August 5, 2016

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd. Baltimore, MD 21244

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

Dear Ms. Jensen:

On behalf of the over 30 hepatitis B community coalitions and organizations representing *Hep B United* we write to express our appreciation and strong support of the Centers for Medicare and Medicaid Services' (CMS) Proposed National Coverage Determination Decision Memo for hepatitis B virus (HBV) screening in persons at high risk for infection, as defined by the United States Preventive Services Task Force (USPSTF). Up to 2.2 million Americans have chronic HBV infection.[i] Unfortunately, 67% are unaware of their infection, placing them at significant risk for advanced liver disease, liver cancer, and/or in need of a liver transplant. HBV is a primary risk factor for liver cancer---the 2nd deadliest cancer for men and women. According to the 2016 *Annual Report to the Nation on the Status of Cancer*, unlike most other kinds of cancer, liver cancer incidence and death rates are increasing.[ii]

We appreciate that CMS' National Coverage Analysis acknowledges that the body of evidence is sufficient to cover HBV screening for Medicare beneficiaries. This is in line with both United States Preventive Services Task Force (USPSTF) and the Centers for Disease Control and Prevention's (CDC) recommendations. USPSTF gave a grade of "B" for risk-based HBV screening, identifying those born in countries and regions with a high prevalence of HBV infection ($\geq$2%) as the most important risk factor of HBV. People born in the U.S. who were not vaccinated as infants and whose parents were born in a region with high prevalence of hepatitis B infection ($\geq$8%), as well as HIV-positive individuals, injection drug users, men who have sex with men, and household partners and sexual partners of people who are HBV infected are also significant risk factors/populations.

Hep B United is a national coalition comprised of over 30 community-based multisectoral coalitions and national partner organizations with a reach of over 4 million, working across 15 states and 25 cities to address and eliminate hepatitis B. Our goals are to 1) raise the profile of hepatitis B and liver cancer as an urgent public health priority; 2) increase hepatitis B testing and vaccination, particularly among Asian Americans and other at-risk communities; and 3) improve access to care and treatment for individuals living with hepatitis B to prevent end-stage liver disease and liver cancer.

HBV is associated with significant health disparities in the U.S. Both chronic HBV and hepatocellular carcinoma (HCC) disproportionately affect AAPIs, who make up 50% of the HBV infection burden in the U.S., and have liver cancer rates that are up to 13 times higher than Caucasian populations in the U.S.

The revised USPSTF hepatitis B screening recommendations are a significant advance in efforts to identify those with chronic HBV and link them to care, and a National Coverage Determination (NCD) from CMS stating the same would have similar benefits. We urge CMS to finalize the addition of hepatitis B screening as an "additional preventive service" in light of the new USPSTF evidence-based recommendations. Of the identified and reported cases of HBV in the U.S. between 2007 and 2012, 15.6% were over the age of 65 and part of the Medicare covered population. Those who are Medicare beneficiaries and are unaware of their HBV infection are likely to have been living with the disease for a very long time. It is vital to ensure they are screened and linked to care and treatment, before they develop advanced liver disease or liver cancer. Those with end stage renal disease are at higher risk for HBV infection and are less likely to respond to the HBV vaccine, and would benefit greatly from screening and subsequent linkage to care.

The limitation of coverage to screenings recommended by primary care practitioners in a primary care setting is inconsistent with Medicare regulations permitting the provision of preventive health assessments and care plan development in a broader array of settings. To clarify and strengthen the proposed decision on HBV screening coverage, we offer the following viewpoint for your consideration.

As a coalition representing community-based organizations, health clinics, community leaders, and physicians, we provide a number of HBV screenings in community-based settings. Conducting these screenings outside of the primary care provider space is essential in order to effectively address the needs of AAPI communities----many of those in our communities do not see a primary care provider (PCP) regularly if at all, and setting up a system in which these community-based screenings would be covered, following the Centers for Disease Control and Prevention's and USPSTF's guidelines would be incredibly beneficial to these patients most at risk. In 2014 alone, Hep B United partners combined, screened over 40,000 high-risk individuals for HBV infection, including many outside of the traditional primary care setting. Additionally, screenings conducted by specialists (i.e. gastroenterologists, hepatologists) need to also be covered. Currently, the average PCP is incredibly burdened and may not have the time to conduct HBV screenings along with the many other services that they provide in a short visit.

We support the recommendation that the determination of whether an individual is "high-risk" for the purposes of HBV screening ideally be made in conjunction with an assessment of the patient's history, "typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan." To this end, Medicare covers both an initial primary preventive exam (IPPE) and/or subsequent annual wellness visits (AWV) that include the creation of personalized prevention plan services (PPPS), and a health risk assessment (HRA). However, neither the IPPE or AWV are limited to performance by primary care providers or in primary care

settings.[iii] Therefore, if the NCD is adopted as written, it is possible that a medical provider (or team of providers) could perform an enrollee's IPPE or AWV but not have authorization to recommend screening for HBV. This could then require a separate appointment with a different provider for that purpose, working against the promotion of care coordination and efficiency. By extending screening coverage to a broader array of providers and settings, CMS could ensure that HBV screenings are a true preventive service.

CMS's own analysis does not provide any data or studies to support its determination that these screenings must be done in a primary care setting. Although there is no statutory or regulatory requirement to limit HBV screening to primary care, there is also no analysis of data or research in the NCD that would justify why this service should be so limited. The CDC's recommendations for screening both at-risk individuals, for example, are not limited to primary care---identifying other settings such as obstetrician and other physician offices, refugee clinics, substance use treatment clinics, and dialysis clinics.[iv] In addition, while the USPSTF makes recommendations based on primary care populations, there is not an explicit requirement in their recommendation that these screenings be performed by a primary care provider in a primary care setting. Additionally, there is no statutory requirement that services recommended by the USPSTF with an A or B grade rating be covered by insurers under only these circumstances.[v]

We thank and applaud CMS for including HBV screening under Medicare's Preventive Services, leading to improved health outcomes for Medicare beneficiaries. However, we strongly encourage CMS to expand the definition of screening settings to beyond primary care. We look forward to the finalization of these recommendations and encourage CMS to issue its final recommendation.

Sincerely,

Hep B United
Hepatitis B Foundation (Co-Chair)
Association of Asian Pacific Community Health Organizations (Co-Chair)
Asian and Pacific Islander American Health Forum
Immunization Action Coalition
National Center for Reducing Asian American Cancer Health Disparities
National Task Force on Hepatitis B
National Viral Hepatitis Roundtable
Asian American Health Coalition (HOPE Clinic), Houston, TX
Asian American Community Services, Upper Arlington, OH
Asian Health Coalition, Chicago, IL
Asian Pacific Community in Action, Phoenix, AZ
Asian Pacific Health Foundation, San Diego, CA
Asian Pacific Liver Center at St. Vincent Medical Center, Los Angeles, CA
Asian Services in Action, Inc., Cleveland, OH
Center for Asian Health, St. Barnabas Medical Center, Livingston, NJ
Center for Pan Asian Community Services, Atlanta, GA
Charles B. Wang Community Health Center, New York, NY
Dallas-Fort Worth Hepatitis B Free Project, Dallas, TX
Hepatitis Education Project, Seattle, WA
Hep B Project, Oakland, CA

Hep B United Philadelphia, Philadelphia, PA
Hep B United - Twin Cities (Lao Assistance Center of MN), Minneapolis, MN
Hep Free Hawaii, Honolulu, HI
Hep B Free Las Vegas, Las Vegas, NV
Hep B Free Los Angeles, Los Angeles, CA
Hepatitis B Initiative of Washington DC, Washington, DC
Midwest Asian Health Association, Chicago, IL
North East Medical Services, San Francisco, CA
New York City Hepatitis B Coalition, New York, NY
New Jersey Hepatitis B Coalition, Trenton, NJ
NYU Center for the Study of Asian American Health, New York, NY
Ohio Asian American Health Coalition, Columbus, OH
Project Prevention, Merced, CA
San Francisco Hep B Free, San Francisco, CA

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[i] Kowdley KV, Wang CC, Welch S, Roberts H, Brosgart CL. Prevalence of chronic hepatitis B among foreign-born persons living in the United States by country of origin. Hepatology 2012. 56(2): 422-433.

[ii] Ryerson AB, Eheman CR, Altekruse SF, Ward JW, Jemal A, Sherman RL, Henley SJ, Holtzman D, Lake A, Noone A-M, Anderson RN, Ma J, Ly KN, Cronin KA, Penburthy L, Kohler BA. Annual Report to the Nation on the Status of Cancer, 1975-2012, featuring the increasing incidence of liver cancer. Cancer 2016. 122(9): 1312-1337.

[iii] Regulations require that both the Initial Preventive Physical Exam (IPPE) and Annual Wellness Visits (AWVs) be performed by qualified health professionals, including physicians and/or other qualified non-physician practitioners. Physician in this context is defined by statute as a doctor of medicine or osteopathy, with no specification related to primary care as would be found in §1883(u)(6), §1833(x)(2)(A)(i)(I) or § 1833(x)(2)(A)(i)(II) of the Social Security Act. (See 42 CFR §§ 410.15-16).

[iv] Weinbaum CM, Williams I, Mast EE, Wang SA, Finelli L, Wasley A, Neitzel SM, Ward JW. Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection. MMWR 2008. 57(RR08): 1-20.

[v] For instance, insurers may use "established techniques and the relevant evidence base" to implement "reasonable medical management techniques to determine the frequency, method, treatment, or setting" for a preventive service recommended by the USPSTF, ACIP, or HRSA to the extent not specified by those bodies. This regulation therefore implies that there is not a pre-established setting in which USPSTF guidelines must be implemented. (See 75 FR 41726 (Jul. 19, 2010), 41728-9; 45 CFR §147.130(a)(iv)(B)(4)(4)). Moreover, CMS has not provided any reference to a "relevant evidence base" with respect to its primary care restriction.