



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Lawrence J. Hogan, Jr., Governor – Boyd K. Rutherford, Lt. Governor – Van T. Mitchell, Secretary

February 2, 2015

The Honorable Thomas M. Middleton
Chair
Senate Finance Committee
3 East Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

The Honorable John C. Astle
Vice-Chair
Senate Finance Committee
123 James Senate Office Building
11 Bladen Street
Annapolis, MD 21401

RE: Report in Response to June 10, 2014 Letter on SB0594 - Hepatitis C - Opportunity for Testing and Follow-Up Health Care Introduced During the 2014 Legislative Session.

Dear Chairman Middleton and Vice-Chairman Astle:

The Department of Health and Mental Hygiene (Department) respectfully submits this report on the estimated number of hepatitis C (HCV) screening and diagnostic tests being administered by hospitals and Federally Qualified Health Centers in the State and HCV cases in the State that can be ascertained from available data and methodologies. Included in this report are obstacles to the Department's current HCV monitoring efforts and measures that would enhance the State's HCV screening, diagnosis, and monitoring efforts.

If you have any questions regarding this report, please contact Ms. Allison Taylor, Director of Governmental Affairs, at 410-767-6481.

Sincerely,

Van T. Mitchell
Secretary

Enclosure

cc: Allison Taylor, Director, Office of Governmental Affairs
Laura Herrera Scott, Deputy Secretary, Public Health Services
Michelle Spencer, Director, Prevention and Health Promotion Administration

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THE SENATE OF MARYLAND
FINANCE COMMITTEE

June 10, 2014

Joshua M. Sharfstein, M.D.
Secretary
Maryland Department of Health and Mental Hygiene
201 West Preston Street
Baltimore, MD 21201

Dear Secretary Sharfstein:

As you know, both the Senate and House considered legislation during the 2014 legislative session (Senate Bill 594/House Bill 543) that would have required hospitals and other specified health care practitioners to offer certain high risk individuals a Hepatitis C (HCV) screening test or an HCV diagnostic test.

These proposals were introduced in response to the 2012 recommendation of the Centers for Disease Control and Prevention that anyone born between 1945 and 1965 be screened for HCV. More than 75 percent of adults with HCV are baby boomers, and most of them do not know that they are infected with HCV. A simple blood test would determine if an individual has ever been infected with HCV. If an HCV infection is detected, the individual can begin potentially lifesaving treatment. Early diagnosis and treatment can help to prevent liver damage, cirrhosis, and even liver cancer.

Concerns were raised by hospitals, physicians, and other health care providers that the screening requirements of the legislation would codify a standard of care. The opponents also maintained that screening for HCV is currently being offered in appropriate clinical settings. However, it is unclear that screening, as well as the reporting of cases, is taking place at the frequency needed to identify individuals with HCV in our State. The Department of Health and Mental Hygiene tracks reported acute HCV cases by county in its Case Counts and Case Rate charts. The chart for 2012 indicates that the State was notified of only 39 reported cases of acute-symptomatic HCV. And it does not appear that the State has data on chronic HCV cases, nor does it have data on acute-asymptomatic HCV cases.

In a letter of information submitted regarding Senate Bill 594, the Department indicated, according to national estimates, that there are between 73,000 and 106,000 individuals living in Maryland who have been infected with HCV during their lifetime. When considering this broad-ranging estimate and the number of acute-symptomatic HCV cases reported to the Department, it

appears that there is a need for more comprehensive and detailed data to monitor and address the incidence and prevalence of acute and chronic HCV cases in the State.

Legislation has been introduced in past legislative sessions requiring DHMH, as funds are available, to conduct needs assessments to determine the incidence, conduct outreach and public awareness campaigns, and develop specified plans and recommendations relating to HCV.

We write to request that the Department submit a report to the Senate Finance Committee by November 30, 2014 on the estimated number of HCV screening and diagnostic tests being administered by hospitals and federally qualified health centers in the State and HCV cases (prevalence), including chronic cases, in the State that can be ascertained from available data and methodologies. The report should also provide information on the rate of HCV in the State by age, race, and ethnicity to the extent that such information is available.

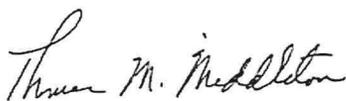
Some states, with federal funding, have engaged in enhanced surveillance for chronic HCV infections, including the use of a registry to track and follow up on cases and capture demographic information. We request that the report (1) identify any obstacles to or limitations on the Department's current HCV monitoring efforts and (2) address whether the Department is considering or implementing measures to enhance its HCV screening, diagnosis, and monitoring efforts, including the feasibility and cost of enhancing screening and diagnosis programs and surveillance efforts to identify and track chronic HCV cases by establishing a registry or through other means.

In addition, we request that the Department advise the committee of any programmatic changes made within the Department to address and decrease HCV infection rates in the State, including plans to address and decrease infection rates in FY 2015.

It is important that we have active monitoring of and accurate information on HCV infections in our State to inform our public health efforts, as well as effective efforts to educate the public, prevent infection, and provide treatment to infected individuals.

Thank you for your assistance on this matter.

Sincerely,



Thomas McLain Middleton
Chairman, Senate Finance Committee



John C. Astle
Vice-Chairman, Senate Finance Committee

TMM/PDC

MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE
PREVENTION AND HEALTH PROMOTION ADMINISTRATION

HEPATITIS C
SCREENING AND DIAGNOSIS
REPORT TO THE SENATE FINANCE COMMITTEE

Lawrence J. Hogan, Jr.
Governor

Boyd K. Rutherford
Lieutenant Governor

Van T. Mitchell
Secretary

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Introduction

In June, 2014, the Senate Finance Committee requested that the Department of Health and Mental Hygiene (the Department) submit a report on (1) the estimated number of Hepatitis C Virus (HCV) screening and diagnostic tests administered by Maryland hospitals and federally qualified health centers (FQHCs); (2) the number of HCV acute and chronic cases; (3) the rate of HCV by age, race, and ethnicity; (4) obstacles or limitations to the Department's current HCV monitoring efforts; (5) measures the Department is considering or implementing to enhance HCV screening, diagnosis, and monitoring, including the feasibility and cost of enhanced screening and diagnosis programs and surveillance to identify and track chronic HCV cases; and (6) information about programmatic changes made to address and decrease HCV infection rates. The Department has gathered information from a variety of sources to address these questions.

The Centers for Disease Control and Prevention (CDC) recommend that anyone born between 1945 and 1965 be screened at least once for Hepatitis C virus infection. It is estimated that more than 75% of adults with HCV are baby boomers, and many of these adults may be untested and unaware of their HCV status. Knowledge of HCV diagnosis through testing can both decrease HCV transmission and improve health as it often results in initiation of medical care that can prevent the long term complications of HCV infection. New treatments are available for HCV infection that offer better cures, shorter treatment durations, and fewer side effects.

While education of the public may increase awareness of testing and treatment of HCV infection, testing by healthcare providers and surveillance by public health experts are essential for managing and monitoring HCV infection in Maryland. The exact number of HCV infections in Maryland is not known, however national estimates suggest there are approximately 73,000 to 106,000 living HCV cases in the state.

Fortunately, other data are available to estimate the many burdens of HCV infection in Maryland. The participation of healthcare partners in testing and caring for HCV infected individuals will assist in understanding the burden of disease, and in planning for the costly treatment of affected individuals. With the advent of expanded healthcare coverage for Marylanders, more of those with HCV infection are able to access primary healthcare and to have HCV testing and medication cost coverage through health insurance.

Definitions

The following definitions will be helpful in reading this report:

- **Acute Hepatitis C** is a short-term illness that occurs within the first six months after someone is exposed to HCV. For most people, acute infection leads to chronic infection.
- **Chronic Hepatitis C** is a long-term illness that occurs when HCV remains in a person's body. HCV infection can last a lifetime and lead to serious liver problems, including cirrhosis (scarring of the liver) or liver cancer.
- **Hepatitis C screening** is laboratory testing for HCV surface antibody that indicates past exposure or current infection with HCV.

- **Hepatitis C diagnostic testing** is laboratory testing to detect and/or quantify the presence of HCV. These tests, called Hepatitis C RNA assay, or “Hepatitis C viral load,” are performed to diagnose active HCV infection and monitor response to HCV antiviral therapy.
- **Incidence of acute Hepatitis C** is the number of all new acute infections occurring in a year. What is tabulated and included in this report are the counts and rates only for reports of acute symptomatic HCV. This falls far short of the incidence of all acute infections since most (70-80%) acute HCV will be asymptomatic. Asymptomatic infections, by their nature, are unrecognized even by the person infected, and therefore cannot be reported to the Department or counted by other means.
- **Prevalence of Hepatitis C** is the total number (or proportion) of cases that exist in the population. What is tabulated and reported in this report are the counts and rates for newly reported chronic HCV. Unfortunately, those counts cannot be simply summed across years to arrive at the total number in the population, as the numbers do not reflect those with an initial diagnosis of HCV who then spontaneously clear the virus (defined as clearing evidence of HCV from the body), who are successfully treated with subsequent cure, or who have died. Additionally, deaths due to HCV infection versus deaths unrelated to, but among those with HCV infection, are variably recorded and tracked.

HCV Testing in Maryland

The Department queried hospitals and obtained information regarding HCV testing done by FQHCs through the U.S. Health Resources and Services Administration Bureau of Primary Care’s Universal Data System. As noted below, hospitals reported the number of tests done, while FQHCs reported the number of patient visits that resulted in HCV testing, therefore these numbers are not directly comparable.

Testing in Hospitals

In the summer of 2014, the Department requested that all acute care hospitals in Maryland report the aggregate number of positive and negative HCV tests performed by the hospital or sent out to a reference lab for testing in 2013. This information included both screening and diagnostic testing. Forty-five (45) out of 46 hospitals responded to the survey and reported an aggregate of 57,637 screening (HCV antibody tests, based on billing codes) and 10,433 diagnostic tests.

Testing in FQHCs

While FQHCs do not report the number of Hepatitis C tests performed, data is available on patient visits where HCV tests were performed, and visits for HCV infection. Data from the Bureau of Primary Care’s Universal Data System provides the combined total number of HCV screening and diagnostic tests being administered by FQHCs in Maryland in 2013 based on billing codes.

Table 1. HCV Testing in Maryland FQHCs, 2013

	Total	Average visit per patient
Number of patient visits resulting in HCV screening or diagnostic tests	6,081	n/a
Number of patients receiving HCV screening or diagnostic tests	5,659	1.07
Number of patient visits with primary diagnosis of HCV infection	7,119	n/a
Number of patients with a primary diagnosis of HCV infection	3,744	1.9

Based on this information, in 2013 at least 63,718 HCV tests were administered by Maryland hospitals and FQHCs. However, since more than one test might be done per patient, the Department cannot precisely determine how many actual individuals were tested. In addition, the Department does not currently have complete information about the number of tests done in non-FQHC outpatient settings.

HCV Acute and Chronic Cases in Maryland/Limitations of Current Surveillance

In Maryland, health care providers are required to report patients with viral hepatitis, including those with HCV, and laboratories are required to report laboratory evidence of viral hepatitis. Most HCV reports are submitted by laboratories; these reports often do not include information about race or ethnicity, since that information is not generally collected by clinical laboratories. Local health departments, using national surveillance case definitions and based on available information or additional information from the health care provider or the case patient, classify the case as “Acute” or “Past or Present,” and enter the case into the National Electronic Disease Surveillance System (NEDSS). It is important to note that although cases classified as “Past or Present” are often referred to as “chronic” infections, this classification does not distinguish recent asymptomatic infections from ongoing past infections. Resources required to conduct the intensive and time consuming case investigation and medical record review necessary to make this distinction do not exist at the majority of Maryland’s local health departments or the Department at this time. Without resources to monitor cases over time, and given that approximately 15% of acute cases spontaneously clear, it cannot be determined whether clearance has occurred on a population level, thus making prevalence more difficult to determine. Given the lack of a vaccine or other widely effective public health intervention for HCV, as well as the high burden of workload on local health departments (in terms of the vast amount of surveillance, case finding, and prevention messaging), especially given the reductions in core funding for local health departments over the past ten years, individual case reporting is not considered an appropriate allocation of resources.

Acute HCV

In Maryland, 53 acute symptomatic HCV cases (0.9 cases per 100,000 population) were reported and confirmed in 2013. This is an increase over the median number of 24 cases (0.4 per 100,000) reported during the previous five-year period of 2008-2012.

Chronic HCV

In 2013, 6,853 past or present/chronic HCV cases (115.6/100,000) were reported, compared to a median of 6,005 cases (104/100,000) in the previous five-year period of 2008-2012.

Table 2. Reported Cases of Chronic HCV in Maryland, 2013

	Total
2013 Cases	6,853
5 year Median (2008-12)	6,005
2013 Rate per 100,000 persons	115.6
5 year Median Rate per 100,000 persons (2008-2012)	104
Male	61.5%
Female	38.5%
Age groups (years)	
0-19	1.2%
20-29	10.1%
30-39	10.3%
40-49	19.2%
50-59	39.1%
60-69	17.2%
70 or greater	2.9%

Race and ethnicity are not reported here, as only 30% of race and 17% of ethnicity were reported for these cases. As noted above, race and ethnicity are often missing from laboratory reports that are the primary reporting source for chronic HCV cases. Laboratories rarely receive this information from the health care provider or the facility submitting the specimen. However, the Department was able to obtain more complete race and ethnicity data from hospital admission data, vital records (death certificates), and Medicaid. Of the 705 individuals with a HCV related hospital admission in 2013, 45% were Black/African American, 44% were White, and 11% were other or unknown. Similarly, between 2008 and 2012, 49% of the 1,332 individuals with HCV related death were Black/African American, 49% were White, and 2% were other. Data from Medicaid indicates that of the 14,927 unduplicated HCV clients seen in any setting in 2013, 54.9% were Black/African American, 39.5% were White, 0.8% were Asian, 0.7% were Hispanic, and 4.2% were other. Hispanic ethnicity was identified in 1.5% of hospitalizations, 1.3% of deaths, and 0.7% of Medicaid clients.

Considerations for Enhanced Surveillance and Detection

The main purpose of public health surveillance is to systematically collect and analyze health information that can be used for directing public health actions, including programs and initiatives. For some common infections it is not necessary to gather individual-level data on every case; HCV is one of those infections. In Maryland some enhancements to existing

surveillance might augment current understanding of HCV infection in the state and help inform public health programs and actions. The following enhancements have been considered by the Department if additional resources were available:

- 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 HCV testing per CDC guidelines and instituting universal reporting of all HCV laboratory test results – positive and negative; screening and diagnostic and follow-up tests, and assessing trends in HCV 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 HCV 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.
- 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 HCV, including providers of those at higher risk for HCV — e.g., in drug treatment programs and human immunodeficiency virus (HIV) clinics — to introduce additional clinical testing for HCV diagnosis when HCV antibody is detected.

It is estimated that implementation and initiation of these enhanced efforts at the Department would take approximately 5 FTEs in the first year, and approximately 3 FTEs for maintenance in subsequent years. Additional staffing needs for local health departments are unknown.

Enhanced Funding and Programmatic Changes in Maryland for HCV Testing and Linkage to HCV Care

The Department aggressively seeks resources to support viral hepatitis program services, including HCV chronic infection surveillance. In May 2014, the Department in partnership with the Baltimore City Health Department, Johns Hopkins University, and the Baltimore County Health Department, succeeded in obtaining an additional \$1.2 million per year for four years from the CDC to extend HCV testing, treatment, and surveillance program efforts in Baltimore City and Baltimore County. This new program, entitled *Community-based Programs to Test and Cure Hepatitis C*, is in the start-up phase. This funding will significantly enhance the HCV chronic infection surveillance infrastructure and capacity of the Baltimore City Health Department which handles the majority of the chronic HCV infection burden in Maryland. The Baltimore County Health Department will also receive surveillance staff support to enhance that agency's efforts in HCV chronic infection surveillance activities.

The over-arching goal of the program is to reduce HCV-related morbidity and mortality by strengthening healthcare capacity in Baltimore City and Baltimore County in order to diagnose and cure HCV infection. This goal will be achieved through implementation of six strategies:

1. Provider training and ongoing telemedicine consultation to increase HCV treatment and case management by primary care providers;
2. Provider and community education to increase HCV testing by primary care providers and in the community;
3. Local health department linkage to care services to ensure HCV infected persons are linked to treatment and supported in adhering to their treatment regimen;
4. Increased HCV surveillance infrastructure and data sharing to refine population level estimates of HCV infection and health outcomes;
5. Increased utilization of EMRs to enhance HCV services, evaluate service outcomes, and inform quality improvement; and
6. Policy initiatives to leverage the Affordable Care Act to improve client access to HCV testing and care.

Conclusion

The Department is engaged in a range of activities to promote prevention and treatment of HCV infection, and uses a variety of techniques and data sources to assess the impact of HCV on Maryland and to monitor the effect of screening and treatment efforts. With additional resources, enhancements to surveillance and other public health efforts could be implemented. In addition, in 2014, through dedicated Department efforts along with increased community partnership involvement and efforts, the Department has obtained special additional federal funding to pilot an expandable program that engages existing health centers to accomplish increased screening, linkage to care, and treatment of HCV infection. The Department will continue to promote efforts that help all Marylanders know their Hepatitis status and that ensure Marylanders have access to HCV related healthcare and treatment.