

April 22, 2025

The Honorable Lori Chavez-DeRemer
Secretary
U.S. Department of Labor
200 Constitution Ave., N.W.
Washington, D.C. 20210

Re: Need for Federal Rulemaking to Close the Essential Health Benefits (EHB) Loophole

Dear Secretary Chavez-DeRemer,

We, the undersigned 80 organizations, who together represent patients, healthcare providers, caregivers, and communities affected by serious and chronic illnesses, write to congratulate you on your confirmation as Secretary of Labor. As advocates for solutions that help patients access, afford, and adhere to their prescription medications, we commend you for your previous efforts in your role as a Member of Congress to support policies that reduce Americans' prescription drug costs and bolster support for patient access initiatives.

We stand ready and eager to work with you in your new role to address key access and affordability challenges facing American patients and their families. As such, **we urge you to issue a promised rule to close the Essential Health Benefits (EHB) loophole.** By doing so you will end a scheme that insurers, pharmacy benefit managers (PBMs), and unscrupulous third-party vendors use to exploit drug manufacturer copay assistance programs meant for patients for their own financial gain. Insurers, PBMs, and third-party vendors do this by designating certain covered drugs as "non-essential" in order to evade cost-sharing protections in federal law. Not only does this lead to profiting by middlemen but increases the financial burden on patients as they try to access essential prescription medications and other health services.

A year ago, the Centers for Medicare & Medicaid Services (CMS) finalized a clarifying rule that protected Americans enrolled in individual market and small group plans from these exploitative benefit design schemes. At that time, the scope of the rule was limited in order to comply with the Administrative Procedures Act, but the rule's preamble stated that a future rule would be issued to extend these protections to large group and self-funded plans.^[1] Unfortunately, that rule has yet to be proposed.

In your leadership role at the Department of Labor, you now have the opportunity to fulfill this commitment by simply issuing a rule that clarifies that all drugs covered by a plan in the large group and self-funded markets are to be considered essential health benefits (EHB).

This is exactly what the **Help Ensure Lower Patient (HELP) Copays Act (H.R. 830)**, which you cosponsored in the 118th Congress, sought to accomplish. That bill would not only ensure that copay assistance counts towards patient cost-sharing requirements but also prohibit the practice of designating a covered drug as a non-essential health benefit.

^[1] "Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting." *Federal Register*, vol. 89, no. 71, 15 Apr. 2024, p. 26351, <https://www.govinfo.gov/content/pkg/FR-2024-04-15/pdf/2024-07274.pdf>.

It is ironic that insurers and their PBMs oppose manufacturer copay assistance programs while simultaneously utilizing these schemes that maximize the exploitation of assistance for themselves. Many insurers and their PBMs implement “copay maximizers” by designating certain covered drugs – usually the very ones with copay assistance -- as “non-essential,” enabling these players to divert and split all available copay assistance among themselves. Patients are forced to sign up with third-party vendors and are able to pick up their drugs at no cost. If they don’t, they are forced to pay full list price or high co-insurance rates of 30 percent or more.^[2]

Since the copay assistance does not count towards the patient’s maximum out-of-pocket in this instance, patients are forced to pay their deductible and other out-of-pocket costs for other health services and drugs. This increases patients’ health care costs and permits the insurer to collect far more money than would be allowed if they were required to abide by federal cost-sharing protections. Because they have been allowed to implement these schemes unchecked by the government, it is estimated that in 2024, 47 percent of a large sample of PBMs and insurers are implementing copay maximizers, more than double the number in 2020.^[3]

We urge the Department of Labor to work with the Department of Treasury to issue a regulation to close the EHB loophole as soon as possible. Issuing this rulemaking clearly aligns with the Trump administration’s healthcare priorities, ensuring all patients can access and afford life-saving prescriptions and eliminating insurer and middlemen profit schemes.

At the same time, we also urge you to work with the Departments of Health and Human Services (HHS) and Treasury to comply with a federal court order that requires copay assistance to count as cost-sharing for brand name drugs that do not have a generic equivalent.

Enacting this rule and complying with the federal court order would be an immediate win for the Trump administration and patients across the country.

We thank you for your leadership and continued attention to this issue that impacts millions of Americans. If you have any questions or if our organizations can be a resource to you, please contact Carl Schmid, Executive Director of HIV+Hepatitis Policy Institute at cschmid@hivhep.org.

Sincerely,

ADAP Advocacy Association
Advocacy House Services Inc.
Advocates for Responsible Care (ARxC)
AIDS Alabama
The AIDS Institute
Aimed Alliance
Alliance for Aging Research
Alliance for Patient Access (AfPA)
American College of Rheumatology (ACR)

^[2] "All Other Products – January 2024." *SaveOnSP*, Oct. 2023, <https://www.saveonsp.com/wp-content/uploads/2023/10/AllOther012024.pdf>.

^[3] Fein, Adam J. "Why Plan Sponsors and PBMs Are Still Embracing Copay Maximizers." *Drug Channels*, Feb. 2025, <https://www.drugchannels.net/2025/02/why-plan-sponsors-and-pbms-are-still.html>.

Arthritis Foundation
Autoimmune Association
Bienestar Human Services
Biomarker Collaborative
Cancer Support Community (CSC)
CancerCare
Caring Ambassadors Program
Chronic Care Policy Alliance (CCPA)
Color of Gastrointestinal Illnesses (COGI)
Community Access National Network (CANN)
Community Liver Alliance (CLA)
Connecticut Oncology Association
Crohn's & Colitis Foundation
Cystic Fibrosis Research Institute (CFRI)
Dermatology Nurses' Association (DNA)
Diabetes Leadership Council (DLC)
Diabetes Patient Advocacy Coalition (DPAC)
Dysautonomia International
Epilepsy Foundation of America
Equality California
Equitas Health
Exon 20 Group
Fabry Support & Information Group (FSIG)
Foundation for Sarcoidosis Research (FSR)
Georgia AIDS Coalition
Global Liver Institute (GLI)
GO2 for Lung Cancer
Hawai'i Health & Harm Reduction Center
HealthHIV
Healthy Men Inc.
HealthyWomen
Hemophilia Association of the Capital Area
Hemophilia Council of California (HCC)
Hep Free Hawai'i
Hepatitis C Mentor and Support Group (HCMSG)
Hereditary Angioedema Association (HAEA)
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation (IAF)
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
LUNGevery Foundation
Lupus and Allied Diseases Association, Inc. (LADA)
Lupus Foundation of America (LFA)
MET Crusaders
Mississippi Oncology Society (MOS)
MLD Foundation
National Alliance of State & Territorial AIDS Directors (NASTAD)
National Consumers League (NCL)

National Infusion Center Association (NICA)
National Psoriasis Foundation (NPF)
Neuropathy Action Foundation (NAF)
Nevada Chronic Care Collaborative (NCCC)
NTM Info & Research, Inc.
Ohio Hematology Oncology Society
Ohio Sickle Cell and Health Association
Patient Access Network (PAN) Foundation
Partnership to Fight Chronic Disease (PFCD)
Patients Rising
PD-L1 Amplifieds
Pharmacists United for Truth and Transparency (PUTT)
PlusInc
Prevent Blindness
Pulmonary Hypertension Association (PHA)
RetireSafe
Silver State Equality
Solve M.E.
Southwest Recovery Alliance
Spondylitis Association of America (SAA)
Triage Cancer
Virginia Hemophilia Foundation (VHF)
Western Pennsylvania Bleeding Disorders Foundation