

August 6, 2016

Centers for Medicare and Medicaid Services (CMS)
Attention: Proposed Decision Memo for Screening for Hepatitis B Virus (HBV) Infection
(CAG-00447N)

To Whom It May Concern:

Trust for America's Health (TFAH) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed decision memo regarding the inclusion of Hepatitis B virus (HBV) screening into the group of preventive services covered under Medicare. As a non-profit, non-partisan organization dedicated to saving lives and working to make disease prevention a national priority, TFAH believes the proposed decision could result in significant progress in disease prevention and early detection.

In 2010, TFAH and the American Association for the Study of Liver Diseases published a report, "HBV & HCV: America's Hidden Epidemics," which recommended steps to preventing and containing viral hepatitis in our country.¹ These steps include identifying the millions of Americans who may be infected with HBV but not know it. According to the Hepatitis B Foundation, 1 out of every 20 Americans is infected with Hepatitis B, for a total of 12 million.² Yet, as many as two out of three people with HBV do not know they have it, according to the Centers for Disease Control and Prevention.³ In addition, as many as 40,000 Americans become infected with the virus yearly and between 2,000 and 4,000 Americans die from liver disease complications associated with Hepatitis B yearly.^{2,4} Further, some populations are at disproportionately higher risk of becoming infected with Hepatitis B, including: individuals who are born in areas with high prevalence of Hepatitis B, those whose parents are from areas with high prevalence of Hepatitis B, and pregnant women.⁵

Screening is a crucial component of public health promotion and disease prevention, and is an integral tool in addressing Hepatitis B. According to the United States Preventive Services Task Force (USPSTF), screening not only correctly identifies those living with Hepatitis B, but also can reduce transmission and development of complications, such as liver cancer.⁶ Thus, given

¹ HBV & HCV: America's Hidden Epidemics. Trust for America's Health and AASLD. Sept 2010.
<http://healthyamericans.org/report/76/hepatitis-report>

² Statistics. (2016, January 15). Hepatitis B Foundation. Retrieved July 21, 2016, from
<http://www.hepb.org/hepb/statistics.htm>

³ Know Hepatitis B FAQs, Centers for Disease Control and Prevention. Retrieved August 1, 2016 from:
<http://www.cdc.gov/knowhepatitisb/faqs.htm>.

⁴ Chronic Viral Hepatitis and Health Care Reform. (n.d.). Retrieved July 21, 2016, from
http://nvhr.org/sites/default/files/docs/Viral_Hepatitis_Reform.pdf

⁵ High Risk Groups. (2014, March). Retrieved July 21, 2016, from http://www.hepb.org/professionals/high-risk_groups.htm

⁶ Screening for Hepatitis B Infection in Nonpregnant Adolescents and Adults: Consumer Guide. (2014, May). Retrieved July 21, 2016, from
<http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/hepatitis-b-virus-infection-screening-2014>

the significant health impact that Hepatitis B has on American communities, and the crucial role screening tests have in prevention and disease management efforts, Trust for America's Health supports CMS' proposed decision memo.

TFAH supports the decision to cover Hepatitis B screening under Medicare.

Hepatitis B screening strives to prevent the advancement of HBV by identifying infections sooner.⁷ Given that approximately one-third of those living with chronic hepatitis are asymptomatic, screening is a vital tool to achieve linkage to necessary care sooner and limit unintentional transmission.^{5, 8} Far too many cases of HBV go undetected until the disease progresses to cause serious complications, such as liver cancer or liver failure. By covering screening, CMS ensures that more individuals can have access to this health resource, and thus have the opportunity to, if necessary, be connected to relevant health resources to manage the disease and protect the health of their communities.

TFAH supports improving healthcare disparities by screening those at high risk for infection and pregnant women.

Hepatitis B disproportionately affects particular American subpopulations, such as the Asian American and Pacific Islander (AAPI) community. Half of the population living with Hepatitis B in the U.S. is AAPI, yet this population makes up only 5 percent of the country's population.⁹ In addition, the Hepatitis B virus can be transmitted from infected pregnant women to their children perinatally, and 30-40 percent of chronic Hepatitis B cases are due to perinatal transmission.^{10,11} Thus, coverage of Hepatitis B screening for these populations in particular is important in improving their health, linking access to necessary healthcare resources, providing preventive vaccinations when needed, and addressing health disparities. For "asymptomatic, nonpregnant adolescents and adults at high risk," screening not only allows for earlier detection of Hepatitis B, but also improved care management to prevent development of chronic disease.¹² For pregnant women, screening not only links the mother to relevant health resources, but also can virtually eliminate the risk she will transmit the virus to her baby if proper care is provided.

TFAH encourages CMS to extend coverage of Hepatitis B screening to other health care settings.

⁷ Chronic Viral Hepatitis Prevention Principles for Sound Health Care Reform. (2008, July). Retrieved July 21, 2016, from <http://nvhr.org/sites/default/files/docs/intro-to-prevention-7-28-09.pdf>

⁸ Closing the Gap in Hepatitis B Prevention, Screening and Care. (2011, June). Retrieved July 21, 2016, from http://nvhr.org/sites/default/files/NVHR_HBV_Advocacy_Brief_June_2011.pdf

⁹ Testing Asian Americans and Pacific Islanders for Hepatitis B. (2013, September). Retrieved July 21, 2016, from <http://www.cdc.gov/hepatitis/hbv/pdfs/hepb-api.pdf>

¹⁰ Perinatal Transmission. (2016, January 25). Retrieved July 21, 2016, from <http://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm>

¹¹ Final Recommendation Statement. (2009, June). Retrieved July 21, 2016, from <http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/hepatitis-b-in-pregnant-women-screening>

¹² Proposed Decision Memo for Screening for Hepatitis B Virus (HBV) Infection (CAG-00447N). (2016, July 7). Retrieved July 25, 2016, from <https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=283>

CMS' proposed decision restricts coverage of Hepatitis B screening under Medicare to primary care settings.¹⁰ This setting limitation may unintentionally hinder access to Hepatitis B screening in other health care settings--for example emergency departments, which often are entry points for care. By extending coverage of Hepatitis B screening to other health care settings, CMS can ensure that populations who may not have access to primary care resources, but still face high risk of infection, do not face unnecessary obstacles to vital screenings simply because of the setting in which care is delivered. Further, by extending coverage to other health care settings, CMS can reach a broader scope of the patient population, and thus have a greater impact on disparities in care.

Thank you again for issuing this important decision memo. We hope to see it finalized and implemented very soon. If you have any questions, please contact Dara Lieberman, TFAH's Senior Government Relations Manager, at dliberman@tfah.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Hamburg". The signature is fluid and cursive, with a long horizontal stroke at the end.

Richard Hamburg
Interim President & Chief Executive Officer