

January 8, 2024

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

[Via Regulations.gov](#)

Re: Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program (CMS-9895-P)

Dear Secretary Yellen, Secretary Becerra, and Administrator Brooks-LaSure:

We are providing the following comments on the Notice of Benefit and Payment Parameters for 2025 (NBPP) on behalf of patients living with serious, chronic health conditions who rely on access to affordable specialty prescription medications.

Background - Prescriptions Drugs and EHB

Prescription drugs are one of the ten categories of essential health benefits (EHBs) described in the ACA that make up the EHB-package and are required to be covered by non-grandfathered individual and small group plans.¹ Large group and self-insured employers are not required to cover essential health benefits (EHBs).² However, under Public Health Service (PHS) Act section 2707(b), if employers offer one of the ten EHBs, then they are required to comply with the ACA's annual limits on cost-sharing and its prohibition on annual and lifetime limits

¹ 42 U.S.C. §18022

² Congressional Research Service, *Federal Requirements on Private Health Insurance Plans*, <https://crsreports.congress.gov/product/pdf/R/R45146>.

applicable to EHBs.³ While employer sponsored plans can select their definition for EHB, the definition must be one that has been authorized by HHS, “including any available benchmark option.”⁴

HHS has never defined “prescription drugs” within the context of EHB, however, the ACA does reference prescription drugs broadly as Food and Drug Administration (FDA)-approved drugs.⁵ The FDA defines prescription drugs as “any human drug required by Federal law or regulation to be dispensed only by a prescription. . . .”⁶ As such, the baseline definition for prescription drugs as an EHB is *all* drugs that are dispensed via a prescription. A drug’s designation as a medication that is dispensed via a prescription does not change because the drug is called a “brand name,” “generic,” “specialty drug” or another plan assigned name used to distinguish beneficiaries’ cost-sharing amounts – these are all still medications that can only be dispensed via a prescription, thereby all of them are prescription drugs.

If plans were required to look solely at the “definition” of prescription drugs, then *all drugs that are dispensed via a prescription* would fall within the definition of the EHB. However, HHS has recognized that a health plan does not fail to provide EHB coverage simply because it does not cover all drugs.⁷ Rather, as explained below, HHS has directed each state to work within the parameters set forth in 45 CFR §156.122 to identify their prescription drug EHB benefits.⁸

Under §156.122(a), a plan is defined as providing EHBs only if its prescription drug benefit covers *at least the greater of* (1) one drug in every United States Pharmacopeia (USP) category and class; or (2) the same number of prescription drugs in each category and class as the EHB benchmark plan.⁹ Section 156.122(c) also requires state benchmark plans to provide a process for consumers to access *clinically appropriate drugs not otherwise covered by the plan*, **and** to treat these drugs as an EHB if the exception request is granted.¹⁰ As such, to provide EHBs, state benchmarks must cover (1) at least one drug in a category and class; and (2) all drugs deemed medically necessary via the exceptions process.

With the addition of paragraph (f), State-benchmarked EHBs would include (1) *at least one* drug in each category and class; (2) all drugs deemed medically necessary via the exception process; and (3) all additional drugs covered in a plan.

§ 156.122 Amendment to Codify Drugs in Excess of State Benchmark as EHB

We applaud the amendment to add paragraph (f) to §156.122 to codify that prescription drugs in a plan that are in excess of those covered by a State’s EHB-benchmark are considered

³ CMS, *Affordable Care Act Implementation FAQs – Set 18*_CMS, https://www.cms.gov/cciiio/resources/fact-sheets-and-faqs/aca_implementation_faqs18 .

⁴ CMS, *Frequently Asked Questions on Essential Health Benefits Bulletin*, <https://www.cms.gov/cciiio/resources/files/downloads/ehb-faq-508.pdf>.

⁵ 45 CFR §156.122.

⁶ 21 CFR 205.3.

⁷ 45 CFR §156.122 (b).

⁸ 45 CFR §156.122.

⁹ *Id.*

¹⁰ 45 CFR §156.122 (c).

EHBs. This codification affirms our long-held and consistently voiced assertion that the “*at least the greater of*” language of §156.122(a) was always intended to be **an EHB floor, not an EHB ceiling**. It is noteworthy that HHS acknowledges in the NBPP that this, too, has been their interpretation of §156.122 and that they have previously stated such in response to prior inquiries about plans’ treatment of new drugs that come to market during a plan year.¹¹

Using the HHS Secretary’s authority to define EHB with regard to coverage and applicability to cost-sharing limits, amending §156.122 to add paragraph (f) to explicitly state that drugs in excess of the benchmark are considered EHB will put an end to plans’ manipulative practice of declaring excess drugs to be “covered non-EHBs” to purposefully circumvent annual cost-sharing limits. We interpret the NBPP’s use of the phrase “in any circumstances” as a proactive and comprehensive effort to prohibit plans from evading the cost sharing limits required for EHBs.¹²

Plans’ Designation of Excess Prescription Drugs as “Covered Non-EHB”

The NBPP seeks comments on how widespread the problem has been with plans’ categorization of prescription drugs as “covered non-EHBs” noting that they have only recently begun receiving comments from interested parties and that they do not believe that there are a large number of plans that “offer” these programs. We appreciate the request for comments and the interest in better understanding the scope and depth of the problem, though we are surprised to learn that the issue is characterized as recent and not widespread. Most, if not all, of the organizations submitting these comments have, for several years, provided written comments, signed-onto coalition comments, and/or participated in meetings with CMS and other agencies specifically addressing the proliferation of these manipulative plan tactics and their designation of drugs as “covered non-EHBs.” The “covered non-EHB designation” has harmful consequences to patients, particularly to patients relying on specialty medications to treat and/or manage serious, complex, and chronic conditions.

Plan abuse of patient protections has been most acute by large group and self-insured plans that cover prescription drugs and therefore are subject to annual cost sharing limits and restrictions on annual and lifetime dollar limits.¹³ These plans often use ERISA’s complexity and patients’ lack of health care literacy to misrepresent the plan’s obligation to comply with applicable laws and regulations, as well as to instill fear into patients that they will confront excessive cost sharing or non-access if they do not abide by the plan’s directives - which are designed to save the plan money at the expense, literally and figuratively, of the patient.

¹¹ CMS, *Proposed 2025 Notice of Benefit and Payment Parameters*, at p. 279-280, <https://www.cms.gov/files/document/cms-9895-p-patient-protection-final.pdf>.

¹² “To resolve these concerns, we propose to amend § 156.122 to add paragraph (f), which would explicitly state that drugs in excess of the benchmark are considered EHB. To the extent that a health plan covers drugs, **in any circumstance**, in excess of the benchmark, these drugs would be considered an EHB and would be required to count towards the annual limitation on cost sharing.” (Emphasis added). CMS, *Proposed 2025 Notice of Benefit and Payment Parameters*, at p. 280, <https://www.cms.gov/files/document/cms-9895-p-patient-protection-final.pdf>.

¹³ CMS, *Affordable Care Act Implementation FAQs – Set 18* CMS, https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/aca_implementation_faqs18

HHS Authority and Applicability of § 156.122 Amendment to Large Group and Self-Insured Plans

The “covered non-EHB” improper interpretation by large group and self-insured plans makes the proposed amendment’s applicability to large group and self-insured plans of significant consequence. We are fully aware and understand that the proposed amendment does not change the core premise that large group and self-insured plans are not required to offer EHBs. However, we interpret the proposed amendment as being applicable to these plans *if* they offer prescription drugs *and* include drugs in excess of the benchmark plan they have selected as their defined EHB.¹⁴

The authority to define EHB rests solely with the Secretary of HHS. Although large group and self-insured plans are not required to offer EHBs, if they do, they are required to use a definition of EHB that has been authorized by the Secretary, including any available benchmark option, to determine if they are complying with the annual limitation on cost sharing and the prohibition against annual and lifetime dollar limits that pertain to EHBs. The amendment to § 156.122 that is being proposed for codification by HHS is specifically intended to address and redress the use of plans’ unauthorized definition of EHB, including by large group and self-insured plans offering EHBs. While HHS has collaboratively engaged with other agencies to enforce ACA protections, joint agency collaboration is not required for HHS to use its statutory purview to define and clarify EHBs.

For example, although stated in the context of routine non-pediatric dental services as compared to prescription drugs, HHS recognizes its authority to define EHB without joint agency action and how its definition may apply to plans not required to offer EHBs.

“This proposal, if finalized, may impact plans that are not directly subject to the EHB requirements, such as self-insured group health plans and fully-insured group health plans in the large group market, that are required to comply with the annual limitation on cost sharing and restrictions on annual or lifetime dollar limits in accordance with applicable regulations with respect to such EHBs. If a State updates its EHB-benchmark plan to add coverage of routine non-pediatric dental services as an EHB and the sponsor of a self-insured group health plan or fully-insured group health plan in the large group market selects that EHB-benchmark plan, any routine non-pediatric dental services covered by such a group health plan would generally be subject to the limitation on cost sharing and restrictions on annual or lifetime dollar limits.”

Coverage Mandated by State Action in § 155.170.

We seek clarification on how the NBPP’s proposed amendment to “Additional Required Benefits (45 CFR 155.170)” will impact that part of the proposed amendment to § 156.122 which excepts the amendment’s application to drugs whose coverage is

¹⁴ “Therefore, if the plan is covering drugs beyond the number of drugs covered by the benchmark, all drugs in excess of the drug count standard at § 156.122(a) are considered EHB, such that they are subject to EHB protections and must count towards the annual limitation on cost sharing.” CMS, *Proposed 2025 Notice of Benefit and Payment Parameters*, at p. 280, <https://www.cms.gov/files/document/cms-9895-p-patient-protection-final.pdf>.

mandated by the State, in which case the drug would not be considered EHB. Specifically, as currently proposed, it appears the NBPP’s amendment to § 156.122 would not apply to coverage of a drug that is mandated by State action and is in addition to EHB pursuant to § 155.170.¹⁵ This “exception” provision appears to conflict with the NBPP’s proposed amendment to § 155.170(a)(2) such that it would provide that benefits covered in a State’s EHB-benchmark plan would not be considered in addition to EHB. While the amendment to § 155.170(a)(2) is in the context of defrayal, we see the potential for confusion and ask for clarification in the final rule. Based on our interest in ensuring that patients have affordable access to the prescription drugs they need, we urge that the “exception to EHB” for drugs mandated by State action in the proposed amendment to § 156.122 be eliminated from the final rule.

Conclusion

We offer these comments to provide our understanding of both the meaning and reach of the NBPP’s proposed amendment to § 156.122. To best assist the patient communities we serve, we ask that the final rule clarify any discrepancies identified in our comments as well as comments submitted by others. If you have any questions, please contact Kim Czubaruk, Associate Vice President of Policy with CancerCare at kczubaruk@cancercare.org.

Sincerely,

CancerCare
Aimed Alliance
Alliance for Patient Access
American Kidney Fund
Arthritis Foundation
Association for Clinical Oncology
Bleeding & Clotting Disorders Institute
Hemophilia Alliance
Hemophilia Federation of America
HIV + Hepatitis Policy Institute
Little Hercules Foundation
National Bleeding Disorders Foundation
National Psoriasis Foundation
Patient Access Network (PAN) Foundation
The AIDS Institute

¹⁵ CMS, *Proposed 2025 Notice of Benefit and Payment Parameters*, at p. 279, <https://www.cms.gov/files/document/cms-9895-p-patient-protection-final.pdf>.