

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](http://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 This regulatory expansion is significant in lifting barriers to coverage that were previously determined by outdated risk recommendations, and is timely, especially considering the Advisory Committee on Immunization Practices (ACIP) universal adult hepatitis B vaccination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.<sup>1</sup>).

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.<sup>2</sup>

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.<sup>3,4</sup> 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.<sup>5</sup>

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”<sup>6</sup>, 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 administration and reimbursement policy would also be streamlined and on par with all other

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<sup>1</sup> 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>

<sup>2</sup> 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

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

<sup>4</sup> Corte et al. *J Gastroenterol Hepatol*. 2014

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

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

preventive Medicare Part B covered vaccines, including the influenza, pneumococcal and COVID vaccines.

These policies comprise is 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](mailto: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