The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

We, the undersigned organizations, are writing to express concerns about a significant barrier to hepatitis B virus (HBV) immunization affecting elderly (age 65 and over) and disabled (under age 65) Fee-for-Service (FFS) Medicare beneficiaries.

There are over 20,000 cases of acute HBV infections each year and more than $1 billion is spent on hepatitis B-related hospitalizations.[1,2] Despite the disease prevalence, HBV vaccine coverage remains low within the Medicare population. Currently, only 19.5% of adults ages 60 years and older received HBV vaccines, even though many Medicare beneficiaries have known risk factors (e.g., 28% of beneficiaries are diagnosed with diabetes mellitus).[3,]

The federal government recognizes the importance of HBV vaccines and understands that HBV vaccination would result in prevention of infections and associated cost savings.[4] We acknowledge our federal partners' commitment to realizing the goals of the Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021-2025). We also commend the Department of Health and Human Services' (HHS) implementation plan, which includes HBV vaccination among the action steps to be used to achieve the common goal of eliminating hepatitis B as a public threat.

In 2021, the Advisory Committee on Immunization Practices (ACIP) substantially expanded its adult hepatitis B vaccination recommendations. HBV vaccination is now recommended for adults aged 19-59, adults aged 60 years and older with risk factors for hepatitis B and adults aged 60 years and older without known risk factors "may receive" the vaccine.[5]

In just the last two years, federal HBV vaccination policy has evolved. Federal strategic goals and the implementation plan to eliminate hepatitis B, to be carried out alongside of the 2021 ACIP recommendations, present a unique call to action for the Centers for Medicare & Medicaid Services (CMS) to consider timely expansion of coverage and access to HBV vaccines by the FFS Medicare elderly and disabled population.

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[1] Center for Disease Control and Prevention. *Viral Hepatitis Surveillance Report 2019*. Available here
[2] Corte et al. J Gastroenterol Hepatol. 2014
[3] Centers for Medicare & Medicaid Services. *Data Snapshot November 2021 Diabetes Disparities in Medicare Fee-For-Service Beneficiaries*. 2021. Available here
[4] Hall, E, Rosenberg, E. *Economic Evaluation of Universal Hepatitis B Vaccination Among Adults*. Presented to the Advisory Committee on Immunization Practices. 2021. Available here
[5] Weng MK, Doshani M, Khan MA, et al. *Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices* — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:477–483. DOI: http://dx.doi.org/10.15585/mmwr.mm7113a1

By way of background, Congress added HBV vaccination as a Medicare Part B reimbursable service for those at "high or intermediate risk of contracting hepatitis B as determined by the Secretary under regulations" in 1986, subsequently codified by the Healthcare Financing Administration (HCFA) in 1990.[6,7] The statutory language allows Medicare Part B coverage of HBV vaccines as a preventive benefit for FFS beneficiaries at "high or intermediate risk", however the "risk-based" definition limits vaccine administration to traditional providers, such as physicians, in the in-office setting. By contrast, all other preventive Medicare Part B vaccines – influenza, pneumococcal and COVID vaccines – are eligible to be administered by traditional providers and non-traditional providers, or "mass immunizers," including pharmacists, chain drug stores, senior centers, or public health clinics.

Of note, the statutory "risk-based" definition of at the discretion of the Agency. We encourage CMS through rulemaking to expand the beneficiary population eligible for hepatitis B vaccine coverage. This would allow, like all other preventive Medicare Part B vaccines, hepatitis B vaccines to be included in the mass immunizer program. Research has shown that expanding the number of vaccination sites could improve access to vaccines.[8] Additionally, in light of ACIP's recommendation to alleviate the "risk-based" approach to protecting adults from hepatitis B, CMS must now utilize its rulemaking authority and facilitate improved FFS beneficiary access to HBV vaccines, including through the pharmacy.

This regulatory change will remove the discrepancy in equity and access to HBV vaccines between Medicare FFS beneficiaries, Medicare Advantage (MA) beneficiaries and Medicare Part D beneficiaries. Since most MA plans contract directly with pharmacies, pharmacists are allowed to administer all vaccines.[9] Where a pharmacy, or non-traditional provider, would be reimbursed for administering HBV vaccines to an MA beneficiary, they would not for an FFS beneficiary. Further, Medicare Part D permits pharmacies to bill for all Part D covered vaccines.[10] Pharmacists can be reimbursed for administering HBV vaccines to Part D beneficiaries, as long as the beneficiary is not at "high or intermediate risk". In effect, Part D beneficiaries at lower risk of contracting hepatitis B have broader access to HBV vaccination than FFS beneficiaries "high or intermediate risk" coverage under Medicare Part B.

Lack of parity in HBV vaccine access and provider reimbursement across all subsets of the Medicare population creates a health equity issue and creates provider and patient confusion. A physician may send an FFS beneficiary from the in-office setting to the pharmacy to receive their HBV vaccines, only for the patient to find that the pharmacist cannot administer HBV vaccines. This is confusing for the patient because they expect to receive their HBV vaccines the same way they receive other preventive Part B covered vaccines in the pharmacy. These patients, who are elderly or disabled FFS beneficiaries, deemed by their physician at high or intermediate risk of contracting hepatitis B, walk away without receiving their HBV vaccination.

Given the disparities in access and equity to preventive Part B vaccines by mass immunizers, we suggest CMS utilize its authority to allow all current preventive Part B vaccines, including HBV

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[6] SSA § 1861 (s)(10)
[7] 42 CFR § 410.63
[8] Prosser LA, O'Brien MA, Molinari NA, et al. Non-traditional settings for influenza vaccination of adults: Costs and cost effectiveness. Pharmacoeconomics. 2008;26(2):163-178. doi:10.2165/00019053-200826020- 00006
[9] Medicare Payment Advisory Commission. Medicare vaccine coverage and payment. Available here.
[10] Centers for Medicare & Medicaid Services. *MLN Fact Sheet: Medicare Part D Vaccines.* MLN908764. 2022. Available here.

vaccines, and all future preventive Medicare Part B vaccines, eligible to administered by mass immunizers. Although the statutory provision authorizing coverage of hepatitis B vaccines is the only place in the Medicare statute that uses the language “high or intermediate risk”, CMS should take further steps in its rulemaking to ensure FFS Medicare elderly and disabled beneficiaries can access all preventive Medicare Part B vaccines by mass immunizers. Such a policy would be a strong step towards improving beneficiary vaccine access by traditional providers and mass immunizers in more sites of care.

Lastly, in accord with the suggested regulatory expansion of HBV vaccine coverage, we recommend that CMS clarify that a physician order is not necessary for hepatitis B vaccines to be covered. This would remove a significant impediment to hepatitis B vaccination by mass immunizers and facilitate consistency in access to vaccines. All other preventive Medicare Part B covered vaccines, including the influenza, pneumococcal and COVID vaccines, may be administered to FFS beneficiaries without a physician order.

Precedent consistently demonstrates that CMS has employ its authority to eliminate vaccine access barriers for all beneficiaries. Examples include establishment of the mass immunizer program, modification of billing procedures to allow administration of preventive Part B vaccines by mass immunizers, previous lifting of physician order requirements and pointing to updated ACIP recommendations to support increasing the scope of Medicare coverage of hepatitis B vaccines. It is timely for CMS to utilize its rulemaking authority to include HBV vaccines, and future preventive Medicare Part B vaccines, to be administered by mass immunizers, without the physician order requirement. This is a critical step in fulfilling the expanded ACIP hepatitis B vaccination recommendation, bringing us closer to elimination of this preventable disease and bringing us closer to vaccine equity and access across the Medicare program.

Sincerely,

Access Support Network
African Family Health Organization
American Association for the Study of Liver Diseases (AASLD)
American Pharmacists Association (ApHA)
Any Positive Change, Inc.
Asian Liver Center at Stanford University
Asian Pacific Community in Action
Association of Asian Pacific Community Health Organizations (AAPCHO)
B-Free Houston
Balanced Imperfection
Being Alive - LA
California Hepatitis Alliance
Canon Senior Center
Caring Ambassadors Program
Community Liver Alliance
Community Youth Center

Delaware County Community Health
End Hep C SF
End The Epidemic: Californians Mobilizing to End HIV, Viral Hepatitis, STIs, and Overdose
Glide SF
Global Liver Institute
GPHA
Greater Philadelphia Health Action
Hawai'i Health and Harm Reduction Center
HBI-DC
Hep Free Hawai'i
Hepatitis B Foundation
Hepatitis C Allies of Philadelphia (HepCAP)
Hepatitis C Mentor and Support Group - HCMSG
HIV+Hep
Legacy Community Health
Liver Coalition of San Diego County
Mid-South Liver Alliance
NASTAD
National Asian Pacific American Families Against Substance Abuse (NAPAFASA)
National Harm Reduction Coalition
National Task Force on Hepatitis B
National Viral Hepatitis Roundtable (NVHR)
Pennsylvania Public Health Association
Pennsylvania Society of Gastroenterology
Prevention Point Pittsburgh
San Francisco AIDS Foundation
Self Help for the Elderly
SF Hep B Free - Bay Area
The AIDS Institute
Trans Legal Aid Clinic Texas
Treatment Action Group
Virginia Harm Reduction Coalition
Will Rodgers Liver Health Foundation