

September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8016,
Baltimore, MD 21244-8016

Via electronic delivery to www.regulations.gov

RE: CMS–1807–P Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

On behalf of the undersigned organizations, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) physician fee schedule (PFS) proposed rule for calendar year (CY) 2025.

We applaud CMS' proposals to alleviate barriers to hepatitis B virus (HBV) vaccination. The CY 2025 proposed rule addresses stakeholder concerns about disparities in access to HBV vaccination across Medicare beneficiaries. CMS proposes to encourage all unprotected Medicare beneficiaries to receive complete hepatitis B vaccination, streamline all Part B preventive vaccines access and payment across Part B settings of care, and takes further steps to facilitate enhanced beneficiary access to the hepatitis B vaccines. We agree with CMS that these policies will contribute to reducing the burden of this preventable disease and eliminating viral hepatitis in the U.S.

It is our pleasure to offer the following comments:

Hepatitis B Vaccination Coverage Expansion and Inclusion in Mass Immunizer Program

We support CMS' proposal to expand the Medicare beneficiary population for which hepatitis B vaccines can be covered. Under this expansion, individuals 65 years of age and above, and people with disabilities under 65 years of age, are determined to be at intermediate risk of contracting hepatitis B if they have not previously received a completed hepatitis B vaccination series, or if their previous vaccination history is unknown. This regulatory expansion is significant in lifting barriers to coverage that were previously determined by outdated risk recommendations, and is timely, especially considering the Advisory Committee on Immunization Practices (ACIP) universal adult hepatitis B vaccination recommendation. (The

ACIP recommends that adults 60 years and older with risk factors for HBV should be immunized and those without known risk factors “may receive” the vaccine.¹).

Concurrent with the regulatory expansion, CMS further proposes to clarify that a physician order is not necessary for hepatitis B vaccines to be covered, which would be consistent with the lack of a physician order requirement for other Medicare Part B covered vaccines. In addition, as with other Medicare Part B covered vaccines, CMS proposes to allow roster billing for hepatitis B vaccines, which augments beneficiary access to hepatitis B vaccines, including by allowing beneficiaries to receive hepatitis B vaccines through mass immunizers, such as pharmacies. Part B claims processing and reimbursement by mass immunizers will significantly expand the number of sites that offer HBV vaccines, particularly pharmacies, and research has shown that expanding the number of vaccination sites could improve access to vaccines.²

There are over 20,000 cases of new acute HBV cases each year and more than \$1 billion is spent on hepatitis B-related hospitalizations.^{3,4} As CMS notes, despite the disease prevalence, HBV vaccine coverage has remained low within the Medicare population with only 19.5% of adults ages 60 years and older vaccinated against HBV.⁵

CMS is proposing to not only eliminate barriers and expand Medicare beneficiaries’ protection against a vaccine preventable disease, but also in doing so, CMS is progressing Goal 4.1 of The Vaccines National Strategic Plan 2021-2025, “increasing the availability of vaccines in a variety of settings”⁶, bringing us closer to national viral hepatitis elimination and helping to overcome health equity disparities in Medicare and among adults. In addition, the proposed policies to expand access to vaccination in the pharmacy setting will help achieve completion of a multiple dose series, especially by those vulnerable Medicare beneficiaries with added challenges to accessing vaccination sites.

Lack of parity in HBV vaccine access and provider reimbursement across all subsets of the Medicare population has created a health equity issue and created provider and patient confusion.

The proposed policies would remove a significant impediment to hepatitis B vaccination by mass immunizers and facilitate consistency in access to vaccines. Hepatitis B vaccine

¹ 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>

² 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

³ Center for Disease Control and Prevention. *Viral Hepatitis Surveillance Report 2019*. Available [here](#)

⁴ Corte et al. *J Gastroenterol Hepatol*. 2014

⁵ Centers for Medicare & Medicaid Services. *Data Snapshot November 2021 Diabetes Disparities in Medicare Fee-For-Service Beneficiaries*. 2021. Available [here](#)

⁶ U.S. Department of Health and Human Services. *Vaccines National Strategic Plan 2021–2025*. Washington, DC. 2021. Available [here](#).

administration and reimbursement policy would also be streamlined and on par with all other preventive Medicare Part B covered vaccines, including the influenza, pneumococcal and COVID vaccines.

These policies comprise a critical step in establishing vaccine equity and access across the Medicare program.

Hepatitis B Vaccination in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

We support CMS' proposal to add hepatitis B vaccines to the list of vaccines covered in rural health clinics (RHCs) and federally qualified health centers (FQHCs) at 100 percent of reasonable cost.

As stakeholders keenly aware of the challenges Medicare beneficiaries face when receiving care in rural and urban areas of shortage, RHCs and FQHCs offer services to vulnerable seniors and disabled. This proposed policy encourages parity in reimbursement for hepatitis B vaccination and allows a consistent, streamlined approach for billing and payments of all Part B preventive vaccines across these critical Part B settings of care.

Future Preventive Part B Vaccines

We look forward to working with CMS further to expand the mass immunizer program to include all future preventive Part B vaccines. CMS has taken great strides to improve utilization of preventive vaccines by Medicare beneficiaries, particularly since the COVID-19 pandemic. Given the public health benefit of preventive immunization, and given the shift in the vaccine landscape to beneficiaries receiving vaccines by traditional providers and mass immunizers, we encourage CMS to consider inclusion of all future preventive Part B vaccines in the mass immunizer program.

We are grateful for your Agency's bold steps in addressing hepatitis B vaccine access and equity in Medicare. We strongly support finalization of CMS' proposals to expand the Medicare beneficiary population for which hepatitis B vaccination is covered, to remove the physician order and to allow mass immunizer administration and reimbursement of HBV vaccines.

Please contact Ryan Clary of the Immunization Alliance for Equity and Access at 323-810-6184 or clarystrategies@gmail.com if you wish to further discuss our comments.

Sincerely,

List in formation

Access Support Network

African Health Coalition
African Services Committee
American Academy of HIV Medicine
American Association of the Study for Liver Diseases (AASLD)
American Family Health Organization
American Pharmacists Association (APhA)
Any Positive Change, Inc.
Asian Center - Southeast Michigan
Asian Health Coalition
Asian Liver Center at Stanford University
Asian Pacific Community in Action
Asian Pacific Medical Student Association
Association of Asian Pacific Community Health Organizations (AAPCHO)
Avita Care Solutions
Being Alive - LA
Bienestar Human Services
BREATHE California
California Hepatitis Alliance
Canon Senior Center
Caring Ambassadors Program
Charles B Wang Community Health Center
Christie's Place
Community Liver Alliance
Community Youth Center
Delaware County Community Health
Empire Liver Foundation
End Hep C SF
End The Epidemics: Californians Mobilizing to End HIV, Viral Hepatitis, STIs, and Overdose
Glide
Global Liver Institute
Greater Philadelphia Health Action
Hawai'i Health and Harm Reduction Center
HBV Patient Advocate
Health Betterment Initiative

Hep B United Philadelphia
Hep Free Hawai'i
Hep Free South West Organization
Hepatitis B Foundation
Hepatitis C Allies of Philadelphia (HepCAP)
Hepatitis C Mentor and Support Group-HCMSF
HIV + Hepatitis Policy Institute
Illinois Public Health Association
Immunization Alliance for Equity and Access
Korean Community Services
Legacy Community Health
Liver Coalition of San Diego County
Malama Pono Health Services
Mid South Liver Alliance
Midwestern Asian Health Association
Mongolian Community Health Network
NASTAD
National Asian Pacific American Families Against Substance Abuse (NAPAFAMA)
National Association of Chain Drug Stores (NACDS)
National Harm Reduction Coalition
National Task Force on Hepatitis B
National Viral Hepatitis Roundtable
North East Medical Services (NEMS)
Ohio Asian American Health Association
Ohio Public Health Association
One Voice Recovery
Pennsylvania Public Health Association
Pennsylvania Society of Gastroenterology
PRC
Prevention Point Pittsburgh
Sacramento Area (S.T.O.P.) Hepatitis Task Force
San Francisco AIDS Foundation
Self Help for the Elderly
SF Hep Free - Bay Area

Taiwan Hepatitis Information & Care Association (THICA)
The African Family Health Organization (AFAHO)
The AIDS Institute
The Center for Health & Prevention of San Luis Obispo (CAPSLO)
The Hepatitis C Mentor & Support Group - HCMSG
The US Coalition for African Immigrant Health
Treatment Action Group
Tribal Health
United Liver
Virginia Harm Reduction Coalition
Will Rogers Liver Health Foundation