MARYLAND
Department of Health
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

January 23, 2018

The Honorable Larry Hogan
Governor
State of Maryland
Annapolis, MD 21401-1991

The Honorable Joan Carter Conway
Senate Education, Health, and
Environmental Affairs Committee
2 West Miller Senate Building
Annapolis, MD 21401-1991

The Honorable Shane E. Pendergrass
House Health and Government
Operations Committee
Room 241 House Office Building
Annapolis, MD 21401-1991

RE: Health-General Article, §18-1002, Annotated Code of Maryland – 2017 Annual Report – Implementation of Hepatitis B and Hepatitis C Prevention and Control in Maryland

Dear Governor Hogan, Chair Conway, and Chair Pendergrass:

Pursuant to Health-General Article, §18-1002, the Maryland Department of Health (the Department) is required to submit an annual report on its activities relating to the prevention and control of hepatitis B virus (HBV) and hepatitis C virus (HCV) infection in Maryland. The attached is a report of the Department's activities in 2017 related to HBV and HCV prevention and control in Maryland.

I hope this information is helpful. If you have any questions or comments concerning the report, please contact Mr. Webster Ye, Deputy Chief of Staff, Office of the Secretary, at 410-767-6480 or webster.ye@maryland.gov.

Sincerely,

Robert R. Neall
Secretary

Enclosure

cc: Webster Ye, J.D., Deputy Chief of Staff, Office of the Secretary
Howard Haft, MD, MMM, CPE, FACPE, Deputy Secretary, Public Health Services
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MARYLAND
Department of Health
Prevention and Health Promotion Administration

2017 Annual Report
Implementation of Hepatitis B and Hepatitis C Prevention and Control in Maryland
Health-General Article §18-1002

Larry Hogan
Governor

Boyd Rutherford
Lieutenant Governor

Robert R. Neall
Secretary, Maryland Department of Health

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I. Background

Hepatitis B in Maryland

Hepatitis B virus (HBV) attacks the liver and can cause both acute and chronic disease. Anyone who comes in contact with blood or other bodily fluids of an HBV-infected person is at risk for transmission.[1] Additionally, infection is transmissible from mother to child and infants are more likely than adults to become chronically infected after viral exposure.[2] There is no cure for chronic HBV infection, but it is vaccine preventable.

Based on national prevalence data, the Centers for Disease Control and Prevention (CDC) estimates that there are 850,000 persons living with HBV in the United States.[3] In Maryland, the rate of reported acute HBV infections decreased in 2016 (0.5 cases per 100,000 population) compared to 2010 (1.1 cases per 100,000 people), mainly due to effective vaccination strategies. However, the rate of reported chronic HBV increased from 22.0 cases per 100,000 in 2010 to 34.4 cases per 100,000 in 2016. In 2016, there were 27 reported cases of acute HBV and 2,061 reported cases of chronic HBV.[4] Based on 2016 surveillance data from the Maryland National Electronic Disease Surveillance System (NEDSS), the counties in Maryland with the highest rates of reported chronic HBV were Montgomery County, Prince George's County, Baltimore County, and Baltimore City.[5]

Hepatitis C in Maryland

Hepatitis C virus (HCV) is a major cause of chronic liver disease. CDC estimates 3.5 million individuals are living with HCV infection in the United States.[6] HCV also poses a significant burden on health in Maryland. In 2013, rates of acute HCV infections in Maryland (0.9 cases per 100,000) surpassed the national rate (0.7 cases per 100,000). Since then, the rate of acute HCV decreased to 0.6 cases per 100,000 people in 2015, but has risen again to 0.8 cases per 100,000 people in 2016.[7] The data reflect the variability of acute case reporting and that a majority of acute HCV cases may go unreported each year due, in part, to the fact that specific symptoms do not consistently present themselves in individuals who are newly infected with the virus.

Maryland has continued to see significant increases in chronic HCV reports with 8,004 cases reported in 2016. From 2010 (103.4 cases per 100,000) to 2016 (133.5 cases per 100,000), the rate of chronic HCV reports increased by almost 30.0 percent. Since there are hard-to-reach

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[1] Centers for Disease Control and Prevention, Viral Hepatitis, 2016, August 4, accessed 31 August 2017 https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.

[2] Centers for Disease Control and Prevention, Viral Hepatitis, 2017, September 19, accessed 11 October 2017 https://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm.

[3] Centers for Disease Control and Prevention, Viral Hepatitis Surveillance—United States, 2015, accessed 30 August 2017 https://www.cdc.gov/hepatitis/statistics/2015surveillance/pdfs/2015HepSurveillanceRpt.pdf.

[4] Maryland Department of Health, Prevention and Health Promotion Administration, Maryland National Electronic Disease Surveillance System (NEDSS), August 2017.

[5] *Id* fn 5.

[6] *Id* fn 4.

[7] *Id* fn 5.

populations impacted by HCV that are not connected to care, the burden of the disease in Maryland is estimated to be higher than what is reported.

Between 2015 and 2016, reported HCV cases increased in 19 of 24 Maryland counties. 17 counties had the highest number of HCV cases reported since before 2010. These increases are likely due to the promotion of screening practices for HCV in those counties. Although Baltimore City continues to have the highest absolute number of HCV cases, Somerset County surpassed Baltimore City in the rate of cases reported in 2016 (380.6 cases per 100,000 people).[8] According to *HepVu*, a website launched by Emory University's Rollins School of Public Health in April 2017, the estimated number of Marylanders living with HCV antibodies in 2010 was 82,000.[9]

According to estimates by CDC, 25 percent of people with HIV are co-infected with HCV.[10] Currently, reported data show that 4,032 people living with HIV in Maryland are co-infected with HCV.[11] Over 55 percent of co-infected people in Maryland live in Baltimore City, followed by Baltimore County (10 percent), Prince George's County (9.4 percent), and correctional facilities located in the State (10 percent).[12] As seen nationally, in Maryland, the baby boomer cohort has the highest prevalence of HCV infection among all age groups. Despite making up only 25.7 percent of Maryland's population, in 2016, people born from 1945-1965 accounted for 54.6 percent of reported chronic HCV cases.[13,14]

II. Maryland Department of Health HBV and HCV Infection Activities, 2017

The Maryland Department of Health (the Department) works with public, private, and community partners to maximize resources to address both HBV and HCV in Maryland. Activities conducted in calendar year 2017 are described below.

Expansion of Maryland Community-based Programs to Test and Cure Hepatitis C

New innovations in HCV treatment have paved the way for therapies that cure the infection in eight to 24 weeks. In the past, liver, transplant, and infectious disease specialists primarily treated HCV, limiting the number of health care providers available to treat the infection. In 2014, the Department was awarded 1.2 million in annual funding from the CDC to establish

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[8] *Id* fn 3.

[9] HepVu, Emory University, Rollins School of Public Health, in partnership with Gilead Sciences, Inc., accessed 2 October 2017 www.hepvu.org.

[10] Centers for Disease Control and Prevention, HIV and Viral Hepatitis, June 2017, accessed 2 October 2017 https://www.cdc.gov/hiv/pdf/library/factsheets/hiv-viral-hepatitis.pdf.

[11] Maryland Department of Health Enhanced HIV/AIDS Reporting System (eHARS), reported through 06/30/2017. Not all data has been geocoded and is therefore preliminary.

[12] *Id* fn12.

[13] U.S. Census Bureau, Population Division, Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States and Puerto Rico Commonwealth: April 1, 2010 to July 1, 2015, 2016, Accessed 2 October 2017 https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2016_PEPSYASEX&prodType=table.

[14] Maryland Department of Health, Prevention and Health Promotion Administration. Data Source: Maryland National Electronic Disease Surveillance System (NEDSS). August 2017.

Maryland Community-based Programs to Test and Cure Hepatitis C (the Maryland Test and Cure Program). This four-year cooperative agreement with CDC supports a multi-pronged approach to clinical integration of HCV testing, care, and treatment at health care settings in Baltimore City and Baltimore County, the Maryland counties with the highest prevalence of HCV. Additionally, the program has expanded provider capacity to identify and treat individuals with HCV infection.

The initiative has grown from a grant program into a coalition of medical and public health experts dedicated to the elimination of HCV in Maryland. The coalition is primarily composed of partners with decades of experience in HIV prevention and care, leading experts in the treatment of HCV mono-infected and HIV/HCV co-infected individuals, and primary care providers who recognize the significant need for local HCV testing and care. The *Maryland Test and Cure Program* includes comprehensive provider training and education, linkage-to-care services by local health departments, and modification of electronic medical records to enhance HCV services and support improved surveillance reporting. This work has revealed that substantial infrastructure and coordination are necessary to implement and maintain high quality HCV service delivery. Additionally, the work has demonstrated the need to develop clinical expertise related to HCV screening, care, and treatment.

The table below provides data on individuals seen for HCV care at primary care sites that participate in the *Maryland Test and Cure Program*. The baseline time period consists of the 12 months before the start of the program. Sites include federally qualified health centers, sexually transmitted disease clinics, and clinical sites for a Maryland Medicaid Managed Care Organization. Providers at these sites participate in the training component of the *Maryland Test and Cure Program*.

Table 1. Selected HCV Care Markers at Clinical Sites in Baltimore City and Baltimore County Partnering in the *Maryland Test and Cure Program*

	Baseline (10/1/13-9/30/14)	**Project Period + Baseline (10/1/13-3/31/17)**
	N (percent)	**N (percent)**
HCV Confirmatory (RNA) positive	1,014 (100.0)	4,100 (100.0)
Genotype or Staging test run	571 (56.3)	3,079 (83.7)
Fibrosis staging test run	43 (4.2)	2,627 (64.1)
Fibrosis score ≥ F2*	25 (58.1)	1,281 (48.8)
Prescribed treatment for HCV	0 (0.0)	548 (13.4)
Started treatment for HCV	0 (0.0)	348 (8.5)
Completed treatment for HCV	0 (0.0)	280 (6.8)

Achieved Sustained Virologic Response	0 (0.0)	187 (4.6)

*Maryland Medicaid's current clinical criteria require a fibrosis score of ≥2 for HCV treatment approval.

A core component of the initiative is the clinician training and telemedicine program, *Sharing the Cure*, administered by Johns Hopkins University, Division of Infectious Diseases. The Department and Johns Hopkins University recently completed training of the third cohort of primary care providers selected from clinical partner sites. To date, 46 clinicians have been trained and another cohort of providers will begin training in January 2018.

Additionally, building upon the clinics' existing comprehensive case management programs, clinicians developed HCV-specific case management services at each clinical site. These services focus on patient adherence to treatment and include insurance screening and assistance to obtain insurance; assessment of barriers to treatment adherence, including psycho-social factors such as unstable housing and lack of employment; appointment and prescription reminders, including providing patients with pocket calendars and reminder calls or texts; outreach to patients when they miss an appointment, lab draw, or fail to pick up a prescription; and transportation assistance. The Baltimore City Health Department provides case management and outreach in collaboration with partners to initiate follow-up and to re-engage clients who clinical staff are unable to locate or engage.

To date, each participating clinic has successfully developed and implemented clinic-wide policies and procedures; enhanced their electronic medical records systems; implemented support tools to facilitate clinical decision making; integrated case management and other treatment adherence supports; and identified additional ways to facilitate clinic-specific approaches to HCV care and treatment, based on target populations and available resources including the integration of pharmacy staff into their HCV care teams.

Early treatment of HCV is associated with several health benefits including overall reduced morbidity and mortality. Providers participating in the program, as well as other clinicians treating HCV in Maryland, have noted challenges due to health plans' differing criteria to obtain HCV treatment coverage. Such criteria include symptom severity, a prescription by or in consultation with a specialist, and abstinence from or treatment for drugs and alcohol abuse (including testing). Due to the complexity of verifying criteria, insurance plans' coverage approval processes require significant staff capacity and coordination to complete the documentation needed to support the patient's request for coverage. The complexity also leads to inconsistencies related to when the beneficiary is determined to meet or not meet the criteria. Due to the difficulty of administration, a low number of HCV patients have been treated through the *Maryland Test and Cure Program* to date. Efforts are underway to inform insurance providers about the burden these processes impose on patients and their care providers.

Enhanced HCV Surveillance Activities and Linkage-to-Care

Communicable disease surveillance is informed by the collection and analysis of information received from providers and institutions that perform infectious disease testing. Maryland regulations require health care providers, health care institutions, and medical laboratories to

report both chronic and acute symptomatic HBV and HCV to local health departments.[15] Local health departments and the Department receive both electronic and paper-based reports. Additionally, local health departments follow-up with individual providers and institutions to complete case investigations, as needed.

A major challenge with HCV surveillance has been the high volume of paper reports received by local health departments. The high volume of paper reports is not specific to HCV, but since the burden of HCV is high in certain counties, systems may be overwhelmed by large numbers of daily paper HCV reports from laboratories. To strengthen HCV surveillance in Baltimore City and Baltimore County, through the *Maryland Test and Cure Program*, the Department provided funding and technical assistance to both counties to increase the number of data entry staff to reduce the backlog of paper HCV lab reports and to continue the timely review of electronic reports. Currently, both Baltimore City and Baltimore County are up-to-date with entry of paper reports and are working in real-time on data entry.

The Department's Center for Disease Surveillance continues to investigate new reports of acute HCV cases to identify clusters and outbreaks in the community, and to assess risk factors. There is also a continued effort to expand the number of laboratories that electronically report lab results to local health departments. Many major hospital and laboratory systems have transitioned to electronic reporting (including Medstar and LabCorp), which has reduced the number of laboratory reports requiring hand entry by local health department staff. In 2017, Johns Hopkins Hospital System, University of Maryland Medical System at Easton/Dorchester/Chestertown, and St. Agnes Hospital started electronic reporting as well.

The Baltimore City Health Department continues *data-to-care* work. Linkage-to-care coordinators use surveillance data to identify individuals who are diagnosed with HCV and link them with providers who can facilitate appropriate care and follow-up. *Data-to-care* (using surveillance data for patient follow-up) is a relatively new public health strategy that was developed to link HIV-diagnosed individuals to care.[16] Linkage-to-care coordinators also connect individuals to health insurance or Maryland Medicaid through the Maryland Health Connection. Coordinators help address immediate barriers to care such as transportation and childcare. By the end of the linkage-to-care program's first year, the Baltimore City Health Department successfully linked 271 clients to care and was in the process of linking an additional 25 clients. These data were presented at the 2017 Council for State and Territorial Epidemiologists' Annual Conference, on a Council for State and Territorial Epidemiologists Hepatitis C Subcommittee call, and at the National Alliance of State and Territorial AIDS Directors' Annual Viral Hepatitis Technical Assistance Meeting in November 2017.

Baltimore County Department of Health has begun a linkage-to-care program based on Baltimore City's work in early 2017. In addition to referrals through their rapid testing program, Baltimore County Department of Health follows-up on historical case reports from surveillance

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[15] Code of Maryland Regulations 10.06.01.03C.

[16] Centers for Disease Control and Prevention, Using HIV Surveillance Data to Support the HIV Care Continuum, accessed 22 September 2016 https://effectiveinterventions.cdc.gov/en/highimpactprevention/publichealthstrategies/DatatoCare.aspx.

data. Local health department rapid testing programs (described in the following section) also contribute to enhanced surveillance through promotion of morbidity report forms. Positive HCV rapid test results are reported to the local health departments with patient demographic information and subsequent HCV RNA results, which provides additional information to what is reported by laboratories. All of the sites participating in HCV rapid testing are also documenting linkage-to-care processes and outcomes.

The Department continues to partner with the Maryland Department of Public Safety and Correctional Services to develop a HCV linkage-to care system for individuals upon release. As of August 2017, staff were hired to serve as linkage-to-care specialists and manage a rapid HCV testing program for inmates who are about to be released. Staff will work with individuals post-release to ensure successful engagement with health care providers.

Launch of Maryland's HCV Rapid Testing Program

In 2017, the Department launched a rapid HCV testing program to identify individuals with HCV who are unaware of their status. The program provides free HCV rapid test kits and controls to local health departments and agencies that serve populations at risk for HCV. Modeled after the Department's HIV testing and linkage-to-care program, initial efforts focused on integration of HCV rapid testing at existing HIV testing partner sites.

Participation in the HCV rapid testing program requires sites to have proven capacity to screen, test, and treat or link individuals to HCV care. The Department created a comprehensive HCV testing guidance document to inform HCV testing procedures at participating testing sites as well as at other local organizations interested in initiating rapid HCV testing.

All rapid testing program participants were required to undergo training on:

- HCV screening, diagnosis, and referral best practices;
- HCV screening protocols, policies, and procedures;
- How to use the rapid testing device;
- Confirmatory (RNA) testing;
- Data collection and State requirements for infectious disease reporting; and
- Resources for client referral to local HCV care providers.

After completion of the training, participating sites received HCV rapid test kits at no cost to the site based on their readiness to begin testing. The number of tests received was based on the staff capacity of each respective site. The Department continues to monitor and provide technical assistance to each site. To date, 4,600 tests have been distributed and 1,536 tests have been administered. At this time, outcomes data are not currently available. However, an update will be provided in a later report. Rapid HCV testing was initiated at the following sites in 2017: Baltimore County Health Department, Carroll County Health Department, Cecil County Health Department, Harford County Health Department, and Worcester County Health Department. The Department expects additional sites will be added before the end of 2017.

Implementation of HBV and HCV Prevention and Control Activities

In November 2016, the Department received $124,629 in new funding from the CDC for a four-year grant to support increased HBV and HCV testing, diagnosis, and referral to treatment. The

new funding opportunity, titled *Improving Hepatitis B and C Care Cascade: Focus on Increased Testing and Diagnosis*, replaced the former Viral Hepatitis Prevention Coordination program, and has allowed Maryland to maintain many of its HBV and HCV prevention and control activities. With this new funding the Department has proposed comprehensive strategies and activities that span a four-year project period with the goals of: (1) increasing the number of individuals in Maryland living with HBV and HCV infection who are tested for HBV and HCV and made aware of their status, and (2) linking individuals with HBV or HCV infection to appropriate care and treatment services.

In the first year of the grant (fiscal year 2017), the Department conducted a statewide situational analysis to: (a) describe disease burden, epidemiological trends, and laws and policies impacting testing, care, and treatment of HBV and HCV infection; (b) identify high prevalence areas of HBV and HCV infection; and (c) identify settings where testing should be conducted. The counties with the highest reported cases of HBV and HCV were identified (and are noted in the Background section of the report). Upon completion of the situational analysis, the Department initiated partnerships with two organizations to address HBV and HCV in three of the highest prevalence counties: Baltimore City, Prince George's County, and Montgomery County.

The Department expanded its rapid HCV testing program to include the Johns Hopkins University Department of Emergency Medicine. Rapid HCV testing was initiated in partnership with Johns Hopkins University to determine the potential added value of offering point of care HCV screening alongside existing traditional blood-based HCV screening in a high acuity, high volume emergency department setting in Baltimore. In addition to providing HCV test kits and controls, the Department provided limited funding to support staffing at the Department of Emergency Medicine to complete HCV screening and confirmatory testing, as well as linkage-to-care for HCV-infected individuals. To date, the Department of Emergency Medicine has administered 1,290 tests and identified 44 HCV antibody positive individuals.

The Department also partners with the Hepatitis B Initiative of Washington, DC (HBI-DC) to provide HBV and HCV screening and referral services to hard-to-reach, at-risk populations. The mission of HBI-DC is to mobilize communities to prevent liver diseases caused by viral hepatitis among high-risk groups. The Department worked with HBI-DC to provide needed outreach, education, screening, and referral to these populations in Baltimore City, Montgomery County, and Prince George's County. In the first five months of program implementation, HBI-DC tested 641 people for HCV and identified 10 antibody positive persons. Additionally, HBI-DC tested 255 people for HBV, of which 28 individuals were positive. The Department will continue its collaboration with HBI-DC in 2018.

HIV and HCV Coordination

As previously noted, 25 percent of persons living with HIV are co-infected with HCV. As such, the Department engages in efforts to integrate HCV testing and treatment into its Ryan White HIV/AIDS programs and services. For example, the Center for HIV Prevention and Health Services, which manages Maryland's CDC cooperative agreement for HIV prevention services, US Health Resources and Services Administration Ryan White B funding for direct patient care and support services, and US Department of Housing and Urban Development Housing Opportunities for Persons With AIDS dollars, has worked to integrate HCV prevention, screening, and treatment throughout the Center's portfolio of funding. Conditions of award to 23

direct-service providers included mandated integration of HCV prevention in all HIV testing programs. Identifying and linking co-infected individuals has been identified as a priority activity for the *Ryan White Region Quality Collaborative*, a National Quality Center-sponsored workgroup of administrators from all Ryan White Parts funded in Maryland. The Department will continue its efforts to integrate HIV/HCV co-infection into its HBV and HCV efforts going forward.

III. Conclusion

In 2017, the Department continued to provide leadership, guidance, and technical assistance across the State to support growing efforts to address HBV and HCV. Over the last year, the Department has significantly expanded work to increase the availability of screening, testing, and treatment for HBV and HCV across the State. In 2018, the Department will continue to work to ensure that all Marylanders know their HBV and HCV status and have access to lifesaving health care and treatment.

Appendix: Glossary of Key Terms

This glossary provides definitions of key terms used in this report.

Acronym	Term	Definition
AIDS	Acquired Immunodeficiency Syndrome	A disease of the human immune system that is characterized cytologically especially by reduction in the numbers of CD4-bearing helper T cells to 20 percent or less of normal, rendering the subject highly vulnerable to life-threatening conditions.
CDC	Centers for Disease Control and Prevention	The US agency charged with tracking and investigating public health trends.
eHARS	Maryland Department of Health Enhanced HIV/AIDS Reporting System	A browser-based application provided by CDC to collect, manage, and report HIV/AIDS case surveillance data to CDC.
HBI-DC	Hepatitis B Initiative of Washington, DC	A community-based organization dedicated to mobilizing communities to prevent liver disease caused by hepatitis B.
HBV	Hepatitis B Virus	A virus that causes hepatitis B and can lead to inflammation and damage to the liver.
HCV	Hepatitis C Virus	A virus that causes hepatitis C and can lead to inflammation and damage of the liver.
HIV	Human Immunodeficiency Virus	A virus that attacks the immune system.
	Linkage-to-care	The process of engaging newly diagnosed HBV and/or HCV infected persons into HBV and/or HCV care for treatment.
MCO	Managed Care Organization	A health care delivery system consisting of affiliated and/or owned hospitals, physicians, and others which provide a wide range of coordinated health services.
Confirmatory (RNA) Testing	Confirmatory Ribonucleic Acid Testing	A follow-up blood test that is used to look for the genetic material of the virus that causes hepatitis in order to confirm active infection.
NEDSS	National Electronic Disease Surveillance System	A secure online framework that allows health care professionals and government agencies to communicate about disease patterns and coordinate national responses to outbreaks.
YRBS	Youth Risk Behavior Survey	An American biennial survey of adolescent health risk and health protective behaviors such as smoking, drinking, drug use, diet, and physical activity conducted by CDC.