July 15, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Comments in response to the Request for Information on Essential Health Benefits [CMS-9874-NC]

Dear Administrator Oz:

We, the undersigned 96 organizations, on behalf of millions of patients and American consumers who live with complex medical conditions and chronic illnesses that rely on prescription drugs to remain healthy and alive write in response to the Request for Information on the Comprehensive Review of the Essential Health Benefits and Typical Employer Plan.

While the Affordable Care Act (ACA) provides the opportunity for the Secretary of Health and Human Services (HHS) to periodically review the definition of Essential Health Benefits (EHBs), **we caution HHS from making any changes or developing any new framework that would reduce the level of prescription drug coverage for beneficiaries. We believe that the current framework and requirements governing prescription drugs that are based on benchmark plans and allow states to add additional benefits are generally working well for patients.** Our biggest concerns are the lack of adequate prescription drug coverage, the lack of enforcement of all EHB regulations, and allowing insurers and pharmacy benefit managers (PBMs) to skirt the EHB law and regulations. Below are our recommendations to strengthen prescription drug coverage and enforcement of existing EHB protections.

Need to Enforce EHB Requirements

There are several EHB laws and regulations, in addition to minimum coverage requirements, that all plans must comply with, including cost-sharing definitions and limits, and discriminatory plan design. Unfortunately, in some instances insurers are violating these EHB requirements and, in others, the federal government is allowing them to bypass the law creating cost barriers for patients as they access their prescription medications. Therefore, we urge the federal government to enforce the current requirements and take any necessary actions, including regulatory changes, to ensure compliance with the law so that patients can access and afford the prescription medications they need.

Cost-sharing Violations: The ACA defines cost-sharing and provides for out-of-pocket maximums, limiting overall out-of-pocket costs on all EHBs. Unfortunately, more and more insurers and PBMs have instituted harmful policies that do not apply copay assistance toward beneficiaries' out-of-pocket costs and deductibles. These copay accumulator policies violate existing EHB regulations that define

"cost-sharing" as "any expenditure required by ***or on behalf of*** an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services" 45 CFR § 155.20 (emphasis added).

Copay accumulators significantly increase out-of-pocket costs for patients, allowing insurers to "double dip" and capture these revenues twice, first directly from the drug manufacturer copay assistance and then, secondly, from the beneficiary who is forced to pay the out-of-pocket costs since the manufacturer assistance was not applied. In doing so, we believe they are collecting more money than they are entitled to, violating the ACA EHB requirements.

The federal government must enforce the law, which was reinforced by a court decision handed down almost three years ago but is still not being enforced. On September 29, 2023, the United States District Court for D.C. in *HIV and Hepatitis Policy Institute et al. v. HHS et al.* struck down the section of the *2021 Notice of Benefits and Payment Parameters* rule that allowed issuers to decide if copay assistance can count or not and clarified that the *2020 Notice of Benefits and Payment Parameters* rule is now in effect. That rule stated that issuers must count copay assistance for brand name drugs without a generic equivalent and not implement copay accumulators.

The Court also gave the federal government the option to issue a new rule defining "cost-sharing." However, after all this time, the federal government has neither provided guidance to issuers to follow their legal obligation to count copay assistance nor issued a new rule.

Every day that this rule is delayed, patients are forced to pay more for their prescription drugs while insurers and PBMs continue to pocket billions of dollars meant for patients who are struggling to afford their medications.

We urge the federal government to uphold the Court's decision, and, if a new rule is proposed, ensure that copay assistance count as cost-sharing, as it is the only reading of the term "cost-sharing" that CMS can lawfully adopt.

Discriminatory Plan Design: The ACA and its implementing EHB regulations are very clear regarding prohibiting discrimination against beneficiaries with pre-existing conditions and specific health needs. The ACA states that plans providing essential health benefits can "not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life."

The implementing regulations reinforce this. Plans must cover a broad range of drugs across therapeutic categories and classes, provide access to drugs included in broadly accepted treatment guidelines, and avoid benefit designs that discourage enrollment by any group of patients. A plan does not provide EHB if its benefit design discriminates based on a person's age, expected length of life, disability, degree of medical dependency, quality of life, or health condition, and a non-discriminatory design is one that is clinically based. CMS has also made clear that it is presumptively discriminatory to

place all or a majority of drugs for a particular condition on a high-cost tier.

These EHB patient protections must be preserved and fully enforced. Benefit designs that result in high cost-sharing, particularly for prescription drugs, should be examined by CMS and state regulators to determine whether they are discriminatory.

To enforce the EHB nondiscrimination rules, CMS must give state regulators adequate tools to conduct annual, thorough plan reviews, and states must review plans and take enforcement action against issuers that are not in compliance. Plans should also include knowledgeable patient representatives on their Pharmacy and Therapeutics committees.

Erosion and Evasion of EHB Protections

There are other schemes insurers, PBMs, and new third-party actors in the drug supply chain are implementing that seek to get around the intent of the ACA that further restrict access to prescription medications that the federal government must address.

Copay Maximizers: Some plans designate certain medicines as "non-essential health benefits" to evade ACA out-of-pocket maximums and then raise the cost-sharing in order to exhaust all available patient assistance offered by the manufacturer while not counting it towards the beneficiary's cost-sharing obligation. For example, one vendor that works with employers that offer these schemes, now designates over 500 drugs as "non-EHB." Under this arrangement, known as a "copay maximizer," plans often collect payments far exceeding the out-of-pocket maximum. Plans should not be able to cover certain drugs and then pick and choose which ones will count toward a beneficiary's out-of-pocket obligations.

It is ironic that insurers and their PBMs publicly oppose manufacturer copay assistance programs while simultaneously implementing policies that maximize the exploitation of assistance for themselves. The drugs they designate as "non-EHB" are precisely those drugs that come with generous copay assistance programs, which enables them to divert and split all available copay assistance among themselves.

CMS codified in the *2025 Notice of Benefit and Payment Parameters* that prescription drugs covered in excess of the state's benchmark plan are to be considered EHBs in the small group and individual markets, and therefore, subject to EHB protections, including annual cost-sharing limits. However, it did not make the same clarification for the large group and self-funded markets, though it said the federal government would do so in the future.

We urge the federal government to issue a rule that clarifies that that all covered drugs are considered EHB for all markets.

Alternative Funding Programs (AFPs): In addition to entities that designate "non-EHB drugs" in order to extract manufacturer copay assistance, there are other vendors that also use "non-EHB drug" designations and other means to implement alternative funding programs. In these programs, patients who use certain medications are directed to enroll in an alternative program (which is not insurance) in

order to bypass ACA laws and regulations relative to patient cost-sharing limits and other patient protections. They then find alternative funding mechanisms, such as illegally imported drugs or patient assistance programs, to supply the drugs to the patient. If the patient does not comply, they will be left paying the full cost of the drug.

There are a growing number of vendors that are working with insurers, employers, and PBMs around the country that are implementing these programs. **The federal government must investigate and prohibit these harmful schemes.**

We thank you for the opportunity to share these comments and look forward to working with you as you seek to make healthcare more affordable and assessable for more Americans.

If you have any questions or comments please contact Carl Schmid, executive director of the HIV+Hepatitis Policy Institute at cschmid@hivhep.org. Thank you very much.

Sincerely,

60 Plus Association
ADAP Advocacy Association
Advocacy House Services Inc.
Advocates for Responsible Care
AiArthritis
AIDS Action Baltimore
AIDS Alabama
Alliance for Aging Research
Alliance for Patient Access
American Association of Senior Citizens
American Behcet's Disease Association
American Kidney Fund
American Liver Foundation
Any Positive Change Inc.
APLA Health
APS Foundation of America, Inc.
Arthritis Foundation
Association of Black Cardiologists
Asthma and Allergy Foundation of America
Autoimmune Association
Axis Advocates
Bienestar Human Services
Biomarker Collaborative
Bleeding Disorders Council of California & CA Rare Disease Access Coalition
California Chronic Care Coalition
Cancer Support Community
Cancer*Care*
Caregiver Action Network
Caring Ambassadors Program
Chronic Care Policy Alliance
Coalition of Skin Diseases
Coalition of State Rheumatology Organizations
Color of Gastrointestinal Illnesses
Community Access National Network
Community Liver Alliance
Connecticut Oncology Association
Crohn's & Colitis Foundation
Derma Care Access Network
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Epilepsy Foundation of America
Equality California
Equitas Health
Exon 20 Group
FORCE: Facing Our Risk of Cancer Empowered
Foundation for Peripheral Neuropathy
Foundation for Sarcoidosis Research
Georgia AIDS Coalition
Global Coalition on Aging
Global Healthy Living Foundation
Good Days

HealthHIV
Healthy Men Inc.
HealthyWomen
Hereditary Angioedema Association
HIV+Hepatitis Policy Institute
Hope Charities
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
International Myeloma Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Colorado
Lupus Foundation of America
MET Crusaders
Multiple Sclerosis Foundation
National Association of Nutrition and Aging Services Programs (NANASP)
National Consumers League
National Hispanic Council on Aging
National Infusion Center Association
National Oncology State Network
National Scleroderma Foundation
Neuropathy Action Foundation
Nevada Chronic Care Collaborative
NRG1 Energizers
Oncology Nursing Society
Organization for Latino Health Advocacy
Partnership to Fight Chronic Disease
Patients Rising
PDL1 Amplifieds
Pharmacists United for Truth and Transparency
PlusInc
Prevent Blindness
Pulmonary Hypertension Association
RetireSafe
Shercare
Silver State Equality
Solve M.E.
Spondylitis Association of America
The Bonnell Foundation: Living with Cystic Fibrosis
The Hepatitis C Mentor and Support Group—HCMSG
The Mended Hearts Inc.
The National Pancreas Foundation
Tigerlily Foundation
Treatment Action Group
Triage Cancer
U.S. Pain Foundation