Biotechnology Innovation Organization
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VIA ELECTRONIC DELIVERY

January 8, 2024

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

The Honorable Chiquita Brooks-LaSure Administrator
Centers for Medicare & Medicaid Services 7500 Security Boulevard
Baltimore, MD 21244

Re: Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025

Dear Secretary Becerra and Administrator Brooks-LaSure:

We are writing on behalf of the Biotechnology Innovation Organization (BIO) to provide comments on the Department of Health and Human Services' (HHS') proposed Notice of Benefit and Payment Parameters (NBPP) for 2025. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology companies, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but have also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

Annual Limit on Cost Sharing (§156.130)

BIO has long expressed our concerns over the proliferation of accumulator adjustment programs (AAPs) that prevent copay assistance from counting toward patient annual limits on cost sharing. HHS has continued to allow insurers to profit from copay assistance by diverting the benefit of the assistance at the expense of patients. A 2021 survey conducted by the National Hemophilia Foundation found that 6 in 10 patients and caregivers would have "extreme difficulty" affording their treatments and medications without copay assistance programs being applied to their out-of-pocket (OOP) costs.[1] Despite HHS' purported commitment to eliminate health disparities and lower patient OOP costs, HHS moving forward with its appeal of the federal court decision on copay accumulators would directly undermine these policy goals. BIO hopes that HHS will reconsider its judgment to side with insurers at the expense of patients.

[1] Patients & Family Caregivers: Prescription Drug Affordability Challenges During COVID-19. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://allcopayscount.org/wp-content/uploads/2022/06/NHF-National-Patients-and-Caregivers-Survey-on-Copay-Assistance-Key-Findings.pdf

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BIO urges HHS to issue regulation to ensure enforcement of the 2020 NBPP final rule that prohibits copay accumulators unless a generic alternative is available. Given the constant challenges with patient affordability as well as the life-threatening impacts of AAPs on patient health outcomes, it is critical that HHS immediately revoke conflicting guidance on this matter. As patient cost sharing obligations increase, many patients are unable to adhere to their prescription regimen. A study directed toward patients taking autoimmune drugs found that AAPs negatively affected the patients' specialty drug use, including lower monthly fill rates and higher risk of drug discontinuation.[2] HHS itself has acknowledged that when "the value of the manufacturer-sponsored assistance was not applied to the patient's deductible… the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for those patients with rare and life threatening conditions."[3] By allowing insurers to implement AAPs, HHS endangers patient health and financial security for the many disadvantaged patients who rely on copay assistance as a critical life line to afford and access their medicines.

Prescription Drug Benefits (§156.122)

Classifying the Prescription Drug Essential Health Benefit (EHB)

HHS seeks comment on a proposal to replace the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) with the USP Drug Classification system (DC) to classify the prescription drugs required to be covered as EHB for private insurance plans serving the individual and small group markets in possible future rulemaking.

BIO supports the switch from USP MMG to USP DC given that USP MMG was developed for the Part D population and does not fully account for the needs of the Affordable Care Act (ACA) marketplace. Meanwhile, the USP DC includes a broader set of prescription medicines, which can help to ensure greater access to prescription drugs to meet the needs of diverse populations who rely on EHB plans. BIO appreciates changes to drug classifications and categories to better align with clinical guidelines and that allow for more frequent updates to ensure that beneficiaries are granted full access to necessary drugs and biologicals. HHS should also ensure the selected formulary that serves as the EHB standard is subject to annual review and public comment so the formulary process is transparent and open to feedback from those affected by the formulary standard.

Above all, the classification for drugs required to be covered as EHB should reinforce beneficiary access to needed therapies, and thus prevent plans from discouraging enrollment of beneficiaries with rare conditions or diseases. Accordingly, we urge the Agency to consider

[2] Sherman BW, Epstein AJ, Meissner B, et al. Impact of a co-pay accumulator adjustment program on specialty drug adherence. Am J Manag Care. 2019;25(7). https://www.ajmc.com/view/impact-of-a-copay-accumulator-adjustment-program-on-specialty-drug-adherence

[3] Final Rule: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS-2482-F) from the Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and

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whether a formulary's category and class structure is comprehensive to ensure the coverage of a variety of drugs to provide meaningful value particularly for those patients living with chronic and rare diseases. HHS can strengthen EHB drug coverage by requiring that plans cover more than the USP-based minimum in situations where the USP classification fails to encompass all clinically necessary drugs to treat all disease states.

Additionally, BIO requests that CMS consider requiring coverage of at least two drugs per category and class. This minimum standard will ensure that vulnerable populations such as those living with rare and chronic conditions can have access to clinically necessary mediation to prevent or treat painful and life and health threatening conditions. This approach can also help to prevent the use of formulary designs to discourage the enrollment of those with pre-existing health conditions, which the ACA aimed to prohibit.

The Agency also seeks comment on the potential effects of covering anti-obesity medications (AOM) if CMS should adopt the USP DC classification system. As HHS noted, despite this innovation and proven clinical value, the USP MMG does not include AOMs while the USP DC does. This creates a coverage gap for patients with obesity as plans required to cover EHBs are not required to cover AOMs. Meanwhile, guidelines for the treatment of obesity recognize the importance of anti-obesity medicines (AOMs). BIO appreciates HHS' recognition of the benefits of covering AOM in the ACA Marketplace. The coverage of chronic conditions including obesity is a significant step in improving patient health and advancing health equity, which will particularly benefit vulnerable populations.

Coverage of Prescription Drugs as EHB

HHS proposes to codify that prescription drugs in excess of those covered by a state's EHB-benchmark plan are considered EHB. As a result, they would be subject to requirements including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits, unless the coverage of the drug is mandated by state action and is in addition to EHB pursuant to §155.170, in which case the drug would not be considered EHB.

While BIO appreciates HHS' proposal to codify their existing EHB policy as an important step, this codification alone is insufficient to address the serious ramifications of insurers who are still exploiting the EHB loophole. As BIO has commented in the past, the EHB loophole allows self-insured and large employer health plans to classify certain prescription drugs as non-essential health benefits (non-EHB), resulting in patients paying hundreds or thousands of dollars in OOP costs without reaching their annual OOP maximum. Insurers use copay maximizers through the EHB loophole to categorize drugs as non-EHBs and extract manufacturer copay assistance from patients. And these tactics are getting worse; IVQIA found that the exposure or prevalence of accumulator and maximizer plans across specialty markets grew from 14% of commercially-insured patients in 2019 to 33% in 2022.[4]

[4] IQVIA. Five Years and Counting: Deductible Accumulators and Copay Maximizers in 2022. December 2022. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2022/five-years-and-counting-deductible-accumulators-and-copay-maximizers-in-2022.pdf.

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BIO continues to urge HHS to take further action and work with the Departments of Labor and the Treasury to block the EHB loophole for all plans- not only individual and small group market plans but also self-insured and large group health plans- so that all covered drugs are EHB and therefore entitled to critical patient protections of the annual cost-sharing limit. The EHB loophole continues to be detrimental for patients who are forced to pay more in cost-sharing for medically necessary and life-saving drugs without any clinical reason for the plans' decision to designate those covered drugs as non-EHB. Closing the loophole would put a cap on the ability of insurers to extract manufacturer copay assistance for themselves at the expense of patients.

Pharmacy and Therapeutics (P&T) Committee Standards (§156.122)

HHS proposes that for plan years beginning on or after January 1, 2026, HHS will require that a P&T committee includes a consumer representative.

BIO remains a strong advocate of integrating patient voices in all facets of policymaking and wholeheartedly supports this proposal. BIO agrees with HHS's rationale that inclusion of a consumer representative can ensure the consumer experience with a disease or condition be considered in the design of formulary benefits. BIO also recommends that the number of consumer representatives be proportional to the size of the committee, which can help to ensure adequate consumer representation.

Non-Standardized Plan Option Limits (§156.201)

HHS proposes an exceptions process that would permit FFE and SBE-FP issuers to offer more than two non-standardized plan options per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent plan years, as long as issuers demonstrate that the non-standardized plan option has reduced cost sharing of 25 percent or more for benefits pertaining to the treatment of chronic and high-cost conditions.

BIO appreciates the Agency's intent to incentivize plans to lower cost sharing for patients, particularly for chronic and rare diseases. However, we recognize that additional plan options may necessitate additional safeguards to protect against potential discriminatory benefit designs for those with chronic and rare conditions. For instance, plans could potentially develop more restrictive formularies and/or increase utilization management on these non-standardized plan options to offset the reduction in cost sharing. Accordingly, we request that the Agency include safeguards within these plan options, such as reviewing the exclusion of drugs for chronic and rare diseases as part of its discriminatory benefit reviews.

HHS Risk Adjustment (§153.320)

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HHS proposes to use data from previous consecutive years for recalibration of the HHS risk adjustment models.

BIO recommends that CMS regularly evaluate the HHS-HCC risk score model to ensure it fully captures the cost of conditions in the model and provides stability for issuers. We ask CMS work to identify and address instances where coefficients have declined or are not sufficiently weighted to adequately compensate issuers for enrollees with serious chronic or rare conditions. This type of dynamic could disincentivize issuers from enrolling those patients or cause them to employ adverse tiering that makes it difficult for those patients to access innovative medicines.

We appreciate HHS' careful consideration of these comments. Should you have additional questions, please do not hesitate to contact us at (202) 962-9200.

Sincerely,

/s/

Crystal Kuntz
Vice President
Healthcare Policy and Research

/s/

Melody Calkins
Senior Manager
Healthcare Policy