



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

JAN 20 2011

The Honorable Martin O'Malley
Governor
State of Maryland
Annapolis, MD 21401-1991

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

The Honorable Peter A. Hammen
Chair, House Health and
Government Operations Committee
Room 241 House Office Building
Annapolis, MD 21401

RE: HB 342/Ch. 457 and SB 336/Ch. 249 of the Acts of 2006 as amended by HB 76/
Ch. 125 of the Acts of 2009 and Health – General § 18-1002 - Hepatitis C Virus Report

Dear Governor O'Malley, Chair Carter Conway, and Chair Hammen:

Md. Code Ann., Health - General §18-1002, requires the Department to annually inform the Governor and the General Assembly about its activities relating to the prevention and control of hepatitis C virus ("HCV") infection in Maryland. I have attached a report of the Department's activities in 2010 related to HCV prevention and control in Maryland.

I hope this information is helpful. If you have any questions or comments concerning the report, please contact Ms. Wynee Hawk, Director, Office of Governmental Affairs at (410) 767-6481.

Sincerely,

Joshua Sharfstein, M.D.
Secretary

Enclosure

cc: Ms. Frances Phillips
Ms. Wynee Hawk
Ms. Heather Hauck
Ms. Sara T. Albert MSAR# 7894

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DHMH Activities toward Implementing Requirements of Md. Code Ann., Health-General § 18-1001, Hepatitis C Prevention and Control within Maryland

Per Maryland Code Ann., Health-General § 18-1002, this report describes the Maryland Department of Health and Mental Hygiene's (DHMH) activities relating to the prevention and control of hepatitis C virus (HCV) infection in Maryland. DHMH's hepatitis prevention programs are conducted within the Infectious Disease and Environmental Health Administration (IDEHA).

Background

Surveillance data suggest that about 20,000 persons are newly infected with hepatitis C virus (HCV) annually in the United States.¹ HCV is the leading cause of liver transplants in this country. The number of HCV related deaths, which now stands at about 12,000 Americans per year, is expected to rise in the coming decade.² Although new cases have dropped sharply, hundreds of thousands of people who were infected decades ago are expected to start experiencing the effects of liver damage.³ Three-quarters of the people who are infected do not know it, because they are not tested for the virus and because infection can be asymptomatic for years while it stealthily attacks the liver.⁴ Because this disease is transmitted by blood, those infected largely are former or current injection drug users – a population that characteristically has little or no health insurance – who may not be the most able to stick to a lengthy treatment regimen that can have serious side effects. It is estimated that 50% to 90% of Human immunodeficiency virus (HIV) positive injection drug users are also infected with HCV.⁵

¹ *Professional Judgment Budget for Comprehensive Viral Hepatitis Prevention and Control in the US as Requested by the U.S. Senate Appropriations Committee*, HHS/CDC, 2010

² National Alliance of State and Territorial AIDS Directors (NASTAD) letter to Dr. Howard Koh, Assistant Secretary for Health, DHHS, Washington, DC, August 10, 2010.

³ National Alliance of State and Territorial AIDS Directors (NASTAD) letter to Dr. Howard Koh, Assistant Secretary for Health, DHHS, Washington, DC, August 10, 2010.

⁴ National Alliance of State and Territorial AIDS Directors (NASTAD) letter to Dr. Howard Koh, Assistant Secretary for Health, DHHS, Washington, DC, August 10, 2010.

⁵ CDC Fact Sheets on CDC website, "Coinfection with HIV and Hepatitis C Virus", Nov. 2005.

In the U.S., viral hepatitis must be understood and addressed in the context of health disparities. HCV infection is two to three times as prevalent among African Americans as it is whites, and African American rates of HCV are twice the national average.⁶

Maryland

Hepatitis C infection is the most common chronic blood borne-viral infection in Maryland. The primary method of HCV transmission is large or repeated direct exposures through needles that contain contaminated blood and are used to pierce skin. While HCV transmission through blood transfusions and tissue transplants represented a significant proportion of cases 20 years ago, improved screening of the blood supply and transplanted tissue has reduced the risk of transmission through these activities to virtually zero. In contrast, since 1992, the majority of new HCV infections have been linked to the practice of sharing needles among injection drug users.⁷ Other sources of HCV infection include sexual exposure, hemodialysis exposure, occupational exposure, and perinatal exposure. Both chronic and acute symptomatic HCV infections are reportable to the local health department by health care providers and medical laboratories operating in Maryland.

According to national estimates, there are between 73,000 to 106,000 people in Maryland who have been infected with HCV during their lifetime.⁸ It was recently estimated that in Baltimore City there are currently 60,000 individuals with HCV and in the Baltimore-Washington area there are an estimated 150,000 individuals.⁹ Maryland has a disproportionate number of injecting heroin users compared to other states.¹⁰ A study on the transmission rates of HCV among injection drug users demonstrated that injection drug users are at high risk for HCV infection.¹¹ The study's findings further indicated that HCV infection occurs shortly after

⁶ NASTAD, "IOM Report on Hepatitis Implications for Health Department Hepatitis Programs", p.1.

⁷ Incidence and risk factors for Hepatitis C among injection drug users in Baltimore MD. By SA Villano et. al. *Journal of Clinical Microbiology* 1997:35, pages 3274-7.

⁸ The Prevalence of Hepatitis C Virus Infection in the US, 1999 through 2002, *Annals of Internal Medicine* 2006, May 16: 144 (10), pages 705-714.

⁹ Dr. Mark Sulkowski in a presentation at an FQHC Symposium on Hepatitis and TB, February, 2010, Baltimore MD

¹⁰ "Outlook and Outcomes", 2002 Annual Report of the Maryland Alcohol and Drug Abuse Administration. ADAA Publication number 03-2-001

¹¹ Correlates of Hepatitis C Virus Infections among Injection Drug Users, by DL Thomas et. al, *Medicine* 1995, July: 74(4), pages 212-20.

individuals initiate injecting illicit drugs.¹² Because HCV often causes no symptoms until late in the disease progression, many Marylanders living with HCV are asymptomatic and unaware of their infection.

2010 Activities

In 2010, viral hepatitis prevention and control activities included: utilizing federally funded staff, coordinating vaccine distribution, increasing public and provider awareness, coordinating between public and private sector agencies, and applying for funding from the public and private sector sources. These activities are described below.

Utilizing Federally Funded Staff

On November 1, 2010, DHMH will begin the fourth year of a five year Adult Viral Hepatitis Prevention Coordinator Cooperative Agreement from the Centers for Disease Control and Prevention (CDC). This cooperative agreement provides funding that supports a full time Adult Viral Hepatitis Prevention Coordinator (AVHPC) position. The AVHPC's role is to coordinate activities to prevent all types of viral hepatitis, including HCV, in Maryland.

In January 2010, the individual serving as the AVHPC transitioned out of the position. The AVHPC's duties were assigned to the Interim AVHPC in collaboration with the Chief of IDEHA's Center for HIV Prevention. Efforts commenced to recruit a Registered Nurse to fill the role of the primary AVHPC. A new AVHPC was hired and assumed the position on October 6, 2010. The individual serving as the Interim AVHPC will continue to support hepatitis prevention activities on a half time basis.

Coordinating Vaccine Distribution

Individuals who are infected with or at risk for contracting HCV should be vaccinated for hepatitis A and B. Hepatitis A or B infection can have significant impact on an individual who is infected with HCV. Since 2008, CDC has provided Maryland with an allotment of adult hepatitis B and combined hepatitis A/B vaccine doses. These vaccine doses are made available to local health departments to vaccinate high risk adults.

¹² Correlates of Hepatitis C Virus Infections among Injection Drug Users, by DL Thomas et. al, Medicine 1995, July: 74(4), pages 212-20.

In January 2010, DHMH requested 15,000 doses (with a market value of \$572,082) for this initiative. Maryland's award from CDC for the adult hepatitis vaccine was \$361,080 or 63% of the amount requested. From April through September 2010, more than 9,990 doses of vaccine were administered.

In September 2010, the CDC announced that it would discontinue funding this initiative. Efforts to find alternative sources of funds for hepatitis A/B and B vaccine have not been successful, but will continue.

Increasing Public and Provider Awareness

DHMH has pursued a number of opportunities to raise awareness about the importance of HCV prevention and to provide information about available resources to providers, partners, and community members. Activities included a collaboration between DHMH and the training coordinator for the Mid-Atlantic Association of Community Health Centers (MACHC). The goal of this collaboration is to plan and implement health care provider training programs at federally qualified health centers (FQHC), using a federal Health Resources and Services Administration (HRSA) grant to MACHC. These training sessions are designed to improve health outcomes for minority patients infected with tuberculosis (TB) and/or HCV by creating and implementing networking systems for coordinating comprehensive health care between HRSA health centers and health departments.

Another mechanism used to educate members of the public and providers is IDEHA's Regional Advisory Committees (RAC). RAC meetings are held four times per year in each of Maryland's five regions and are used to gather community input and to disseminate information to the community and to care providers. While RAC meetings primarily focus on HIV/AIDS, updates about viral hepatitis prevention, sexually transmitted infections (STI) and TB, have been provided at the RAC meetings beginning in March 2010.

DHMH conducted and supported activities commemorating Hepatitis Awareness Month in May 2010. The support included a press release and an educational presentation held at IDEHA's Calvert Street office. DHMH promoted the distribution of hepatitis educational brochures to individuals who may be at high risk for hepatitis. The information was disseminated by collaborating with other IDEHA programs such as: 1) the VOICES HIV prevention public

education project, which is conducted in venues such as parole and probation waiting rooms and public housing; and 2) the Faith Based Community Initiative, which partners with many religious organizations to provide prevention messages to their congregations. Additionally, brochures and fact sheets about the various forms of hepatitis for individuals at-risk and providers have been distributed to local health departments and other sites.

DHMH collaborated with a Johns Hopkins University graduate student to develop a poster to be used as part of a HCV public information campaign in Baltimore City. The graduate student worked with a graphic artist to create a HCV poster image which was designed to increase awareness about HCV among injection drug users. The Maryland Hepatitis Coalition requested and received private sector support to print the poster. These posters are being distributed to Maryland's local health departments, community based organizations, community health centers, and other organizations who serve populations at-risk for HCV.

Coordinating Between Public and Private Sector Agencies

A number of activities continue to be conducted to promote integration of hepatitis prevention and treatment services into existing programs and to educate professionals about viral hepatitis. DHMH is represented at a number of collaboration meetings. These include:

- Quarterly collaboration workgroup meetings with personnel from STI, HIV and TB statewide programs and Baltimore City Health Department;
- Monthly Department of Public Safety and Correctional Services infection control meetings;
- Monthly National Alliance of State and Territorial AIDS Directors Viral Hepatitis Work Group technical assistance conference calls;
- The Hepatitis C Corrections symposium;
- Bi-monthly Maryland Hepatitis Coalition meetings; and
- The Hepatitis B Free DC Network meetings; and
- Conference calls with AVHPCs from South Carolina and Ohio.

Another ongoing effort to promote integration of hepatitis related services into existing programs is the CDC-funded Hepatitis C Testing Project at FQHCs in Baltimore City. This project began in January 2010 at one clinic. The Department collaborated with a range of stakeholders in the overall planning and development of the project. The Department also worked with partners at the Johns Hopkins School of Public Health to develop a plan for enhanced surveillance to describe the burden of HCV patients at an FQHC in Baltimore City. The testing project utilized the MACHC training curriculum and incorporated the community health center model developed by the National Viral Hepatitis Technical Assistance Center at the New York State Health Department into project activities. The primary goals of the testing project are: 1) to increase the identification of HCV positive persons; 2) to provide counseling and referral to services for care and treatment, to the extent possible; 3) to improve health outcomes for HCV infected persons; and 4) to measure the burden of disease in this population and establish a risk-stratified prevalence.

The project components include:

- A letter of agreement between DHMH and the participating FQHC;
- Staff training;
- Implementation of a protocol to document, collect and analyze hepatitis C data, including risk factor information;
- Completion of a hepatitis C screening tool for all clients during the intake process;
- Provision of hepatitis C screening antibody testing as a voluntary, universal offering to clients who are 18 years or older, including walk-in patients;
- Provision of test results and their meaning; provision of post-test counseling and education about preventing transmission to others, and liver health;
- Referral to TB and substance abuse treatment, when appropriate;
- Offer of hepatitis A/B or B vaccination to patients with chronic HCV infection;
- Linkage to medical evaluation; and
- Linkage to clinical trials for patients for whom treatment is clinically indicated.

This project was initiated at the Men's Clinic at Total Health Care. The limited population provides increased ability to monitor progress. After the evaluation of the initial pilot site, a

determination will be made whether to extend the project to additional clinics at Total Health Care or other FQHCs. DHMH has worked extensively to recruit other FQHC sites to participate. CDC has allowed DHMH to extend participation in the project to a non-FQHC community based organization to ensure that available resources are maximized. Beginning early October 2010, Sisters Together and Reaching (STAR), a Baltimore City community based organization with extensive experience in hepatitis C testing began testing as part of the project.

Applying for Funding from Public and Private Sector Sources

There has been a lack of public and private sector funding opportunities for viral hepatitis prevention activities and technical assistance. DHMH submitted the application and progress report for the fourth year of the five year cooperative agreement that funds the AVHPC position. Given the recent decision by CDC to eliminate funding for Hepatitis A and B vaccines, DHMH is considering options for sustaining the access to hepatitis A/B and B vaccines for at-risk adults until health care reform implementation will provide greater access for this population.

Status of Report of the Advisory Council on Hepatitis C State of Maryland

Recommendation: Seek funding to develop user-friendly Internet based resources for HCV awareness and education, both for healthcare professionals and for the general public.

Status: DHMH is monitoring potential opportunities. No appropriate funding options have been available during this period.

DHMH is updating viral hepatitis pages on the DHMH website. The process is in the final stages of overall structural revision. Educational materials, resource links, and presentations will be included on the Viral Hepatitis web pages. Educational modules and presentations from a variety of sources such as CDC, U.S. Department of Veterans' Affairs National Hepatitis C Program, and the National Digestive Disease Information Clearinghouse will be available through their respective links.

Recommendation: Develop recommendations for HCV screening and treatment and assess compliance of all state and local agencies.

Status: While national recommendations for screening/blood testing and treatment have been published, screening/blood testing protocols at local health departments vary due to

resource constraints and significant barriers for treatment continue. Additionally, resource constraints at the State laboratory are a limiting factor in expanding screening. Challenges remain in the development of a policy aimed at integrating viral hepatitis into existing public health programs serving clients for whom screening is appropriate (e.g. STIs, HIV/AIDS, reproductive health, substance abuse, and mental health clinics.) Hepatitis integration efforts will be coordinated through IDEHA.

Recommendation: Support a Maryland-specific needs assessment to identify gaps in public awareness and professional education

Status: A comprehensive needs assessment has not been conducted and will likely not occur given the lack of funding.

Recommendation: Review current surveillance and case follow-up methods, and, if needed, seek funding for additional professional and/or clerical resources to ensure complete, accurate and timely case investigation, data entry, and triage of all HCV reports in Maryland and to ensure that all Maryland residents are aware of their status and how to access health care resources.

Status: Regulations governing reporting procedures of communicable diseases, including viral hepatitis, were updated in the Code of Maryland Regulations (COMAR) Reporting Procedures (COMAR 10.06.01.04). More detailed demographic information on reports will have a positive impact in case follow-up at the local health department level. Currently, fiscal and staff resources are not adequate to conduct complete case surveillance for HCV. Additionally, there are no resources for follow-up with Maryland residents to ensure that they know their HCV status. Further, there are no public resources to assist Marylanders with HCV in accessing health care for disease treatment and management.

Recommendation: Ensure that a schedule for annual review of the Maryland Hepatitis C Prevention and Control Plan is established and that this review includes comments solicited from HCV positive individuals and providers administering health care to patients living with HCV.

Status: A draft Maryland Viral Hepatitis Prevention Plan will be developed by DHMH. The plan will address all types of hepatitis. Revisions to the plan will reflect recommendations of the Hepatitis C Advisory Council.

Future Activities

The following activities are planned:

- Develop the Maryland Adult Viral Hepatitis Prevention and Control Plan, which will address all types of hepatitis. The Maryland Viral Hepatitis Prevention and Control Plan will guide viral hepatitis prevention and control activities and will serve as a framework for prioritizing initiatives and projects. One of the first duties of the AVHPC will be to draft a new timeline for completion of the plan and to begin to work on developing the plan. Once it is developed, potential opportunities of a funding source to implement the state plan and Hepatitis C Advisory Council's Recommendations will be identified.
- Develop a viral hepatitis education and public awareness plan. The plan will use existing resources to provide prevention messages to the public and to raise awareness among healthcare professionals, the populations at-risk, and the community at large about the public health crisis, and recommending potential new funding streams for testing, vaccination and treatment of viral hepatitis.
- Identify additional funding sources to enable the development of hepatitis prevention, care and treatment activities. Specific activities which are under consideration, should funds become available include:
 - Development of user-friendly Internet based resources for HCV awareness and education, both for healthcare professionals and for the general public.
 - Development of recommendations for HCV screening and treatment, and an assessment of compliance of all state and local agencies.
 - Development of a Maryland-specific needs assessment to identify gaps in public awareness and professional education.

- Review of current surveillance and case follow-up methods, and, if needed, ensure complete, accurate and timely case investigation, data entry, and triage of all HCV reports in Maryland and ensure that all Maryland residents are aware of their status and how to access healthcare resources.
- Purchase and distribution of hepatitis A/B and B vaccines to local health departments, federally qualified health centers and community based organizations.
- Beginning development of a plan to assist local health departments in the integration of screening, testing and counseling of adults at risk for adult viral hepatitis and referral for appropriate services into their existing programs.
- Collaboration with other relevant agencies to promote improved surveillance of viral hepatitis.

Resource Needs for Hepatitis Prevention

At the national level, there are a number of new and important hepatitis related developments that have taken place which indicate the need for more resources to be applied to hepatitis prevention. A recent Institute of Medicine (IOM) report *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C* (2010) found that the public health response to hepatitis needs to be significantly ramped up. According to the report, state health departments and federal agencies must receive adequate funding to effectively prevent and control hepatitis B virus and HCV. “The only dedicated federal funding for viral hepatitis is \$19.3 million from the Centers for Disease Control and Prevention. Of this, states receive \$5 million, which averages \$90,000, which is primarily used for funding an AVHPC. This provides for little more than a position in the health department and no core prevention services such as outreach, awareness and education, testing and screening, referral into care, social and peer support, and medical management. Additionally there is no federal funding for a national chronic hepatitis surveillance system to monitor hepatitis B and C incidence, prevalence and trends.

Without surveillance data, public health entities cannot fully describe or assess basic demographic trends and the full epidemiological impact of these diseases.”¹³

The IOM Report indicates that the following are consequences of the lack of hepatitis funding:

- Individuals do not know how to prevent infection;
- Individuals do not have adequate access to preventive services;
- Chronically infected individuals do not know that they are infected;
- Chronically infected individuals do not have adequate access to testing, support services and medical management;
- Providers neither test nor screen their patients;
- Providers do not know how to manage infected patients;
- Actual disease burden remains unknown because there is no national chronic surveillance system; and
- There remains insufficient understanding about the extent and seriousness of this public health problem overall.

In addition to the IOM report, an Interagency Working Group on Viral Hepatitis created by the Department of Health and Human Services is preparing to complete a national action plan this fall. Additionally, the House of Representatives’ Oversight and Government Reform Committee held a hearing on hepatitis in June 2010. The consensus of the hearing was that there is an urgent need for significant new funds for hepatitis prevention and treatment.

¹³ NASTAD, “IOM Report on Hepatitis: Implications for Health Department Hepatitis Programs”, p. 1, 2010