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March 1, 2024

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

Via email to: PartDRedesignPI@cms.hhs.gov

RE: Draft CY 2025 Part D Redesign Program Instructions

Dear Administrator Brooks-LaSure:

We are writing on behalf of the Biotechnology Innovation Organization (BIO) to provide comments on the Centers for Medicare & Medicaid Services' Draft CY 2025 Part D Redesign Program Instructions. 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.

While BIO acknowledges the inherent limitations of this program guidance, which is intended to address technical specifications for the implementation of the IRA, we are disheartened that CMS has not addressed the unintended consequences of increased Part D plan liabilities under the IRA that could endanger patient access to critical drugs. BIO remains strongly concerned that Part D plan sponsors will respond to their increased financial liability by attempting to block or severely limit patient access to critical drugs. As BIO has previously expressed, patients face significant risk that Part D plan sponsors may implement more restrictive formulary coverage, including coverage of fewer drugs, increased utilization management (UM), and discriminatory tier placement in order to limit their financial exposure under the new benefit design. As CMS examines plan bids and formularies for the upcoming plan year, it is critical that CMS closely monitor the effects of IRA changes to ensure patient access to needed drugs. At a minimum, we urge CMS to:

- Clarify how the Agency will ensure beneficiary access to needed drugs through sufficient safeguards;
- Facilitate transparent disclosure around how the Agency will monitor plan coverage and tiering design, clinical appropriateness of utilization management policies, and patient cost-sharing levels;
- Improve the exception request/ appeals process by streamlining, monitoring, and publishing data on exceptions and appeals, including formulary coverage of drugs frequently granted exceptions;

- Preserve and consider additional enhancements to current formulary standards given different incentives under the new benefit structure;
- Consider new methodologies or changes needed to CMS' review of plan formularies; and
- Address technical considerations with regard to plan benefit packages and risk corridors as described in this program guidance.

Concerns with the Lack of Patient Protections to Ensure Access

As an initial matter, BIO remains seriously concerned that CMS has neglected to consider necessary patient protections as plans take on increased liability from the IRA. In BIO's comments to the April 2023 comment solicitation on "HPMS to Subscribers on Part D Redesign in the Inflation Reduction Act" as well as our October 2023 follow-up letter to CMS on the Part D redesign, we have consistently raised the concern regarding the IRA's unintentional adverse impacts that will negatively affect beneficiary access in Part D. It is evident that Part D sponsors may attempt to offset increases in their liability through implementing more restrictive formularies, increased utilization management, and other access restrictions including, but not limited to, differential formulary tiering tied to patient cost sharing; step-edits/fail-first options; NDC blocks; prior authorizations; quantity limits; etc. As a result, beneficiaries face a significant and growing risk of potential treatment delays or even the loss of coverage altogether. Low-Income Subsidy (LIS) beneficiaries are especially likely to lose coverage due to the significant number of plans that will no longer qualify as benchmark plans in 2024.[1] BIO remains disappointed that CMS has not taken the opportunity within the Draft Redesign Program Instructions to recognize these significant issues and pose solutions to protect beneficiary access.

BIO has previously advocated for CMS to monitor formularies pre- and post-redesign/MFP implementation and impose stricter enforcement mechanisms for inappropriate formulary management that hinders beneficiary access to needed medicines. Given that CMS is declining to implement any changes to tiering structures or tier thresholds for 2025, BIO believes this enhanced monitoring and enforcement is even more critical. Current statutory requirements around formulary composition and design, as well as guidance under the Medicare Prescription Drug Benefit Manual, do not account for the significant unintentional impacts of the IRA and do not provide transparency into the data and methodology used by CMS in its formulary reviews. Accordingly, it is essential that CMS closely monitor the effects of the redesign on plan coverage and tiering design, utilization management policies, and patient cost-sharing levels. At a minimum, CMS should provide stakeholders with greater transparency on how formularies are changing under the IRA, including across MA-PDs, PDPs, LIS benchmark plans, as well as releasing data regarding potential changes in top therapeutic areas. It is critical that CMS prioritizes protecting beneficiary access in light of the of formulary access challenges that may occur under the IRA. Likewise, CMS should ensure patients have timely access to needed medications by streamlining the exception request/appeal process and publishing data on these appeals.

CMS should also ensure that Part D plans do not discriminate against applicable drugs subject to the phase-in of discounts under the Manufacturer Discount Program. The Part D

[1] Avalere, "Part D Premium Increases, Market Disruption Expected in 2024," October 11, 2023. https://avalere.com/insights/part-d-premium-increases-market-disruption-expected-in-2024

statute, as amended by the IRA, reflects Congress's intent to grant financial relief to certain small manufacturers under the new Part D benefit redesign. To effectuate this purpose, Part D plans must not impede beneficiary access to drugs subject to the phase-in of discounts under the Manufacturer Discount Program by imposing unfavorable coverage, tiering, or utilization management requirements on phase-in products. Unfavorable treatment and access restrictions for these products could hinder beneficiary access in all plans, in that beneficiaries may no longer have any plan options that favorably cover the products they need. In addition, plans may attempt to limit their liability under the Small Manufacturer Phase-in through inappropriate cost-shifting and other financial offsets. Any changes in plan behavior have serious implications on patient access to necessary medications. Thus, it is critical that CMS closely monitor plan behavior to ensure that changes in plan dynamics are not overlooked.

Definition of Enhanced Alternative Benefit Design (§ 423.104(f))

For CY 2025, CMS proposes to utilize the Part D Out-of-Pocket Costs (OOPC) model to estimate the value of enhanced alternative (EA) plans relative to the value of the defined standard benefit. As BIO has stated in previous comments, BIO does not believe that measuring differences based on OOP spending is an appropriate metric to determine the relative value of EA vs. basic plans because the new $2,000 OOP cap under the redesign is already more generous than many enhanced plans today. CMS' proposed approach for calculating an OOPC estimate based on reductions in deductible and/or cost-sharing is also negligible given that these enhancements would only benefit members who do not reach the OOP cap. Accordingly, we request that CMS consider other metrics to assess meaningful difference, such as beneficiary access, satisfaction, and convenience measures.

As CMS evaluates plan offerings, we encourage CMS to ensure an equal playing field between MA-PD and PDP plans so that neither is subject to greater scrutiny or advantages relative to the other. It is critical that CMS facilitates robust competition within the plan market so that beneficiaries have access to a variety of plans and are able to effectively choose the best plan for their needs.

PDP Meaningful Difference (§ 423.265(b)(2))

CMS proposes an "absolute percent" threshold approach to conduct annual PDP meaningful difference evaluations. CMS states that it will not take into account UM when evaluating meaningful difference because "it is difficult to conceive an approach that could evaluate the impact of a plan's UM across its enrollees, much less across enrollees in all PDPs."

BIO rejects the assertion that evaluating the impact of UM across enrollees would not be feasible or necessary. Inappropriate use of UM is a significant issue that is particularly detrimental for patients with chronic and life-threatening conditions, whereby any delay in treatment may be fatal. In its December 2023 Letter to Plans and Pharmacy Benefit Managers, CMS itself admits that UM practices have become "increasingly unsustainable and burdensome," particularly in rural areas.[2] Accordingly, it is essential that CMS appropriately track and monitor UM, particularly given the stricter use of UM by plan sponsors due to the IRA. As an example, CMS could compare utilization patterns among different demographic

[2] CMS Letter to Plans and Pharmacy Benefit Managers. CMS Fact Sheet. Dec 2023.

groups, geographical regions, or health conditions to identify disparities or areas of inappropriate UM, as well as track UM trends pre- and post-IRA.

CMS also states that it will conduct a sub-analysis to determine the proportion of meaningful difference derived from formulary robustness. Within CMS' rationale, CMS notes that they "often find that sponsors simply add drugs to their formularies, particularly those that are high cost but with low utilization, rather than improving on the benefit."

BIO strongly rejects the assertion that adding a drug to a formulary does not offer a benefit improvement if it has low utilization. Often, rare and orphan diseases may have small patient populations and therefore medications may have low utilization, but nonetheless offer a substantial, durable health benefit. Effective coverage and robust formularies are essential to address the high unmet medical needs for each patient's unique condition. To effectively consider formulary robustness, we encourage CMS to consider within its sub-analysis whether plans are giving inappropriate preference to drugs in a discriminatory fashion in order to falsely provide benefit enhancements.

Further, while noting those plan sponsors that add drugs to their formularies, CMS neglects to mention those plans that do the opposite. Over the past decade, there has been a rapid expansion in the number of prescription medications excluded from formularies. In 2022, 1,156 unique prescription medicines were excluded from standard formularies, which represented an increase of a whopping 961 percent since 2014.[3] It is troubling that CMS has not acknowledged these harmful formulary exclusions that restrict patient access to the medications they need.

Risk Corridor Methodology (§§ 423.308, 423.336)

CMS states that it will not adjust the parameters of the risk corridor due to the lack of statutory authorization to narrow the risk corridors relative to CY 2011 thresholds. While BIO recognizes the statutory limitations of the IRA, we urge CMS to consider alternative solutions due to the continued need to mitigate the adverse effects felt by Part D plans in light of the benefit redesign. It is critical that CMS act to prevent a potential exodus of plan sponsors that would further reduce choice for beneficiaries.

We appreciate CMS' 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
Senior Vice President
Healthcare Policy & Research
Biotechnology Innovation Organization

/s/
Melody Calkins
Senior Manager
Healthcare Policy & Research
Biotechnology Innovation Organization

[3] Xcenda. Skyrocketing Growth in PBM Formulary Exclusions Continues to Raise Concerns About Patient Access. May 2022.