March 11, 2019

Admiral Brett P. Giroir, MD
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 715-G
Washington, DC 20201

Tammy R. Beckham, DVM, PhD
Director, Office of HIV/AIDS & ID Policy
U.S. Department of Health and Human Services
330 C Street SW, Room L001
Washington, DC 20024

Re: Update to the National Viral Hepatitis Action Plan

Dear Dr. Beckham:

On behalf of the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA), thank you for the opportunity to provide input on the update to the National Viral Hepatitis Action Plan. IDSA and HIVMA represent nearly 12,000 physicians, researchers, scientists and other healthcare professionals, including many who work on the frontlines of infectious diseases, providing prevention and care and conducting research in communities across the country.

Despite the availability of effective prevention and treatment for viral hepatitis including vaccines for hepatitis A and B and curative treatment for hepatitis C, the number of new cases continues at alarming rates in the U.S. with hepatitis C cases increasing about 3.5 fold from 2010 to 2016.[i] Similar to HIV, we have many of the tools to end the viral hepatitis epidemics, but there remains a significant divide between the science and access to services and treatment on the frontlines. The synergies between the viral hepatitis epidemics and the opioid epidemic have fueled spikes in new cases and challenged health care and public health systems in meeting the demand for prevention, care and treatment.

National Plan to Eliminate Viral Hepatitis

In 2016 and 2017, the National Academy of Medicine (NAM) released a series of reports with the first *Eliminating the Public Health Problem of Hepatitis B and C in the United States: Phase One Report* concluding that hepatitis B and C could be eliminated as a public health threat in the U.S. but not without overcoming significant obstacles.[ii] The second report *A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report* offered recommendations for reaching the goals of reducing hepatitis C incidence by 90 percent by 2030 and a reduction in mortality due to hepatitis B by 50 percent by 2030. This document highlighted the need for the federal government to oversee a coordinated effort to manage viral hepatitis elimination.[iii]

Given the NAM findings and recommendations, we strongly urge HHS to rename and redefine the action plan as a National Plan to Eliminate Viral Hepatitis. To do so will require strong, coordinated efforts that leverage the existing public health and research infrastructure across HHS agencies, including CDC, HRSA, SAMHSA, CMS and NIH to integrate approaches to the opioid, HIV and viral hepatitis epidemics. In the following comments, we combine recommendations from NAM and our members who have been leaders in responding to viral hepatitis. To support the following recommendations, increased federal investment in viral hepatitis prevention, care, treatment and research must be a critical component of the revised plan to reverse course on this worsening epidemic and achieve the goal of elimination.

Improve Surveillance and Access to All Effective Prevention Interventions

Strengthen Viral Hepatitis Surveillance Systems Across the Country: Enhanced and more sophisticated electronic surveillance systems are urgently needed to monitor better the viral hepatitis disease burden and to improve the targeting of both prevention and treatment resources.

Dramatically Scale Up Harm Reduction Programs: Syringe exchange programs are highly effective at preventing transmission of hepatitis C and other infectious diseases and must be dramatically scaled up and better resourced across the U.S.[iv] [v] New models for providing syringe exchange services also should be evaluated including through innovative partnerships with retail stores and pharmacies to improve accessibility to the services. In addition, safe consumption sites, which have significantly reduced overdose deaths and other harms due to injection drug use for nearly three decades in countries where they have been deployed, should be implemented without interference in jurisdictions that have approved them.[vi]

Increase Routine Screening and Vaccination for Hepatitis A and B: Screening for viral hepatitis and vaccinations for hepatitis A and B should be significantly expanded and provided in substance use treatment and syringe services programs, health departments, community health centers and other public health clinics without any barriers including cost sharing to those at risk. Recent hepatitis A and B outbreaks among individuals who inject drugs, men who have sex with men and individuals with unstable housing highlight the urgent need to increase access among adults to these easily administered and affordable vaccines.[vii] [viii]

Significantly Scale Up and Increase Access to Treatment

Eliminate Barriers to Treatment: We recommend requiring state Medicaid programs to eliminate restrictions on direct-acting antivirals (DAA) that currently have no clinical justification. The American Association for the Study of Liver Disease and the Infectious Diseases Society of America maintain guidance for treating hepatitis C that is regularly updated and widely recognized by providers as setting the treatment standard for hepatitis C.[ix] We strongly recommend that HHS requires that the utilization management techniques employed by state Medicaid programs adhere to the standards set by the guidance. With the availability of more DAA drugs for hepatitis C treatment, the cost has dropped significantly. The treatment regimen is cost-effective given highly effective responses of 98-99% using eight- to twelve-week courses. Despite the effectiveness of treatment and the importance of intervening early, providers continue to report denials by Medicaid programs that are delaying access to treatment without any clinical justification. *See attached Examples of West Virginia Medicaid Denials of Direct-Acting Antivirals submitted by an IDSA/HIVMA member*. Like HIV, scaling up treatment for patients with hepatitis C is important to improve health outcomes for the individual infected as well as to stop transmission of the virus. Treatment of HCV also should be prioritized to prevent new HCV cases similar to public health efforts to end the HIV epidemic by expanding access to treatment.

Address Workforce Shortages: While the pressing need for robust infectious diseases and HIV workforces continues to grow in response to the hepatitis C, opioid crisis and other public health epidemics, fewer physicians are pursuing this career path, due in large part to financial barriers. We urge that ID and HIV clinicians diagnosing and treating hepatitis C related to substance use be included in loan repayment programs designed to boost the workforce needed to care for patients with substance use disorders. This will be important for the recently launched NHSC Substance Use Disorder Workforce Loan Repayment Program and the new loan repayment program authorized by the Substance Use-

Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act that has yet to be fully funded or implemented. In addition, critical support is needed that expands grant funding to support infrastructure for telehealth services and enables the Centers for Medicare and Medicaid Services to develop and promote innovative reimbursement mechanisms to ensure the sustainability of telehealth programs.

Support Innovative Models to Reduce Treatment Costs: Given the scale of the hepatitis C epidemic and the individual and public health imperative to dramatically scale up treatment – we urge for HHS to pursue and support novel models for financing DAAs in safety-net settings, including Medicaid programs, the Indian Health Service and correctional settings. Models to pursue include the subscription model where a lump sum payment is negotiated with one or more companies to support expanded or universal treatment access. Such an approach is being implemented by the Louisiana Medicaid program and has proven successful in Australia.[x]

Address Prevention and Treatment Disparities for Justice-involved Individuals: Work with the Department of Justice to significantly expand the delivery of viral hepatitis prevention and treatment within correctional settings. Increase opt-out testing upon an individual's entry into the system and implement innovative approaches to lower treatment costs within correctional settings. Support and promote efforts under Medicaid and other federal programs to facilitate initiation of care and treatment for hepatitis C, HIV, substance use treatment and other services before release to support successful linkages to care in the community.

Increase Resources to Support Enhanced and Innovative Linkage and Retention Services through Community Health Centers, Substance Use Treatment Programs and other Public Health Clinics: Many persons with hepatitis C have multiple co-morbidities including HIV, substance use and mental health disorders that require resource-intensive case management services that are critical and necessary to improve health outcomes. Also, to improve care adherence and treatment outcomes, new delivery models that reduce access barriers, including by allowing walk-in visits and employing trauma-informed practices, are essential to provide the support necessary for patients with hepatitis C to achieve sustained viral suppression.

Expand Access to Medication Assisted Treatment: A dramatic scale-up of Medication Assisted Treatment (MAT) for substance use is urgently needed across health, public health and correctional settings. Increased resources are required to have a meaningful impact on the opioid epidemic and reduce the associated infectious diseases consequences, including transmission of hepatitis C.[xi] Ideally MAT should be integrated into the care of hepatitis C and other medical conditions or at a minimum MAT treatment and support services should be co-located.

<u>Increase Investments in Research on Hepatitis C</u>

Funding for hepatitis C research should be commensurate with its significant public health impact. Research is needed to evaluate models that are effective at co-treating viral hepatitis and opioid use disorder and to identify innovative approaches to linkage and retention in care. In addition, new treatment modalities such as injectables would reduce barriers to treatment for some populations. Safe consumption sites also should be evaluated for their potential to reduce overdose deaths in addition to their effectiveness at preventing infectious disease transmission and facilitating early detection and treatment of hepatitis C and other infections.

In the process for updating the national strategy for responding to the viral hepatitis epidemic, please consider IDSA and HIVMA members as a resource. We would welcome the opportunity to discuss these recommendations and others in more depth. We can be reached through the IDSA Senior Vice President for Public Policy and Government Relations Amanda Jezek at ajezek@idsociety.org or the HIVMA Executive Director Andrea Weddle at aweddle@hivma.org.

W. David Hardy, MD
Chair, HIV Medicine Association

Cynthia L. Sears, MD, FIDSA
President, Infectious Disease Society of America

---

[i] CDC. Viral Hepatitis Surveillance United States, 2016 Online at: https://www.cdc.gov/hepatitis/statistics/2016surveillance/pdfs/2016HepSurveillanceRpt.pdf.

[ii] National Academy of Medicine. Eliminating the Public Health Problem of Hepatitis B and C in the United States: Phase One Report. Online at: http://www.nationalacademies.org/hmd/Reports/2016/Eliminating-the-Public-Health-Problem-of-Hepatitis-B-and-C-in-the-US.aspx.

[iii] National Academy of Medicine. A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report Online at: http://www.nationalacademies.org/hmd/reports/2017/national-strategy-for-the-elimination-of-hepatitis-b-and-c.aspx.

[iv] CDC. Access to Clean Syringes. Online at: https://www.cdc.gov/policy/hst/hi5/cleansyringes/index.html.

[v] Canary, L, et al. Geographic Disparities in Access to Syringe Services Programs Among Young Persons With Hepatitis C Virus Infection in the United States. *Clin Infect Dis 2017;*65 (3): 514–517.

[vi] IDSA, HIVMA, SIDP. Policy Statement on the Evaluation of Safe Consumption Sites in the U.S. to Reduce Overdose Deaths and Prevent the Spread of Infections as Part of a Comprehensive Response to the Opioid Epidemic. April 2017.

[vii] CDC. Hepatitis A Outbreaks in the United States. Online at: https://www.cdc.gov/hepatitis/outbreaks/hepatitisaoutbreaks.htm.

[viii] CDC. The Rise in Acute Hepatitis B Infection in the U.S. Online at: https://www.hhs.gov/hepatitis/blog/2018/02/21/the-rise-in-acute-hepatitis-b-infection-in-the-us.html.

[ix] AASLD, IDSA. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Maintained online at: https://www.hcvguidelines.org/.

[x] Moon, S, Erickson, E. Universal Medicine Access through Lump-Sum Remuneration — Australia's Approach to Hepatitis C. N Engl J Med 2019; 380:607-610.

[xi] Del Rio, C, Springer, SA, Korthuis. Integrating Treatment at the Intersection of Opioid Use Disorder and Infectious Disease Epidemics in Medical Settings: A Call for Action After a National Academies of Sciences, Engineering, and Medicine Workshop. Ann Intern Med. 2018;169(5):335-336.

Attachment: Examples of West Virginia Medicaid Denials of Direct-Acting Antivirals

39 year-old female with PMH aggressive rheumatoid arthritis and untreated hepatitis c infection (genotype 1a, F0A0 via serum biomarkers and median liver elastography value) denied hep c treatment with 8 weeks Harvoni given lack of fibrosis. Rheumatology feels if her RA is left untreated will likely result in permanent disability and irreversible joint damage hesitant but have been hesitant to treat her RA with more aggressive options given untreated hepatitis c. Trialed sulfasalazine, hydroxychloroquine, prednisone. Appealed her case through insurer which was also denied. Patient was hesitant to start anti-TNF agent (etanercept) given side effects and administration concerns. She became frustrated and ultimately fell out of care in 2017.

33 year-old male with PMH injection drug use but has been clean well over a year and continues to do excellent in recovery on MAT Suboxone. Had been involved in church, coaching daughter's soccer team, working full time. Denied Harvoni x 8 weeks April 2018 for genotype 1A infection given lack of fibrosis (F2 or greater). Patient is F1-2, A3 via serum biomarkers Jan 2018, liver elastography median value consistent with F1. Recently seen in clinic Feb 2019 and experiencing profound fatigue he attributes to his hepatitis c that is greatly impacting his quality of life. Over the last 3 months has not been able to participate in the activities previously mentioned that he enjoys. He has demonstrated compliance with all of his follow up and there are not concerns he will not adhere with hep c treatment. He was submitted again for Harvoni x 8 weeks March 2019 with review still pending, but fibrosis level at this time is unchanged so will likely be denied. Plan to appeal his case.

32 year-old female with PMH stage III cervical cancer s/p radical hysterectomy and cystectomy with chemoradiation at age 29 complicated by fibrotic structuring necessitating partial bowel resection with colostomy and ileal conduit formation with stage III CKD secondary to obstructive nephropathy with multiple AKI insults who was denied hepatitis c treatment (naïve) with 8 weeks Mavyret for genotype 1a infection given lack of liver fibrosis (F2 or greater). She was eventually approved through the appeal process given her extent of renal disease.

21 year-old female denied hepatitis c treatment with 8 weeks Mavyret for genotype 3 infection given lack of fibrosis not being F2 or greater. (Patient is F1-2 via serum biomarkers, with HCV VL as high as 11.8 million). Her case was appealed to insurer as she is of childbearing age and wants to conceive. She is otherwise healthy and highly motivated for treatment with no concerns for noncompliance and no history of drug use. She expresses concern over transmission from mother to baby. Her appeal was denied.