SB 512

Department of Legislative Services

Maryland General Assembly
2015 Session

FISCAL AND POLICY NOTE

Senate Bill 512 (Senator Nathan-Pulliam)
Education, Health, and Environmental Affairs

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

This bill requires a hospital or health care practitioner to offer (to the extent practicable and 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, to the extent practicable. 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 $283,000 beginning in FY 2016 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 annualization, employee turnover, and increases in ongoing 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 2016	FY 2017	FY 2018	FY 2019	FY 2020
Revenues	$0	$0	$0	$0	$0
GF Expenditure	283,000	366,700	376,000	385,700	395,800
Net Effect	($283,000)	($366,700)	($376,000)	($385,700)	($395,800)

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. Revenues

are 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 the human immunodeficiency virus (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, to the extent practicable. A "hepatitis C diagnostic test" means a viral RNA laboratory test that detects the presence of hepatitis C virus in an individual's blood and provides confirmation on whether the individual has a hepatitis C viral infection.

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.

The bill's provisions may not be construed to affect a health care practitioner's scope of practice or legal or professional obligation to offer hepatitis C screening or diagnostic tests, or to provide health care to an individual who has had a hepatitis C screening or diagnostic test.

Subject to the limitations of the State budget, 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 heath 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.

In February 2015, DHMH submitted a report based on a study conducted at the request of several senators that addressed (1) obstacles to and limitations on DHMH's current hepatitis C monitoring efforts and (2) whether DHMH is considering or implementing measures to enhance its screening, diagnosis, and monitoring efforts, including the feasibility and cost of enhancing screening and diagnosis programs and surveillance efforts to identify and track chronic hepatitis C cases by establishing a registry or through other means.

DHMH identified a number of enhancements that could improve screening, diagnostic, and surveillance efforts in Maryland that the department would pursue with additional funding:

- development of new methods to triage lab reports, including electronic laboratory records received by health departments to identify and target those reports needing further investigation;
- promotion of hepatitis C testing per CDC guidelines and instituting universal reporting of all hepatitis C laboratory test results – positive and negative screening and diagnostic and follow-up tests, and assessing trends in hepatitis C RNA testing, which measures diagnostic evaluation and clinical treatment;
- expansion of capacity to manage and analyze more clinical data – especially existing electronic health record data – at the department to better understand trends in treatment and treatment outcomes;
- development of clinical performance indicators, clinical reminders, and clinical decision support systems by maximizing electronic health record technology to improve the quality of hepatitis C care and systematically collecting, analyzing, and disseminating those data to providers and to other stakeholders;
- greater use of surveys modeled after national surveys that assess population health to gather additional data on hospitalizations, transplants, and mortality; and

- support of outreach to primary care, infectious disease, and gastroenterology physicians in hospitals, hospital-affiliated clinics, and community health centers in Maryland neighborhoods with the greatest burden of hepatitis C, including providers of those at higher risk for hepatitis C – *e.g.*, in drug treatment programs and HIV clinics – to introduce additional clinical testing for hepatitis C diagnosis when hepatitis C antibody is detected.

State Expenditures: General fund expenditures increase by $282,970 in fiscal 2016, which accounts for the bill's October 1, 2015 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, 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 discussed below by each affected administration.

Laboratory Testing at DHMH's Laboratories Administration

- The administration provides testing to detect viral markers for hepatitis C for LHDs and the Baltimore City Health Department. 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 receive an additional 10,210 specimens per year for hepatitis C antibody screening and that evaluating these specimens costs 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 Laboratory, 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 receives an additional 1,021 specimens per year for hepatitis C RNA diagnostic testing and that evaluating these specimens costs 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 costs $36,400 annually.

DHMH's Prevention and Health Promotion Administration

DHMH advises that, under the bill, PHPA is 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.

Total Impact for DHMH

Positions (Full-time Equivalents)	2.0
Salaries and Fringe Benefits	$111,108
Laboratory Supplies and Reagents	131,709
Courier Services	27,300
Operating Expenses	12,853
Total FY 2016 State Expenditures	**$282,970**

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

Additional Considerations

PHPA advises that it needs five full-time employees in the first year and three full-time employees in subsequent years to fully establish and implement the program, even though it estimated the need for one employee for a substantially similar (and more prescriptive) bill in 2014. PHPA based this estimate on the cost to implement enhanced screening and diagnostic programs and surveillance efforts to identify and track chronic hepatitis C cases

by establishing a registry, or through other means, as identified in the report published in February 2015. However, the Department of Legislative Services (DLS) disagrees because as written, the bill does not require this level of service, tracking, or reporting. Thus, DLS advises that one full-time epidemiologist can likely collect and analyze data on the effect of the bill, ensure accuracy of reports, conduct ongoing queries on data received, and comply with the requirements in the bill.

Even so, DLS 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 changes the 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.

Previously, DHMH's Developmental Disabilities Administration and Behavioral Health Administration advised 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 is also likely to 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: HB 543 of 2014, a substantially similar bill, received a hearing in the House Health and Government Operations Committee, but no further action was taken. Its cross file, SB 594, received a hearing in the Senate Finance Committee, but no further action was taken.

Cross File: HB 984 (Delegate Oaks, *et al.*) - Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, Maryland Association of County Health Officers, U.S. Centers for Disease Control and Prevention, Department of Legislative Services

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