May 31, 2024

Julie A. Su
Secretary
Department of Labor

Xavier Becerra
Secretary
Department of Health and Human Services

Janet Yellen
Secretary
Department of Treasury

Re: Alternative Funding Programs and 2025 NBPP

Dear Secretaries Su, Becerra, and Yellen:

We are writing on behalf of the Alternative Funding Task Force, a group of patient advocacy and provider organizations working to end a new insurance practice harming our communities. We greatly appreciate the time your staff have spent with us to better understand the impact of alternative funding programs (AFPs) on patients living with serious and complex chronic illnesses and rare disorders. We were especially pleased to see that the Departments of the Treasury, Health and Human Services, and Labor (the Departments) intend to issue a new rule related to one issue that came up in our recent meeting with DOL: ensuring that the Affordable Care Act (ACA)'s cost-sharing requirements apply to all prescription drugs covered by all non-grandfathered health insurance plans. We write today with suggestions to ensure that this new rule provides the greatest protections possible to health insurance enrollees in large groups and self-insured plans.

In the *Notice of Benefit and Payment Parameters for 2025*, the Department of the Treasury and the Department of Health and Human Services (HHS) added 45 CFR 156.122(f), codifying pre-existing policy that requires individual and small group health plans to consider all prescription drugs covered by a plan that are in excess of those covered by a State's essential health benefit (EHB)-benchmark are EHBs subject to EHB protections, including annual limitation on cost-sharing and restrictions on annual and lifetime dollar limits.[1]

Issued the same day, *FAQ about Affordable Care Act Implementation Part 66* (FAQ) states that the Departments intend to issue a proposed rule requiring all non-grandfathered plans "to treat prescription drugs covered by the plan or coverage in excess of the applicable EHB-Benchmark plan as EHB for purposes of the prohibition of lifetime and annual limits and the annual limitation on cost sharing."[2] To accomplish this alignment, **we urge you to include §156.122(c), (d), and (f) in the forthcoming rule.** Together, these provisions would:

[1] https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2025-final-rule
[2] https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-66

(1) Ensure that large group and self-insured plans are required to consider all prescription drugs covered by a plan, in excess of the state benchmark, to be EHBs;
(2) Require large group and self-insured plans that provide prescription drug coverage, to have an exception process in place to enable enrollees to request access to medically necessary drugs not otherwise covered by the plan;
(3) Ensure that all prescription drugs deemed medically necessary by an exception or appeal process to be considered EHBs; and
(4) Require all non-grandfathered health plans to publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure and any restrictions on the manner in which the drugs can be obtained.

We further urge the Departments to add two additional clarifications to ensure that plans comply with EHB protections and ensure consumers have a meaningful ability to challenge an improper plan decision.

(5) Clarify that all FDA-Approved Prescription Drugs are part of the "Prescription Drug" EHB definition; and
(6) Create a new provision prohibiting all non-grandfathered plans from requiring enrollees to apply for or enroll in third-party sources of assistance as a condition of drug coverage, eligibility for an exception process request, or eligibility for a coverage determination appeal.

I. Background Information Regarding Alternative Funding Programs (AFPs)

While AFP programs vary, generally, these programs implement a plan design that either does not cover entire categories of prescription drugs or uses an unduly burdensome and drawn-out prior authorization process that delays access to medically necessary prescription drugs.

- Under the first pathway, a health plan carves out specialty and/or orphan medications from coverage, with the justification that the ACA does not include these drugs in its definition of EHB. Plans deny coverage of these drugs even if they have been deemed medically necessary by the patient's health care provider.
- Under the second AFP pathway a health plan may include specialty or orphan drugs on its formulary but requires enrollees who are prescribed these drugs to undergo an extensive prior authorization review that is premised upon enabling the AFP to identify alternative sources of the drug (i.e., Patient Assistance Programs [PAP] for the uninsured, importation, etc.). Under this pathway, if the AFP is unable to identify another source, or the enrollee's PAP application is denied, the drug may or may not be covered. Often, the enrollee has no recourse or ability to appeal until this required and often lengthy process has been completed.

These additional, plan-imposed processes at a minimum may cause patient delays in gaining access to their medications and, at worst, deny patients access to necessary and often life-saving medications. Fortunately, many of the AFP harms can be addressed by clarifying the definition of EHB; confirming the exceptions process under §156.122 (c) applies to large group and self-insured plans; and adding a new

provision that protects the ability of consumers to promptly appeal a coverage determination without unnecessary plan-imposed barriers.

II. Clarify That C.F.R. §156.122(c), (d) and (f) Apply to All Non-Grandfathered Plans

We applaud DOL for stating in FAQ 66 that it plans to ensure the treatments of prescription drugs as EHBs is consistent across health insurance markets. As explained above, clarifying that §156.122 (c), (d), and (f) apply to all non-grandfathered plans will address several of the concerns raised by the operation of AFPs.

We recognize that the forthcoming rule will not require health plans to cover all prescription drugs. However, by clarifying that §156.122(c), (d), and (f) do apply to all non-grandfathered plans, the Departments will ensure that enrollees:

(1) Will have a way to request an exception to the formulary restriction to gain access to a non-covered, medically necessary medication;
(2) Will have the benefit of ACA cost-sharing protections for any drugs covered after a medical necessity exception; and
(3) Will easily see which drugs are covered and what the enrollee will be expected to pay for them, as well as any permissible restrictions on access.

III. Clarify All FDA-Approved Prescription Drugs are part of the "Prescription Drug" EHB Definition.

The ACA does not define the term "prescription drugs," but the ACA regulation governing prescription drugs as an EHB refers to "FDA-approved drugs." [3] The FDA defines a "prescription drug" as "any human drug required by Federal law or regulation to be dispensed only by a prescription. . . ."[4] Likewise, the plain meaning of the word "prescription drug" is a "drug that can be obtained only by means of a [health care practitioner's] prescription."[5] Moreover, the ACA regulations only mention one class or category of drugs that health plans may choose not to cover as an EHB—drugs intended for abortion.[6]

However, as explained above, some health plans have alleged that by referring to certain prescription drugs as "brand name," "orphan drug," "specialty drug," "biologics," or another plan assigned name used to distinguish beneficiaries' cost-sharing amounts, these prescription drugs can be considered non-essential health benefits**. Therefore, we ask that the proposed rule clarify that a plan's designation of a drug as "orphan," "specialty" or any other designation does not change the drug's status as an EHB.** *This would not require plans to cover all prescriptions drugs*, but rather confirm that all FDA-approved prescription drugs, with the exception of medications used for abortion, are considered EHBs if covered.

[3] 42 C.F.R. §156.122.
[4] 42 U.S.C §18022(b); 42 C.F.R. §156.122
[5] 21 C.F.R. 205.3(e)
[6] https://www.merriam-webster.com/dictionary/prescription%20drug

IV. Create a New Provision Ensuring Consumers Can Access the Appeals Process Without Unnecessary Barriers

AFPs often require consumers to apply to a PAP to access their prescription drugs before the plan will make a coverage determination. In some cases, the plan will refuse to review a coverage determination appeal until the individual has applied to and received a response from the PAP. Under either version, the plan predicates its coverage decision and the timing of that decision on whether an alternative source for the medication is available. This results in a lack of uniform benefit application, unnecessary delays, confusing administrative requirements for consumers, and an undue interference with the right to appeal.

Therefore, we ask that the upcoming rulemaking include a new provision, 156.122(g), which could state "A health plan cannot require an enrollee to apply for or enroll in, a third-party assistance program including, but not limited to, manufacturer copay assistance, manufacturer patient assistance programs, charitable funds, or any other third-party entity, as a prerequisite for an enrollee receiving a coverage determination; requesting access through an exceptions process; or initiating an appeal."

V. In Conclusion

In conclusion, we appreciate the steps the Departments have taken to protect EHBs, and we appreciate an opportunity to continue this conversation and discuss our concerns and considerations regarding the upcoming rulemaking. Please reach out to Kim Czubaruk at kczubaruk@cancercare.org; and Kollet Barkhouse at kollet@p3hbc.com to schedule a meeting with us to discuss this letter in greater detail.

Sincerely,

Cancer*Care*
Hemophilia Alliance
Aimed Alliance
Alliance for Patient Access
Alliance of Dedicated Cancer Centers
Arthritis Foundation
Association for Clinical Oncology
Bleeding & Clotting Disorders Institute
Cancer Support Community
Coalition for Hemophilia B
EveryLife Foundation for Rare Diseases
Hemophilia Federation of America
HIV+Hepatitis Policy Institute
Little Hercules Foundation
Melanoma Research Foundation
National Bleeding Disorders Foundation
National Psoriasis Foundation
PAN Foundation
The AIDS Institute