

January 31, 2023

Dr. Ellen Montz
Deputy Administrator and Director
Center for Consumer Information & Insurance Oversight
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Comments in response to the Request for Information on Essential Health Benefits [CMS-9898-NC]

Dear Deputy Administrator Montz:

We, the undersigned 50 organizations, on behalf of millions of patients and American consumers who live with complex conditions such as HIV, autoimmune diseases, cancer, diabetes, lupus, hemophilia, mental illness, hepatitis, neurological diseases, and other chronic illnesses, write to respond to the [Request for Information on Essential Health Benefits](#).

We are pleased that CMS is conducting this long overdue review of the essential health benefits (EHB) as required by the Affordable Care Act. Having robust and current essential health benefit standards is vital to the health and well-being of the patients we represent. While there are 10 defined essential health benefits, and each of them is important to our patients and the delivery of healthcare services, this letter focuses only on one of the essential health benefits: prescription drugs.

We believe that the EHB regulations governing prescription drugs have generally been working well for patients; however, we propose some areas for improvement and are very concerned that there has been a lack of enforcement of the EHB regulations, an erosion of essential health benefits over the years, and some insurers and pharmacy benefit managers (PBMs) are devising ways to skirt the intent of the EHB law and regulations.

Suggested Improvements

Classification System: CMS has requested comment on whether the drug classification currently used to assist in developing EHB be changed from the current United States Pharmacopeia (USP) Medicare Model Guidelines (USP Guidelines) to another system, including USP Drug Classification (USP DC). **We strongly support requiring the use of USP DC for the development of prescription drugs for EHB.**

The Medicare Model Guidelines were developed for Medicare Part D. Since it was designed to implement Medicare Part D it does not include all classes of drugs, such as those used for weight loss, reproduction, and sexual disorders. It is updated every three years. On the other hand, USP DC includes more drug classes and is updated annually. Therefore, it can consist of new medical advancements faster for the benefit of patients. USP guidelines dated February 2020 included 47 drug categories, 156 Pharmacotherapeutic classes, and listed 1,986 examples of drugs; current USP DC

guidelines, dated December 2022, includes 50 categories, 172 classes, and lists 1,961 examples of drugs. The USP DC is developed through USP's independent, science-based, expert-led process that relies on stakeholder input, including formal public comment periods. The USP Drug Classification Subcommittee comprises academicians, practitioners, formulary experts, patient advocates, and clinicians.

Since it is more inclusive of drug classes relevant to the private insurance patient base and updated more frequently, we urge CMS to use the USP DC.

Minimum Drug Coverage Requirements: Currently, the minimum requirement for drug plans is to cover either 1) one drug per category or class, or 2) at least the same number of prescription drugs in every United States Pharmacopeia (USP) category and class as covered by the State's EHB-benchmark plan, whichever is greater.

Often times this is not a sufficient number of drugs to meet the needs of patients with complex and severe health conditions. **Therefore, we recommend that CMS mirror the minimum drug requirements of the Medicare Part D program, which requires a minimum of two drugs per class and all or substantially all drugs in six protected classes.** These classes of clinical concern include anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. Following the number of drugs in the state benchmark should continue for classes outside the six protected classes.

When Medicare Part D was created, Congress recognized the need of patients and their providers to treat certain serious health conditions and the complexity of treating them, including the need for a wide array of medications to treat patients' individual needs. Typical employer plans usually meet these drug coverage needs and should be required in the private insurance market as well.

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, we are witnessing examples of numerous insurers that we believe are violating these EHB requirements and creating barriers to patient access to prescription medications. Therefore, we urge CMS and state regulators to enforce the current requirements and take necessary actions, including policy changes, to ensure compliance to protect patients.

Cost-sharing violations: The ACA details cost-sharing and provides for out-of-pocket maximums, limiting overall out-of-pocket costs on all essential health benefits (EHB). 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).

This significantly increases out-of-pocket costs for patients, allowing insurers to “double dip” and increase their revenue by receiving patient copayments twice—first by the drug manufacturer and second by the beneficiary. In doing so, they are collecting more money than they are entitled, violating the ACA EHB requirements.

To comply with the ACA EHB law and regulations, we urge CMS to issue regulations that require insurers to count copay assistance towards patient cost-sharing requirements for at least brand-name drugs that do not have a generic equivalent.

Due to the inaction by CMS on this matter, the growth of both accumulators and maximizers has skyrocketed. According to [IQVIA](#), in 2021, 43 percent of covered lives in commercial plans were in plans with accumulators, while 45 percent were in plans with maximizers.

Discriminatory Plan Design: The ACA and its implementing regulations about EHB are very clear regarding prohibiting discrimination against beneficiaries with pre-existing conditions and specific health needs.

The ACA states that 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.”

Regulations regarding EHB are clearer. Plans must:

“ - (1) Cover[] a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and

- (2) Provide[] appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.”

Additionally, an “[i]ssuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions; and that a non-discriminatory benefit design that provides EHB is one that is clinically based.”

And

“It is presumptively discriminatory . . . to place all drugs for a particular condition on a high-cost tier to discourage enrollment by those with that condition.”

While we appreciate these EHB patient protections, we believe they need to be fully upheld and adequately enforced.

Consider some of the following statistics:

- While after premiums are paid there are cost-sharing limits, they too are rising. For the plan year 2024, CMS has set the maximum out-of-pocket responsibility at \$9,400 for an individual

and \$18,800 for all others. Due to the proliferation of high deductible plans, depending on the drug, a patient may be required to pay the total amount of \$9,400 all at once for their medication at the beginning of the year.

- According to CMS' National Health Expenditures report, while overall healthcare spending grew at only 2.7 percent in 2021, out-of-pocket spending increased substantially higher by 10.4 percent. For prescription drugs, out-of-pocket spending totaled \$49.8 billion, or 13.2 percent of the total spending on prescription drugs. However, for hospital care, which accounts for more than three and a half times more of the total spending than prescription drugs, patients were responsible for paying only 2.6 percent. Despite the smaller spending for prescription drugs, the total out-of-pocket spending for prescription drugs (\$49.8 billion) was higher than all the out-of-pocket spending for hospitals (\$34.1 billion).¹
- For qualified health plans, CMS reports the median annual deductible for an individual on a Silver plan in 2023 is \$5,388, an increase of 4 percent from 2022 and 21 percent from 2021. For Bronze plans, the median deductible for the plan year 2023 is \$7,471, an increase of 8 percent from 2022 and 17 percent from 2021.²
- According to the [Kaiser Family Foundation](#), the average payments towards coinsurance rose 67 percent from 2006 to 2016.
- According to an IQVIA analysis, due in part to high costs, an estimated 81 million prescriptions were abandoned at the pharmacy in 2021, with the abandonment rate over one in three for prescriptions above \$75 in out-of-pocket cost, especially for high-cost specialty medicines that treat cancer and immunology. In addition, of prescriptions with a final cost above \$250, 61 percent are not picked up by patients, as compared with 7 percent of patients who do not fill when the cost is less than \$10.³
- A recent comprehensive literature review by the National Pharmaceutical Council found that, "When taken together, the included studies appear to suggest not only that increased cost-sharing is associated with decreased adherence but also that there is a 'dose-response' relationship, in which larger differences in cost-sharing were associated with worse adherence. Similarly, increased cost-sharing was associated with more patients discontinuing treatment."⁴

¹ "National Health Expenditure Data," CMS, last modified 12/15/22, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>.

² "Plan Year 2023 Qualified Health Plan Choice and Premiums in HealthCare.gov Marketplaces," CMS, Dept. of Health and Human Services, October 26, 2022, <https://www.cms.gov/cciio/resources/data-resources/downloads/2023qhppremiumschoicereport.pdf>.

³ "The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026," IQVIA Institute, April 2022, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf>.

⁴ Nicole Fusco, Brian Sils, Jennifer S. Graff, Kristin Kistler, and Kimberly Ruiz, "Cost-Sharing and Adherence, Clinical Outcomes, Health Care Utilization, and Costs: A Systematic Literature Review," *Journal of Managed Care and Specialty Pharmacy*, 29, no. 1 (January 2022), <https://www.jmcp.org/doi/full/10.18553/jmcp.2022.21270>.

- According to the Urban Institute, in its examination of 2018-2019 Medical Expenditure Panel Survey data, nearly 13 million adults delayed or did not get needed prescription drugs because of the cost, including 3.8 million nonelderly adults with private insurance.⁵

Insurance benefit designs that translate into high cost-sharing levels, particularly for prescription drugs, should be examined by CMS and state regulators to determine if they are designed in a discriminatory manner. Patients are saddled with higher cost-sharing because they are forced to pay on the list price of the drug, even though insurers and PBMs receive substantial rebates and discounts. This particularly hurts beneficiaries as they meet their deductible and when patient cost-sharing is expressed in terms of co-insurance rather than copays. No other class of health service is administered in this manner. In addition, patients always benefit from negotiated discounts with hospitals, providers, and labs, but it does not happen with prescription drugs.

Insurers and PBMs that are implanting cost-sharing policies such as copay accumulators and maximizers unfairly discriminate against beneficiaries with illnesses that rely on prescription medications. **CMS should investigate such practices and take appropriate enforcement action.**

The practice of adverse tiering, which insurers engage in when they place all or substantially all drugs to treat a certain condition on the highest tier, forces beneficiaries to pay more for their medications and is presumptive discriminatory, according to CMS EHB regulation (see above). **We are pleased that CMS has indicated it will conduct adverse tiering reviews beginning in 2024 for four classes of drugs. However, we question why federal and state regulators did not conduct these reviews in the past and even in this past year, when the new EHB nondiscrimination regulations became effective. More medical conditions should also be included in the review.**

CMS must ensure there are sufficient tools provided to state regulators to conduct annual and thorough plan reviews. States also must take the responsibility to fully review plans and take enforcement actions against issuers that are not in compliance.

Erosion & Evasion of EHB Law & Regulation

There are other schemes insurers, PBMs, and other new actors in the drug supply chain are implementing that seek to get around the intent of the ACA that further restricts access to prescription medications that CMS must address. Some plans designate certain medicines as “non-essential” and then raise the cost-sharing to ensure that they collect all of the patient assistance offered by the manufacturer but do not count it towards the beneficiary’s cost-sharing obligation. Under this arrangement, the plans often collect payments far exceeding the out-of-pocket maximum. Plans should not be able to cover certain drugs or medical benefits and then pick and choose which ones will

⁵ Michael Karpan, Frederic Blavin, Stacy McMorrow, and Claire O’Brien, “In the Years Before the COVID-19 Pandemic, Nearly 13 Million Adults Delayed or Did Not Get Needed Prescription Drugs Because of Costs,” Urban Institute, December 2021, <https://www.urban.org/research/publication/years-covid-19-pandemic-nearly-13-million-adults-delayed-or-did-not-get-needed-prescription-drugs-because-costs>.

count toward a beneficiary's out-of-pocket obligations. **We strongly urge CMS to require all cost-sharing associated with covered benefits and services to count as patient cost-sharing.**

In alternative funding 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 remove these drugs from the formulary and the entity finds alternative funding mechanisms to pay for the drugs. If the patient does not comply, they will be left paying the full cost of the drug.

One such [company](#) is very upfront in how it works. They clearly state that they are not insurance (thereby bypassing federal and state regulations) and describe that they access medications "through manufacturer free programs, grants/charities, our International Mail Order Pharmacy partner, domestic wholesale pharmacy and occasionally a copay card." It should be noted that importing medications is currently illegal in the United States. Further, the company asks patients for their income level so that they can utilize drug manufacturer-free drug programs. However, these free drug programs are only available to people who do not have insurance. People in these plans do have insurance, but their drug has been removed from the plan's formulary, and the company has forced them to enroll in an alternative "program," which is not insurance.

There are a growing number of other companies that are working with insurers, employers, and PBMs around the country. **CMS 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 and Guardricos Driskell, vice president of public policy and government affairs of the Autoimmune Association at guardricos@autoimmune.org.

Sincerely,

ADAP Advocacy Association
 Advocacy & Awareness for Immune Disorders
 Association (AAIDA)
 Advocacy House Services Inc.
 AIDS Action Baltimore
 AIDS Alabama
 Allergy & Asthma Network
 Alliance for Patient Access
 American Kidney Fund
 Applied Pharmacy Solutions
 APS Foundation of America, Inc.

Autoimmune Association
 California Chronic Care Coalition
 California Hepatitis C Task Force
 CancerCare
 Chronic Care Policy Alliance
 Coalition of Skin Diseases
 Color of Crohn's and Chronic Illness
 Community Access National Network
 Cystic Fibrosis Research Institute (CFRI)
 Depression and Bipolar Support Alliance
 Dermatology Nurses' Association

Digestive Disease National Coalition
Dysautonomia International
Equitas Health
Gaucher Community Alliance
Georgia AIDS Coalition
Good Days
Hawai'i Health and Harm Reduction Center
Haystack Project
HBI
HealthHIV
HealthyWomen
Hep Free Hawai'i
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation (IAF)

International Foundation for Autoimmune &
Autoinflammatory Arthritis
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
MLD Foundation
NASTAD
Nevada Chronic Care Collaborative
NTM Info & Research
Partnership to Fight Chronic Disease
Patients Rising Now
PlusInc
Pulmonary Hypertension Association
Rheumatology Nurses Society
Treatment Action Group
Triage Cancer