MARYLAND HEPATITIS C STRATEGIC PLAN

Maryland Department of Health

January 2019

MARYLAND
Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

January 21, 2019

The Honorable Nancy J. King
Chair
Senate Budget and Taxation Committee
3 West Miller Senate Building
Annapolis, Maryland 21401-1991

The Honorable Maggie McIntosh
Chair
House Appropriations Committee
121 House Office Building
Annapolis, Maryland 21401-1991

RE: 2018 Joint Chairmen's Report (p. 92) – Broad-based plan to address Hepatitis C in Maryland

Dear Chairs King and McIntosh:

The Maryland Department of Health (Department) respectfully submits the Joint Chairmen's Report on the Broad-based plan to address Hepatitis C in Maryland (p. 92). Specifically, the Department was asked to report on:

> *In January 2018, the American Civil Liberties Union of Maryland indicated that it would be instituting legal action concerning the criteria adopted by Maryland Medicaid for access to Hepatitis C therapies. In its response to that letter, the Maryland Department of Health (MDH) indicated that it was developing a broad-based plan to address Hepatitis C in the State. The language withholds funding until that plan is submitted to the budget committees.*

If you have any questions regarding this request, please contact Deputy Chief of Staff Webster Ye. He may be reached at (410) 767-6480 or at webster.ye@maryland.gov

Sincerely,

Robert R. Neall
Secretary

Maryland Hepatitis C Strategic Plan
January 2019

EXECUTIVE SUMMARY

Hepatitis C is a major cause of chronic liver disease and its related complications, including liver cirrhosis and hepatocellular carcinoma. To continue the work addressing this major health issue, Maryland intends to work towards the elimination of hepatitis C virus (HCV) as a public health threat by prioritizing the prevention, testing and treatment of infection with hepatitis C virus to reduce the number of new infections, ensure access to high-quality health care services and prevent the negative health impacts of this disease, particularly among groups at highest risk of disease. A comprehensive, broad-based strategy includes a 4-pronged approach that encompasses prevention and education, testing, treatment and strengthening the disease surveillance system.

The goals and strategies for Maryland's hepatitis C approach are outlined below:

Goal 1: Prevent new hepatitis C infections.

Strategy 1.1: Increase community awareness of viral hepatitis and decrease stigma and discrimination.

Strategy 1.2: Ensure that all people have access to HCV prevention services that are culturally and linguistically appropriate.

Goal 2: Expand hepatitis C testing, particularly among people who are high risk.

Strategy 2.1: Identify persons infected with HCV early in the course of disease through promotion of routine testing at key points of contact with service providers.

Strategy 2.2: Promote complete hepatitis C testing (RNA confirmatory, genotype, and liver fibrosis assessment) after a positive screening test.

Goal 3: Improve access to treatment and adherence services.

Strategy 3.1: Improve linkage to timely and accessible hepatitis C care and adherence services.

Strategy 3.2: Increase health care provider capacity to screen and treat hepatitis C in both rural and urban settings.

Strategy 3.3: Address the high cost of treatment drugs.

Goal 4: Enhance hepatitis C surveillance, monitoring and evaluation.

Strategy 4.1: Improve timely submission of complete HCV reports to state and local surveillance by laboratories and clinical providers.

Strategy 4.2: Expand reporting to include HCV RNA negative test results.

Strategy 4.3: Monitor HCV-related health services and outcomes through clinical data such as electronic health records, claims data, and information shared over the state's health information exchange (CRISP).

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INTRODUCTION

I. Background

Hepatitis C in Maryland

Hepatitis C virus (HCV) is a major cause of chronic liver disease, which places individuals at risk for liver cirrhosis, liver failure, hepatocellular cancer and other complications. Infection can be spread through exposure to infected blood, such as through injection drug use, needle stick injuries, birth to an HCV-infected mother or sexual activity. The U.S. Centers for Disease Control and Prevention (CDC) estimates 3.5 million individuals are living with HCV infection in the United States.[1] In Maryland, there has continued to be increases in chronic HCV reports with 7,922 cases in 2017 (Figure 1).[2] Between 2015 and 2016, 19 of the 24 Maryland jurisdictions experienced an increase in reported HCV cases. Seventeen counties had the highest number of HCV cases reported since before 2010.

According to HepVu, a website launched by Emory University Rollins School of Public Health in April 2017, the estimated number of Marylanders living with HCV antibodies in 2010 was 80,500 which is an estimated prevalence of 1,890 per 100,000 population.[3] This number is only indicative of people who have been exposed to HCV. In 2017, 7,922 cases of probable and confirmed chronic HCV were reported.[] The statewide average rate for newly reported cases in 2017 was 130.9 cases per 100,000 people (Figure 2).[4] From 2010 (103.4 cases per 100,000) to 2017 (130.9 cases per 100,000), the rate of chronic HCV reports increased by over 25 percent. Since there are hard-to-reach 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.

Baltimore City has the highest rate in the State of Maryland at 384.9 cases per 100,000 people; however, Somerset County follows with 335.7 cases per 100,000 people.[5] Cecil, Kent, Washington, Allegany and Dorchester counties are among the counties with the highest rates at 274.5, 216.7, 216.5, 192.7 and 189.7 reported cases per 100,000 people, respectively.[6]

It is important to distinguish that reported cases may have either acute or chronic HCV infection. The clinical case definition for acute HCV is dependent on the presentation of symptoms (e.g., jaundice, fever, headache, nausea) or elevated liver enzyme levels detected in a blood test.[7] However, due to the often-asymptomatic nature of HCV, most who become newly infected are not aware of their disease status. In addition, about 15-25% of acutely infected individuals spontaneously clear the virus without treatment.[8] It is thus difficult to make meaningful inferences about acute cases reported through surveillance because they are often vastly underestimated and not representative of true disease burden.

Diagnosis of chronic HCV usually occurs if a person has been infected for greater than six months and is done using two blood tests: a positive test for HCV antibodies (anti-HCV) as well as a positive RNA confirmatory test (either a nucleic acid test or HCV antigen test).[9] The state relies on mandatory clinical and laboratory reporting to generate estimates for newly reported cases of chronic HCV. Due to lack of clinical symptoms and regular screening, as well as the two-step process for screening, approximately half of individuals with HCV are unaware of their chronic infection.[10] For this reason, HCV is often referred to as the "silent epidemic."

[] Maryland uses the Centers for Disease Control and Prevention's 2016 case definition of chronic hepatitis C available at: https://wwwn.cdc.gov/nndss/conditions/hepatitis-c-chronic/case-definition/2016/

Figure 1. Number of Reported Chronic Hepatitis C Cases in Maryland, 2017

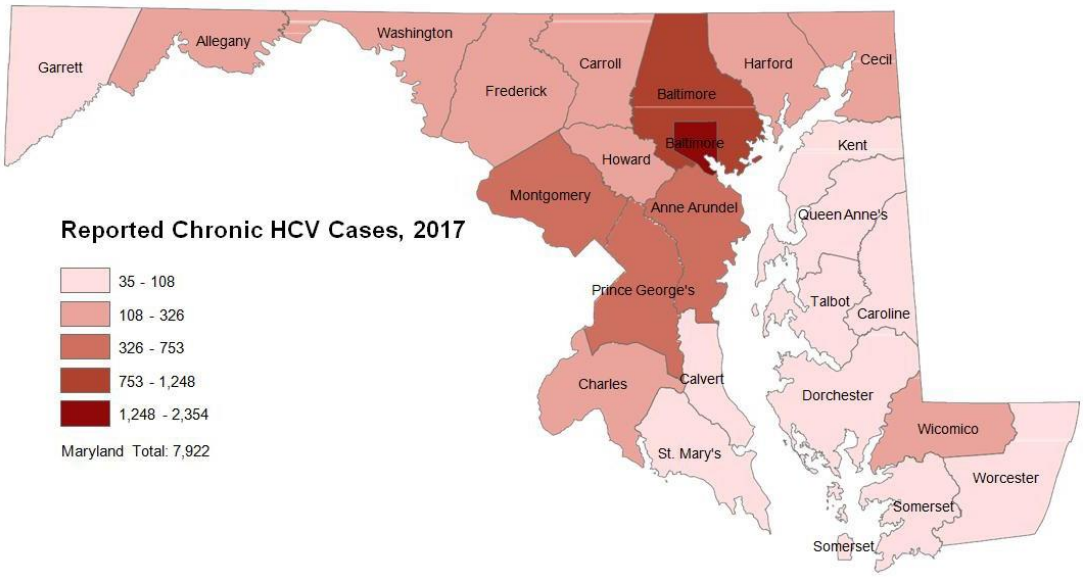
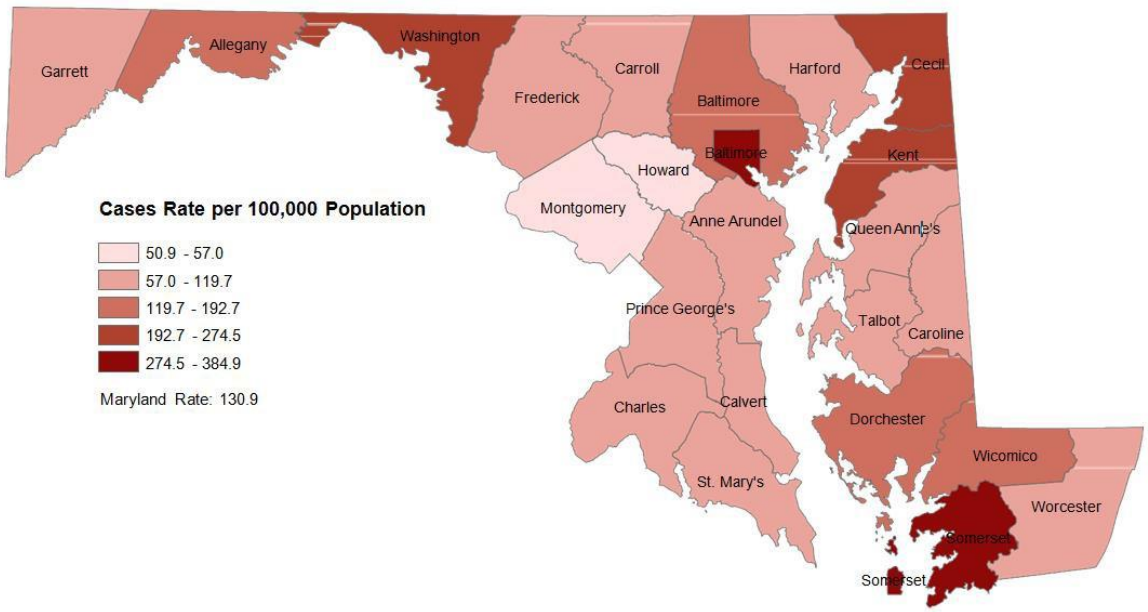


Figure 2. Rate of Reported Chronic Hepatitis C Cases in Maryland, 2017



Special Populations

According to estimates by the CDC, 25 percent of people with HIV are co-infected with HCV.[11] Reported data from 2016 showed that 4,032 people living with HIV in Maryland were co-infected with HCV.[12] 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).[13]

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.[14,15] While information about race and ethnicity is incomplete among reported cases, data from death certificates show a disproportionate impact among some racial and ethnic minority group. The 2016 U.S. rates of hepatitis C-related deaths are higher among American Indian/Alaskan Natives (10.8 deaths per 100,000 population), black non-Hispanics (7.4 per 100,000), and Hispanics (5.7 per 100,000) compared to white non-Hispanics (4.0 per 100,000).[16]

Hepatitis C infection can also occur through mother-to-child transmission during pregnancy. Rates of transmission vary between 2-14%, with a higher risk in women co-infected with HIV or who have injection drug use.[17,18] One report showed that the rate of HCV detection among women of childbearing age (15 to 44 years) being tested increased by 22% between 2011 and 2014 from 139 to 169 per 100,000, demonstrating that the risk in this group is growing, which in some areas of the country may be related to increasing injection drug use.[19]

People who inject drugs (PWID) are also at higher risk for having hepatitis C because needle-sharing behaviors increase the risk of infection, there is a relatively low utilization of health services and the stigma of substance use in the community, including among health care providers, which is seen as a barrier to seeking and obtaining appropriate care. In people 20-59 years with hepatitis C, 51% reported injection drug use as a potential risk factor or exposure.[20] A higher HCV prevalence exists among PWID, with some studies showing an estimated HCV antibody prevalence of 73% in the U.S.[21] In Maryland, 51% of PWID in Baltimore were reported to be HCV antibody positive between 2002 – 2004, indicating that these individuals have been exposed to HCV.[22]

Prevalence and incidence of HCV within corrections systems are also known to be very high, corresponding in part to the higher prevalence of substance use disorders in this population. The most recent data from Maryland are from 2002 during which investigators screened for anti-HCV antibody among newly incarcerated individuals in state correctional facilities over a two-month period. They found a prevalence of almost 30% in that population.[23] A more recent national estimate from the CDC reports 17.4% of inmates living with past or present HCV infection.[24]

Hepatitis C Treatment

Treatment for hepatitis C has changed considerably in the last decade. Previously, treatment was primarily comprised of pegylated interferon and ribavirin, which had significant side effects and relatively low efficacy when compared with the more recently introduced direct acting antivirals (DAA's), first approved by the Federal Drug Administration in 2011. The second generation of DAA's which came to the market in 2014 represent a significant improvement over the older treatment regimens because they are >95% effective, are taken for shorter durations, and have minimal side effects and drug interactions.[25] The primary barrier has been the high cost of an 8- to 12-week course of treatment, which ranged from $26,000 to more than $90,000, before rebates or discounts.[26] Drug prices have decreased over time with the introduction of lower cost medications such as glecaprevir/pibrentasvir (Mayvret), and it is anticipated that generic versions of ledipasvir/sofosbuvir (Harvoni) and sofosbuvir/velpatasvir (Epclusa) will be introduced in January 2019 at a list price of $24,000.[27]

The Maryland Medicaid program has long covered hepatitis C virus treatment in the state plan, including the newer direct-acting antiviral therapies first approved in 2013. Maryland generally

follows genotype treatment recommendations for testing, managing, and treating HCV as directed by the American Association for the Study of Liver Diseases. As of September 20, 2018, the Department covers the recently-approved glecaprevir/pibrentasvir (Mavyret) drug, as well as daclatasvir (Daklinza), elbasvir/grazoprevir (Zepatier), ledipasvir/sofosbuvir (Harvoni), ombitasvir, sofosbuvir/velpatasvir (Epclusa), sofosbuvir (Sovaldi), and sofosbuvir/velpatasvir/voxilaprevir (Vosevi).[28]

The Maryland Medicaid Pharmacy Program requires providers to submit prior authorization for new HCV therapies. As of December 1, 2018, the program treats patients with a Metavir score of F2 or above, unless the individual has a viral condition known to result in more rapid disease progression and/or liver decompensation than normally expected from the course of chronic HCV. However, Governor Hogan's most recent budget allowance includes funds to enable expansion of treatment to those in the Medicaid program with Metavir scores of F1 and above beginning in Fiscal Year 2020. The Metavir score indicates the level of liver damage, with the scale going from no fibrosis (F0) to cirrhosis (F4). A patient's entire medical history is also considered, including treatment history, history of substance use disorder, history of medication non-adherence, and co-occurring conditions (such as cancer or HIV) though the program does not have requirements based on specialty provider care or length of time in substance use treatment.[29]

II. Strengths and Challenges of the Hepatitis C System in Maryland

Maryland's existing viral hepatitis infrastructure provides a strong foundation for HCV prevention and control. The state's public health, healthcare, and other public and private sector partners are actively engaged in expansion of prevention, diagnosis, care, and treatment services for people living with HCV. The Maryland Department of Health has established programs that contribute to an improved HCV care system, including enhanced surveillance, increased screening in key populations including people with substance use disorders and in corrections facilities, expansion of medication assisted treatment for substance use disorders and integration of HCV screening and treatment into primary care.

However, a number of challenges remain. There is a general lack of awareness about the potential risk factors for having hepatitis C, consequences of infection and the need for testing and treatment. Because there may be few symptoms early in the disease course, many Marylanders do not know they are infected with HCV and live in jurisdictions where opportunities for testing are limited. In addition, the disease surveillance system relies on incomplete reporting from clinicians and institutions mandated to notify public health and does not have the ability to collect more detailed clinical information from those who are treated. The current opioid overdose epidemic also presents a threat for increased spread of the disease, with the increased number of people who are using illicit opioids and other drugs. Those with confirmed chronic infection may lack social supports and resources needed to link them to and sustain them during treatment and follow-up care. Both the disease and people with the disease face stigma, which can also contribute to reluctance to seek testing or treatment. Finally, while generic pharmaceuticals will be available, the cost has posed a threat to the health care system's ability to meet the demands of improving access and the overall health of the population while containing costs. This includes the state's responsibility to maximize public funds to be able to fully support treatment services among the low-income residents of the state. There is also a need to increase the number of community providers, particularly in underserved communities.

III. National and Global Perspectives on Hepatitis C

Worldwide, there are an estimated 130 to 150 million people living with chronic HCV infection. The advent of highly effective and well tolerated oral medications that cure HCV has led to a shift in focus from HCV control to disease elimination. According to the World Health Organization, global elimination of hepatitis C as a public health threat is an achievable goal.[30] In the United States, multi-disciplinary experts, convened by the National Academies of Sciences, Engineering, and Medicine, also concluded that the nation can eliminate HCV and published comprehensive national strategies to inform action towards national elimination of hepatitis C as a public health threat.[31,32] The U.S. Department of Health and Human Services released the National Viral Hepatitis Action Plan, 2017-2020 that provides a more detailed set of strategies that are similar to the National Academies' recommendations, including enhancing hepatitis testing, improving viral hepatitis surveillance, expanding access to syringe services and medication assisted treatment, and building the capacity of primary care providers to treat.[33]

To progress towards statewide HCV prevention and control, Maryland will build upon an infrastructure to employ and sustain strategic coordinated multi-sector efforts to increase both the awareness of the infection as well as opportunities to be tested and treated. This strategic plan outlines the goals, strategies and current activities to progress towards improved prevention and management of hepatitis C infection in the state.

MARYLAND HEPATITIS C GOALS AND STRATEGIES

I. Mission

Maryland will work towards the elimination of hepatitis C disease as a public health threat by prioritizing the prevention, testing and treatment of infection with hepatitis C virus (HCV) to reduce the number of new infections, ensure access to high-quality health care services and prevent the negative health impacts of this disease.

II. Goals and Strategies

Maryland's Hepatitis C Strategy builds on the foundation of programs and services that have been established since the 2002 Maryland Hepatitis C Prevention and Control Plan was released.[34] The plan is based on 4 pillars which provide the structure for the broad-based approaches needed in the state in order to achieve the mission (see Figure 3). The pillars include:

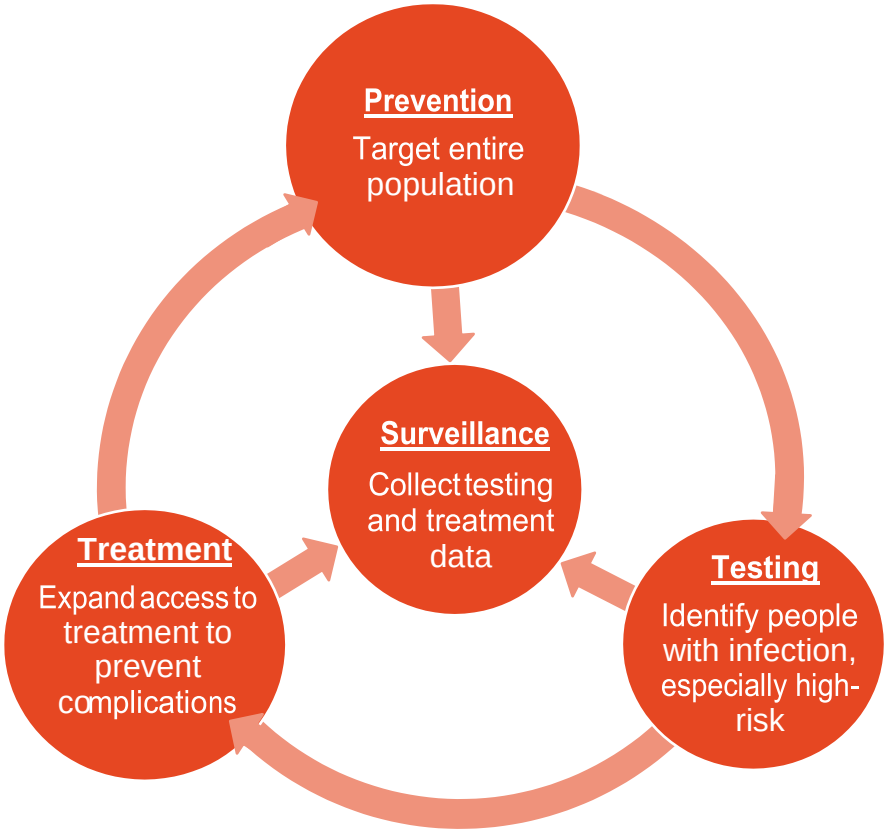
1) Prevent new hepatitis C infections;

2) Expand hepatitis C testing, particularly among people who are high-risk;

3) Improve access to treatment and adherence services; and

4) Enhance hepatitis C surveillance, monitoring and evaluation.

Figure 3. Maryland's Hepatitis C Strategy: Four Pillars



Goal 1: Prevent new hepatitis C infections.

Efforts to eliminate HCV must include primary prevention. As noted in the federal Health and Human Services' Action Plan, low public awareness about hepatitis and low perceived risk lead to late diagnoses, more severe disease outcomes, and premature death among those who are chronically infected.[35] Evidence-based prevention methods include educating individuals and communities about risk factors for HCV infection, risk reduction techniques, treatment options, and how to access testing and care. In addition to targeting the general population, Maryland's prevention efforts should focus on developing targeted interventions for populations at highest risk for HCV infection, especially people who inject drugs (PWID). HCV prevention efforts can build on existing partnerships with community- and faith-based organizations around the state.

Strategy 1.1: Increase community awareness of viral hepatitis and decrease stigma and discrimination.

Many people may remain unaware of risk factors for contracting HCV infection, such as age (people born between 1945 and 1965) or risky behaviors such as IV drug use. The introduction of highly effective cures for HCV is relatively new, and many are still uninformed about the availability of these new treatments with fewer side effects and better outcomes. An important aspect of promoting testing and treatment is that curing HCV prevents onward transmission of the infection, a concept of treatment as prevention. Social stigma about hepatitis C infection as well as about high-risk groups (e.g. people with history of substance use disorders or incarceration) can prevent people from seeking testing or treatment. Educating providers, communities, government, and law enforcement may reduce stigma of both HCV and drug use to further promote a test and treat approach for these populations. Increased messaging and education about the importance of routine screening is needed for people at higher risk for infection as well as health care providers. Education should include information about the availability and effectiveness of treatment and the personal and public health benefits of treatment.

Strategy 1.2: Ensure that all people have access to HCV prevention services that are culturally and linguistically appropriate.

Outreach and education on HCV prevention and treatment are needed for everyone, but especially important for high-risk populations such as people who inject drugs (PWID) and incarcerated persons. One key strategy is to target programs within settings such as prisons and jails, homeless and housing services, substance use treatment facilities, and peer networks of active drug users. Access to high-quality substance use disorder treatment and recovery support services, including medication-assisted treatment, can also reduce the risk of hepatitis C infection by decreasing risky behaviors and facilitate hepatitis C testing and linkage to treatment.

In addition to reducing overdose deaths and drug-use related injury, syringe service programs (SSP) can reduce new HIV and viral hepatitis infections by decreasing needle and other equipment sharing, providing infectious disease prevention education, and offering HIV and viral hepatitis testing. SSP's provide ongoing contact with, improve the health of, and encourage treatment for, persons who inject drugs. The 2016 authorization of SSP's in Maryland counties presented the opportunity for statewide implementation of harm reduction models that incorporate infectious disease prevention. The Department has partnered with local health departments and community-based programs to implement SSP, with 4 jurisdictions having operational programs as of August 2018. Local communities should work together across health, public safety, and community advocates to expand access to syringe services programs.

Goal 2: Expand hepatitis C testing, particularly among people who are high risk.

Identification of people with HCV requires that diverse and flexible opportunities for screening and confirmatory testing are available. Methods to increase universal testing in Maryland should build upon existing healthcare provider trainings on screening and diagnosis of HCV and increase resources to support testing, diagnosis, and linkage to care in non-clinical settings, including in the community. Increasing knowledge of hepatitis C status can also impact behaviors that can transmit infection; some studies have shown that people who are aware of being infected with hepatitis C have a decrease in risky behaviors such as needle sharing and injection drug use.[36]

The Centers for Disease Control and Prevention (CDC) recommends HCV testing for people based on their individual risks:[37]

- Adults born from 1945 through 1965 should be tested once (without prior ascertainment of HCV risk factors).
- HCV testing is recommended for those who:
    - Currently injecting drugs.
    - Ever injected drugs, including those who injected once or a few times many years ago.
    - Have certain medical conditions, including persons:
        - who received clotting factor concentrates produced before 1987.
        - who were ever on long-term hemodialysis.
        - with persistently abnormal alanine aminotransferase levels (ALT)
        - who have HIV infection.
    - Were prior recipients of transfusions or organ transplants, including persons who:
        - were notified that they received blood from a donor who later tested positive for HCV infection.
        - received a transfusion of blood, blood components, or an organ transplant before July 1992.
- HCV- testing based on a recognized exposure is recommended for:
    - Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood.
    - Children born to HCV-positive women.

However, while not explicitly included in the CDC recommended screening categories, there may be other groups who may benefit for hepatitis C screening, including pregnant women and people who have a history of incarceration, use non-injection illicit drugs or frequent non-licensed tattoo parlors.[38] It is also important to conduct risk-based screening for women of child-bearing age to prevent mother-to-child transmission.

Strategy 2.1: Identify persons infected with HCV early in the course of disease through promotion of routine testing at key points of contact with service providers.

Promoting routine testing is a key component of a comprehensive plan, particularly among high-risk individuals, including people who inject drugs (PWID), persons born between 1945 and 1965, persons who were formerly or are currently incarcerated. Approaches to improve the availability of testing in the community must engage all providers of care and services, including primary care providers, pharmacies, local health departments, syringe service programs, substance use disorder treatment centers, urgent care centers, hospital emergency departments, and community-based organizations.

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 a growing number of 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. While still limited in scope, increasing access to rapid testing in more locations has the potential to reach even more people.

Strategy 2.2: Promote complete hepatitis C testing (RNA confirmatory, genotype, and liver fibrosis assessment) after a positive screening test.

After an initial screening test is found positive, a viral RNA test is necessary to confirm HCV infection and is also used to track treatment response. Despite long standing clinical guidelines emphasizing the need for confirmatory HCV RNA testing following an initial reactive HCV antibody test, recent surveys have indicated that 50% of those with a positive HCV antibody have not completed HCV RNA testing.[39,40] New York City recently made RNA reflex testing a requirement for laboratories when they identify a reactive antibody test, and this may also be a strategy in Maryland. Additional testing, including viral genotyping and liver fibrosis assessment should be completed when an individual with confirmed hepatitis C infection is connected to a treatment provider to guide clinical decision making. At this time, Maryland law does not require reporting of this additional information to the MDH disease surveillance program.

Goal 3: Improve access to treatment and adherence services.

Early treatment in the course of HCV is associated with an overall reduction in morbidity and mortality as well as health care costs for treatment of complications of advanced disease including cirrhosis, liver transplant and liver cancer. A significant challenge to treatment of HCV has been the relatively high cost of new medications. Efforts to expand treatment access must continue to include strategies to reduce the cost of HCV medications. Some states have explored opportunities to work directly with pharmaceutical companies to negotiate lower drug costs charged to Medicaid to improve the feasibility of expanding HCV treatment criteria. Working towards removing barriers to treatment in Medicaid and commercial insurers and addressing care for those without insurance are key strategies.

Maryland must have a healthcare workforce sufficiently resourced, sizeable, and competent enough to address the burden of HCV in the state. The National Academies of Science recommend building the capacity of primary care providers to address HCV as a strategy for elimination. To expand the capacity of primary care in Maryland, clinicians need training to provide them with the tools and skills required to screen, diagnose, and treat HCV. Clinicians must also be able to effectively communicate to patients the benefits of screening, the benefits and risks of HCV treatment, and describe potential barriers HCV patients may encounter when seeking treatment coverage.

Strategy 3.1: Improve linkage to timely and accessible hepatitis C care and adherence services.

Screening is essential to identify persons living with HCV, and by increasing testing opportunities across the state, a greater number of previously undiagnosed individuals will be identified who will need to be referred for follow-up testing and treatment. A number of barriers can prevent or delay linkage to treatment and adherence to treatment regimens, including unknown insurance status, lack of provider referral, and patient drug or alcohol misuse. The next crucial step is linking diagnosed individuals to appropriate care and support, so they can receive and be able to adhere to the prescribed treatment and follow-up care. This is a strategy that has been successful among people with HIV such as through Ryan White case management services and has also shown similar positive outcomes among people with HCV infection.[41,42,43]

Maryland Medicaid currently provides hepatitis C treatment services to its enrollees who meet certain clinical criteria, including having a Metavir score of F2 or above. Table 1 presents HCV-related intervention data for CY 2016. Of the approximate 1.5 million individuals with any period of Medicaid enrollment in CY 2016, 61,849 received an HCV antibody test and 12,436 received an HCV RNA test for diagnosis of HCV. A total of 22,352 unique participants had an HCV diagnosis code, corresponding to an HCV prevalence of 1.47 percent among all Maryland Medicaid participants. Of the 22,352 participants with HCV diagnoses, 1,041 received non-interferon-based treatment. Assuming only people with an F2 score or above (an estimated 54 percent of people with chronic HCV are F2 or above, or 12,070 people) accessed treatment, the overall treatment rate was 8.62 percent.[44] Overall for CY 2015 and CY 2016, the percentage of eligible people receiving treatment is 11.64 percent across all Metavir score groups (average of proportion of people with F2 Metavir score or above that received DAA treatment in CY 2015 and CY 2016). Working towards the expansion of treatment criteria for low-income residents will allow additional people to be treated and cured.

Table 1. Frequency of Hepatitis C Interventions Among Medicaid Participants Meeting Clinical Criteria and with Any Period of Enrollment, CY 2016.

Total Number of Unique Participants	Unique Participants with HCV Antibody Test	Unique Participants with HCV RNA Test	Unique Participants with HCV Diagnosis Code	Unique Participants with Prescription for Interferon-Based HCV Treatment	Unique Participants with Prescription for Non-Interferon-Based HCV Treatment
1,535,414	**61,849**	**12,436**	**22,352**	*****	**1,041**

**Not reported due to small cell size.*

In addition to these efforts, targeted work must be done to address the special needs of key populations often at highest risk for infection.

People Who Inject Drugs

People who inject drugs (PWID) are one of the populations at highest risk for chronic HCV infection in Maryland. Therefore, primary care-based HCV interventions present one means to engage PWID. Partnerships with substance use providers and recovery support services are another key strategy in reaching this population. Syringe service programs (SSP) are also an important avenue to offer a comprehensive approach to harm reduction and support services for PWID. These programs include the integration of HCV testing and linkage to care. In 2019, the Department will launch a hepatitis C peer navigation program to help newly diagnosed SSP clients navigate linkage to HCV care in their respective communities.

Women of Child-Bearing Age

The number and rate of HCV infections among women of child-bearing age in the U.S. has increased—driven at in least in part by the opioid epidemic in some geographic locations.[19] Therefore, in addition to increased HCV screening among high-risk women of child-bearing age, additional efforts are needed to ensure that women who are diagnosed with HCV receive follow up care and treatment prior to becoming pregnant. Women diagnosed during pregnancy should receive HCV management in accordance with accepted standards of care to protect the health of the woman and her infant. This requires that providers have access to comprehensive guidance on how to care for pregnant women with HCV and monitoring of infants at risk for vertical transmission.

Currently or Previously Incarcerated Individuals

Hepatitis C disproportionately affects individuals who are currently incarcerated and individuals with a history of incarceration. The Maryland Department of Public Safety and Correctional Services (DPSCS) enrolls incarcerated individuals with HCV in a chronic care clinic. Each individual is then referred to and assessed by an infectious disease specialist. Finally, DPSCS' HCV panel completes a comprehensive clinical review and determines whether the inmate will begin treatment while incarcerated. Although a person may be released prior to treatment initiation, DPSCS makes every effort to begin treatment as soon as possible after a positive screening. In October 2017, the Maryland Department of Public Safety and Correctional Services (DPSCS) launched a Testing and Linkage to Care program in collaboration with Maryland Department of

Health. This program aims to increase the number of inmates who are aware of their HCV status prior to being released into the general population. Inmates due for release from corrections are tested using rapid HCV test kits. All inmates with a positive rapid HCV result and those known to be HCV positive are linked to clinical providers in their respective communities.

Strategy 3.2: Increase health care provider capacity to screen and treat hepatitis C in both rural and urban settings.

The burden of HCV disease far outstrips the capacity to treat expeditiously. More providers must be engaged to treat HCV in their practices. This means moving beyond specialist-only treatment. Studies have found no significant difference in sustained virologic response (SVR) among patients treated with direct acting antiviral (DAA) therapy prescribed by non-specialists versus specialists.[45] By engaging both specialists and non-specialists in HCV treatment, the state's overall capacity to cure HCV infection can be increased.

To increase the availability of HCV care in Maryland, health care providers throughout the state have taken the initiative to integrate HCV services into their practices or expand their HCV patient panel size to facilitate increased treatment access. To meet this need, the Department established the Maryland Community-based Programs to Test and Cure Hepatitis C ("Test and Cure Program") through a CDC grant totaling $1.2 million. 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, Baltimore County, Montgomery County, and Prince George's County, which are the Maryland counties with the highest prevalence of HCV. This work has revealed the substantial infrastructure and coordination necessary to implement and maintain high quality HCV service delivery. Additionally, it has demonstrated the need to develop clinical expertise related to HCV screening, care and treatment in community-based health care centers. Most importantly, it has increased the availability of HCV care in settings where individuals in the state's highest burden jurisdictions already access health care and other services. The Maryland Primary Care Program, an essential element of the State's Total Cost of Care Model,[19] launched in 2018 and will include primary care providers from across the state who could be part of these efforts to increase integration of comprehensive HCV care into their practices. Governor Hogan's Fiscal Year 2020 budget allowance includes state funds to continue the HCV surveillance after the CDC funding ends.

In 2015, the Johns Hopkins University, in collaboration with the Maryland Department of Health, launched a comprehensive clinical hepatitis C training and certification program for primary care providers in Baltimore City and Baltimore County. Titled *Sharing the Cure*, the HCV training and certification program for clinicians (physicians, physicians assistants, and nurse practitioners) was modeled after the University of New Mexico's Project ECHO (Extension for Community Healthcare Outcomes), clinicians from the participating clinical sites receive HCV certification upon completion of a one-day intensive training, a half-day preceptorship at an HCV specialty clinic, and ongoing videoconference training by leading specialists. Additionally, the training addresses the need for improved cultural competency of providers to care for the key populations noted in Strategy 3.1. Provider training in conjunction with developing internal clinical infrastructure to support HCV services is leading to the overall aims of increased screening and treatment at participating clinics.

The program's success is evidenced not only by staff outreach to over 1,600 people for HCV linkage to care and over 5,000 patients seen by trained providers, but also by interest in the training that surpasses the program's current capacity and requests from specialists and other medical professionals (e.g., pharmacists) seeking to participate in the training program. In 2019, the training program will expand to include clinicians who provide Ryan White HIV/AIDS services throughout

the state, including western Maryland and the lower Eastern Shore. Initiating an HCV training cohort for HIV care providers will increase HCV treatment among individuals co-infected with HIV and HCV. Additionally, the training program will run two simultaneous training cohorts for primary care providers, thereby doubling the number of trainees that will be certified in the coming year.

Strategy 3.3: Address the high cost of treatment drugs.

Hepatitis C drug pricing is a significant barrier to HCV treatment. The cost of some of the newer HCV direct-acting antivirals have been upwards of $90,000 for 8-12 weeks of treatment per patient.[♦] While the recent introduction of lower cost and effective DAA's have created downward market pressures on prices, many states continue actively exploring options to drive down the cost of HCV DAAs through a variety of strategies such as use of multi-state agreements with pharmacy benefit management companies, direct negotiation with pharmaceutical companies or purchasing patents for HCV DAAs. Generic versions of ledipasvir/sofosbuvir (Harvoni) and sofosbuvir/velpatasvir (Epclusa) will be introduced in the U.S. in January 2019, which will also continue to drive down costs and improve treatment accessibility. However, people who have high-deductible insurance or are uninsured may not be able to afford the total cost of treatment, including not only the medications but also health care provider visits and testing.

In the state's Medicaid program, due to the high cost of treatment, new HCV drugs are carved out of MCO capitation rates. The Department makes supplemental payments to the MCOs for the prescriptions prescribed to Medicaid participants. The Department pays the cost for Fee for Service (FFS) enrollees directly. Both the FFS program and MCOs are eligible for rebates, which make estimating the total cost of treatment difficult.

Using Medicaid data from CY 2016 about people treated with new HCV drugs, the total cost of treating 1,042 participants in Medicaid MCOs or FFS was $138,912,867, or about $133,000 per person before rebates. The cost was $71,000 after rebates, which accounts for 47 percent of the total per-person cost.[46] The actual amount per person may be lower if certain individuals required retreatment (if their HCV was not cured by the initial treatment course) or became re-infected. The cost per person has decreased further since that time as lower cost drugs have been introduced.

Similar to approaches employed by other states, the state may consider options to lower HCV drug costs paid by including an intra-agency approach to negotiation with pharmaceutical companies. Options to negotiate may include bulk purchasing at a fixed price. In considering these options, the state can utilize the assistance of and lessons learned from the National Governors Association's initiative to lower HCV treatment costs through collaboration between states and pharmaceutical companies. Additionally, the state could coordinate with all payers to identify strategies that can address costs to expand treatment availability and establish a standardized approach for covering HCV care and treatment.

♦ For Medicaid, this would represent the pre-rebate cost.

Goal 4: Enhance hepatitis C surveillance, monitoring and evaluation.

Both knowing the burden of HCV in Maryland and having the capacity to evaluate whether efforts to prevent and cure HCV infection are successful are essential to the development of effective elimination strategies. The Maryland Department of Health's Infectious Disease Epidemiology and Outbreak Response Bureau manages statewide surveillance processes and data for reportable infectious diseases, including hepatitis C. Currently, Maryland has a passive surveillance system with a limited capacity to investigate and monitor HCV infections at the local and state level. Reported cases often have incomplete information, such as about race demographics, which limits the ability to fully characterize the disease in Maryland. Working towards an improved HCV data collection system will allow the state to better understand the burden of HCV in Maryland and to evaluate whether efforts to prevent and cure HCV infection are successful, both of which are essential to the development of effective prevention and control strategies.

Strategy 4.1: Improve timely submission of complete HCV reports to state and local surveillance by laboratories and clinical providers.

Maryland has continued to expand electronic laboratory reporting (ELR), which will vastly strengthen HCV surveillance data. Laboratories are the source of the majority of reports of HCV in the state and ELR reduces the need for hand entry by surveillance staff at local health departments and makes timely data available through the electronic National Notifiable Diseases Surveillance System (NNDSS). In addition to laboratories, health providers are also accountable for reporting cases of HCV per COMAR 10.06.01.03. Educating providers about reporting responsibilities and encouraging adherence to regulation ensures more complete demographic and health data are included in surveillance cases reports. More complete and accurate surveillance data will require additional follow-up with providers by local and state health department staff. Such detail allows the state and local surveillance teams to better quantify and characterize disease burden, outcomes, and HCV-related health disparities. Governor Hogan's fiscal year 2020 budget allowance also includes state funds to further enhance the HCV surveillance system.

Strategy 4.2: Expand reporting to include HCV RNA negative test results.

Currently, only positive/reactive RNA tests for HCV are reportable. In order to accurately characterize the burden of HCV and the success of cure efforts, the Department must also have negative RNA test results. A negative HCV RNA test result after an initial positive test reflects cure (if tested twelve weeks after completion of a full treatment course) or spontaneous clearance of the virus, which occurs in about 15 – 25% of those infected. Without negative results, the prevalence of chronic HCV disease cannot be accurately reported, nor can the population-level impacts of the state's efforts to cure and prevent HCV. The Department will consider regulatory changes to establish a requirement for laboratories and providers to also report negative RNA test results.

Strategy 4.3: Monitor HCV-related health services and outcomes through clinical data such as electronic health records, claims data, and information shared over the state's health information exchange (CRISP).

Even with expanded surveillance activity, HCV population-level data will remain limited for some time and will likely not include important data points such as fibrosis staging and complete SVR data. These data could be monitored within other systems, such as large medical systems and insurers, to be able to follow more detailed information about testing, staging, and cure. Promising avenues for data to supplement surveillance include Medicaid and other insurers, large specialty

providers such as Johns Hopkins Viral Hepatitis Center, University of Maryland Medical System, and providers participating in the MDH-JHU Community Based HCV Test and Cure project.

In 2017, Maryland Medicaid and the Infectious Disease Bureau at the Prevention and Health Promotion Administration (PHPA) partnered to participate in a national Affinity Group for states working on hepatitis C-related projects. The Maryland team is working to improve collaboration and data sharing to gain a better understanding of the continuum from initial diagnosis to treatment for Medicaid enrollees. The team is developing a Cure Cascade, which is a visual representation of people in all stages of HCV care, from tested and diagnosed to treated and cured. Maryland anticipates developing Cure Cascades for each Medicaid MCO to identify strengths and opportunities for improvement in testing, diagnosis, and treatment. Additionally, Medicaid and PHPA are in the process of finalizing a data use agreement that will facilitate data matching to better identify high-risk enrollees with HIV/AIDS and HCV.

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