratory, which is currently staffed by two full-time employees. The additional samples resulting from the bill represent an approximate 30% increase in the lab's workload. Thus, the administration requires an additional permanent part-time employee in this lab.

- Additionally, the current U.S. Food and Drug Administration approved Hepatitis C RNA test requires that blood samples be separated within six hours of collection. Therefore, samples must be driven to a laboratory facility quickly after they are taken. The Laboratories Administration advises that organizing a courier service for weekly pick-ups from LHD clinics will cost \$36,400 annually.

DHMH Prevention and Health Promotion Administration (PHPA): DHMH advises that, under the bill, PHPA will be responsible for collecting and analyzing data and fulfilling the bill's reporting requirements.

- PHPA estimates that at least 1.5 million Maryland adults would be recommended for Hepatitis C screening under the bill.
- CDC estimates that, in a given year, 82% of adults visit a health care provider and that at least 3.5% of adults born between the years of 1945 and 1965 are infected with Hepatitis C.
- Therefore, a minimum of 43,000 Maryland adults could be tested and diagnosed as positive for Hepatitis C. Thus, PHPA requires one full-time epidemiologist to fulfill the bill's requirements.

Positions (Full-time Equivalents)	2
Salaries and Fringe Benefits	\$111,740
Laboratory Supplies and Reagents	131,709
Operating Expenses	<u>41,550</u>
Total FY 2015 State Expenditures	\$284,999

Future year expenditures reflect full salaries with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

The Department of Legislative Services notes that the bill requires DHMH to collect and analyze information on positive Hepatitis C screenings and the number of individuals who have accessed care following a positive result. This will result in a change from current reporting procedure. Currently, labs must report positive test results, but individuals are not tracked by name or follow-up care. Even with a change in procedure, it may be difficult to track individuals to determine which patients received follow-up treatment.

DHMH's Developmental Disabilities Administration and Behavioral Health Administration advise that DHMH already implements a screening policy that screens patients for Hepatitis C at all DHMH hospital inpatient units, nursing home units, residential treatment centers, State Residential Centers, and Secure Evaluation and Therapeutic Programs.

Local Fiscal Effect: The Maryland Association of County Health Officers advises that many individuals already receive offers for Hepatitis C screening at LHD clinics. However, the bill's specificity and scope mean that there could be up to 11,000 additional screenings, as estimated by the Laboratories Administration. This could result in additional expenditures for LHDs.

LHDs rely on income-based sliding scales to bill patients who are uninsured or privately insured. Thus, additional testing is likely to be heavily subsidized and any follow-up care will also likely be heavily subsidized and otherwise might not be provided. Thus, costs to LHDs may increase to the extent that patients receive additional testing or follow-up care.

Additional Information

Prior Introductions: None.

Cross File: HB 543 (Delegate Nathan-Pulliam, *et al.*) - Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, Maryland Association of County Health Officers, Department of Legislative Services

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