Biotechnology Innovation Organization
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November 8, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1810

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) is reaching out to highlight Part D formulary management reforms that we believe are necessary to protect patient access given the significant changes that will be implemented in Medicare Part D in the coming years, particularly the redesign of the Part D benefit that takes effect in 2025 and "negotiated" prices taking effect for selected drugs beginning in 2026.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO and its member companies are committed to expanding the boundaries of science by discovering, developing and delivering innovative and needed medications to patients. Our products not only enhance the quality of life, they also often offer patients the best option for medical treatment.

We believe that all patients who can benefit from our member's medications and therapies should have access to them, and we believe that physicians, not third parties, are best equipped to decide whether and which prescription drugs are most appropriate for patients. Our goal is to get the right medical product to the right patient at the right time. However, BIO and its member companies can only help achieve this goal if effective and sustainable policy solutions are developed to ensure that patients secure the health care coverage they need.

It is evident that the IRA's Medicare negotiation and benefit redesign provisions will change plan dynamics and may result in Part D plan sponsors implementing more restrictive formularies. Under the Part D redesign, plan liability will significantly increase, particularly in the Part D catastrophic coverage phase and for low-income subsidy (LIS) enrollees. In response to this increased plan liability, plans may implement formulary restrictions, including but not limited to more restrictive tier management, increased utilization management (UM), benefit changes, and narrower pharmacy networks. Part D plans may reduce the number of products that are covered within a given class or even block all products aside from the two drug per class minimum. As a result, beneficiaries face a growing risk that they will lose coverage of products that will no longer be available on their plan's formulary.

BIO remains concerned that without adequate patient protections, patient access to critical prescription drugs may be severely limited or blocked entirely. To that end, BIO has identified

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the following Part D guardrails (both MA-PD and PDP) for consideration as CMS develops guidance to plans for CY2025 and beyond.

- **Protecting Patient Access:** CMS should take steps to protect patient access to needed therapies in all Medicare Part D Plans as the Part D redesign is implemented in 2025 and negotiation of selected drugs takes effect in 2026. BIO recommends that CMS clarify how it will ensure robust beneficiary access to needed therapies and asks CMS to develop safeguards that allow for diversity across formularies to meet patient needs. CMS should monitor plan coverage and tiering design, clinical appropriateness of utilization management policies, cost-sharing levels, and patient out of pocket exposure. CMS should seek to minimize class effects from the negotiation process that would result in narrower formularies and provide fewer choices to patients. CMS should also closely monitor formularies to ensure appropriate coverage of drugs that qualify for phased-in manufacturer discounts as part of the 2025 Part D redesign.

- **Develop "Best Practice" Guidelines around Formularies:** CMS should develop a set of guidelines or "best practices" for Part D formulary creation, in conjunction with stakeholder feedback and informed by clinical guidelines. These guidelines can be used as an industry standard to ensure that plans are not systematically implementing inappropriate formulary management due to the IRA. CMS should also consider developing stricter enforcement mechanisms for inappropriate formulary design.

- **Strengthen Formulary Review Process:** We encourage CMS to provide greater transparency into the formulary review process to ensure adequate patient access. CMS should use a portion of the funding appropriated under the IRA to bolster formulary reviews, such as developing additional metrics to assess formulary adequacy, and monitoring formularies pre-and post-MFP to ensure appropriateness of cost-sharing changes year-over-year.

- **Improve Data Collection and Transparency in Formulary Appeals:** CMS should consider releasing timely and more detailed information on beneficiary formulary appeals, including appeal outcomes and other information at the coverage determinations and redetermination level of appeals. This will help provide transparency into the formulary access challenges that may exist under the IRA.

- **Conduct Outlier Tests to Assess Changes in Plan Formularies Due to IRA:** CMS should provide more transparency into its current use of outlier tests and expand the tests to compare plan years pre- and post-IRA.

- **Consider IRA Implications for Protected Classes:** Currently, Part D plans are required to cover all Part D drugs in six protected classes but may apply prior authorization and step therapy for new starts (e.g., enrollees initiating therapy). CMS should reiterate its current six protected classes policy and ensure that MFP drugs within

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the six protected classes are not penalized compared to non-MFP drugs within the six protected classes. CMS should also reverse its policy and ban UM for new starts.

- **Streamline Prior Authorization for Rare Disease Treatment & Specialty Drugs:** CMS should consider expanding or developing a simplified prior authorization and appeal process for non-formulary rare disease and specialty treatment to minimize denials and delays of getting patients on clinically appropriate treatments. Part of this streamlined prior authorization process could involve implementing a "gold card program" modeled after the GOLD Card Act (H.R. 4698) that exempts certain qualified physicians from Medicare Advantage prior authorization requirements. CMS should ensure that the gold card program accounts for under-resourced providers and support the ability of under-resourced physicians to receive gold card status. This program will help to streamline the prior authorization process for providers who have consistently demonstrated adherence to evidence-based guidelines and therefore minimize unnecessary treatment delays.

- **Expand Step Therapy Protections for Specialty Drugs:** Currently, cross-benefit step therapy may only be applied to new prescriptions or to members that are not actively receiving the affected medication, with a 365-day lookback period to identify new prescriptions. CMS should consider expanding this lookback period to protect against step therapy restrictions for beneficiaries who previously used a given treatment. CMS should also require an annual review of all plans' prior authorization (PA) policies and practices and mandate that adjustments be made to allow greater patient access to specialty drugs.

- **Develop Greater Protections for LIS enrollees**: CMS should require Part D plans to cover all single sourced drugs and substantially all drugs that are highly utilized by LIS enrollees on a formulary without UM requirements.

- **Strengthen Non-Discrimination Policies:** CMS should evolve formulary management and clinical appropriateness guidelines to consider the differing health care needs among patients and subpopulations with diverse personal and clinical characteristics. CMS should also allow for ample stakeholder feedback on non-discrimination policies.

BIO welcomes the opportunity to work with policymakers and other stakeholders to develop more specific recommendations around the policy guardrails discussed in this letter. We look forward to engaging with CMS around solutions to protect patient access to necessary prescription drugs and ensure that the most appropriate care is delivered to each patient.

Sincerely,

/s/
Crystal Kuntz
Senior Vice President
Healthcare Policy & Research