Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

VIA ELECTRONIC DELIVERY

March 15, 2024

Representative Virginia Foxx (R-NC)
U.S. House Committee on Education and the Workforce
Via email to: EdandWorkforceRFI@mail.house.gov

Re: Request for Information: ERISA's 50th Anniversary: Reforms to Increase Affordability and Quality in Employer-Sponsored Health Coverage

Dear U.S. House Committee on Education and the Workforce:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the U.S. Committee on Education and the Workforce's (Committee's) Request for Information on Reforms to Increase Affordability and Quality in Employer-Sponsored Health Coverage (ERISA RFI). BIO strongly supports efforts to help improve patient access to, and the affordability of, the amazing medical breakthroughs that our member companies are developing, and we pledge to work constructively with Congress to achieve this goal.

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's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO's member companies work to discover innovative, transformative therapies, including cell and gene therapies, that provide a significant, durable benefit and value for patient health outcomes, delivery of care, and overall health care spending. These novel therapies are aimed at serious and rare diseases where patients often have limited treatment options. Taken together, our companies offer hope for cures and treatments where there was none, help reduce health care costs, and ensure a better quality of life.

BIO shares the Committee's goal of reducing barriers for employers to cover innovative specialty drugs. We appreciate the Committee's recognition of the tremendous value of innovative specialty drugs that yield long-term savings through improved health of patients, reduced utilization of traditional treatments, lower hospitalization rates, and improved productivity. As employers express concerns with the upfront cost of specialty drugs, it is clear that traditional payment systems need to evolve to encompass the lifetime value of these drugs and their impact for patients, their families, and the healthcare system.

However, it is also important for policymakers to recognize that while specialty drugs will have upfront costs, they will also offset costs of older, less effective treatments. Further, many treatments will eventually lose exclusivity, becoming significantly more affordable over time. Therefore, in order to truly reduce barriers for employer coverage of specialty drugs, it is critical that the Committee examine insurance coverage trends that have shifted more and more cost-sharing burden to patients and other access barriers within the commercial market.

While BIO has specific feedback regarding topics on specialty drug coverage identified in the RFI (described below), as a general matter, we urge lawmakers to investigate the use of alternative funding programs (AFPs) within the commercial market and how they harm patient access to specialty drugs. As BIO has expressed in the past, AFPs are a growing concern for commercially insured patients. AFPs involve "third-party vendors" who eliminate patients' coverage for all or select specialty drugs and mislead employers into believing that their specialty drug spending will be reduced. Often unbeknownst to the employer, the patient is inappropriately directed to an associated drug manufacturer's charitable foundation, thus siphoning resources from low-income and uninsured patients, while the third-party vendor takes a share of the charity's funds. AFPs may also lead to the improper and illegal use of federal resources as the cost of the patient's specialty medications is diverted to a secondary payer such as Medicaid. AFPs are also known to source prescriptions from unlicensed pharmacies located outside of the United States, posing serious issues for patient safety.[1] As AFPs provide inaccurate and misleading information to employers, patients are burdened with additional processes which may delay treatment and potentially lead to worsened health outcomes.

In addition, AFPs may lead employers to violate ERISA prohibitions on non-discrimination for groups of "similarly situated individuals." When third-party vendors inappropriately direct employees to a manufacturer sponsored patient assistance program (PAP), it is evident that some of the employees will be eligible for the assistance program and some will not, based on income and other eligibility conditions. Those beneficiaries who are forced to go through an AFP are subject to the potential dangers and risks of medication delays and illegal importations, while those beneficiaries who are of higher income are able to go through regular channels because they do not qualify for charitable assistance. Given the discriminatory impacts and significant harms that AFPs pose on patients, employer-sponsored coverage, and the healthcare system, BIO urges the Committee to take action against this deceptive and harmful practice that impedes specialty drug coverage and access.

In our letter below, BIO responds to the specific questions that the Committee poses within the RFI while highlighting challenges that impact employer coverage of specialty drugs and subsequently impede patient access.

[1] Fein, Adam J. "The Shady Business of Specialty Carve-Outs, a.k.a., Alternative Funding Programs." Drug Channels. August 2, 2022.

I. Specialty Drug Coverage

What challenges do employers face in offering coverage of high-cost specialty drugs, and how can those challenges be addressed?

Employers face challenges navigating complex benefit structures, pharmacy networks, and formularies that are obscured by the perverse incentives of PBMs. Over time, the rapid growth and market consolidation of PBMs have led to the current state where the three largest PBMs control nearly 80% of the market.[2] As a result, employer coverage of medicines is increasingly influenced by PBMs. While employers under ERISA have a fiduciary duty to effectively manage plan assets to the benefit of their employees, the lack of transparency of PBM practices makes it difficult for employers to assess whether the administration of drug benefits align with the best interest and well-being of their employees. PBMs have systematically attempted to conceal their business practices, choosing drugs for their formulary that generate the highest rebate for themselves, rather than those products that are more clinically appropriate or less expensive for the patient.[3] Meanwhile, PBMs exclude essential drugs from formularies to the detriment of patients. From 2014 through 2022, PBMs excluded a total of 1,357 unique medications for at least one year from one PBM.[4] Of these, 48% (654) were drugs without a generic equivalent or biosimilar alternative.[5]

As the Committee evaluates ways to reduce barriers in the coverage of specialty drugs in employer plans, it is critical that the Committee addresses the barriers imposed by PBMs that prevent patients from getting the medications they need. There are only limited protections in place today to hold PBMs accountable when their financial interests conflict with the interests of patients or the employers they serve. And, even where these protections do exist, few have clear enforcement mechanisms to support them. Policymakers should take an important step by requiring PBMs to operate more transparently, act in the best interest of patients and their employer clients, and pass through savings to patients in the form of out-of-pocket costs based on the net price of the drug.

What role can reinsurance models play in helping employers pay for high-cost specialty drugs?

Reinsurance allows employer-sponsored plans to transfer a portion of the financial risk to reinsurers, thus mitigating fiscal risks for issuers and allowing issuers to avoid passing the full cost burden to policyholders in the form of significantly higher premiums. Several states have created reinsurance pools to stabilize insurance premiums under the exchanges created by the Affordable Care Act (ACA).[6] Twelve states[7] have attempted a few different models of reinsurance in the individual markets with varying levels of success through the

[2] Werble, Cole. "Pharmacy Benefit Managers," Health Affairs Health Policy Brief, September 14, 2017.
[3] "Skyrocketing Growth in PBM Formulary Exclusions Continues to Raise Concerns About Patient Access." Xcenda White Paper, May 2022,
[4] Fein, Adam J. "The Big Three PBMs' 2024 Formulary Exclusions: Biosimilar Humira Battles, CVS Health's Weird Strategy, and the Insulin Shakeup." Drug Channels. January 2024.
[5] Fein, Adam (2024). Ibid.
[6] "Next Generation Therapies in Massachusetts: New Solutions for Coverage and Payment," Network for Excellence in Health Innovation (NEHI), 2019.
[7] "Benefits and Limitations of State-Run Individual Market Reinsurance." Issue Briefs, The Commonwealth Fund. November 11, 2020

use of a State Innovation Waiver granted by CMS. While not all states have seen an increase in enrollment through the health insurance exchanges, all states that have used a State Innovation Waiver for reinsurance programs have successfully reduced premiums in their individual health insurance markets, thus, lowering out-of-pocket costs for consumers.[8]

To that end, reinsurance and other risk mitigation programs have shown great promise as suitable tools in lowering overall premiums for certain commercially insured patients, thus bringing down total out-of-pocket costs for the chronically ill. Further, these programs have made insurance more attainable for some who might not have otherwise been able to afford it. Reinsurance can help address key challenges in the marketplace, such as affordability of premiums and excess volatility/uncertainty.[9] BIO welcomes the opportunity to discuss more detailed recommendations with lawmakers on implementing reinsurance programs and exploring other risk mitigation opportunities.

What barriers exist in ERISA or elsewhere that hinder employers' ability to leverage reinsurance for the purposes of mitigating the risks of covering high-cost specialty drugs?

The unique market characteristics of certain states and regions may pose challenges for employers to leverage reinsurance in certain areas to cover high-cost specialty drugs. For instance, some states may have large regional variations in premiums, which may impact the ability for certain high-cost areas to retain insurers. Federal pass-through funding has helped many states operationalize reinsurance programs that cater to the unique needs of their state. Without adequate federal resources, reinsurance programs may not be robust enough to attract the level of participation that would benefit employers.

What tools can employers use to expand risk pools to lower the collective costs of coverage of high-cost specialty drugs?

Risk pools can be useful to manage costs of high claim patients. However, because these patients can be highly case managed given their higher cost claims, there are some concerns that this approach could lead to benefit cuts for these vulnerable patients. Accordingly, any solutions employers use to expand risk pools should prioritize access and continuity of care for those enrollees.

Can employers enter into multiple employer welfare arrangements or similar risk-sharing models to help decrease the cost of high-cost specialty drugs?

The efficacy of any risk-sharing model must be assessed on a case-by-case basis to determine its impact toward patients. However, as a whole, the structure of any risk sharing model should:

- ✓ Allow for robust access not only to specialty drugs but necessary ancillary services and travel to certified treatment centers, etc;

[8] Commonwealth Fund (2020). Ibid.
[9] NEHI (2019) Op. Cit.

- ✓ Continue to provide coverage over patient's lifetime to address chronic conditions or other ongoing unmet needs; and
- ✓ Consider holistic clinical and non-clinical savings over a patient's lifetime rather than any inappropriate emphasis on list price.

What role should the federal government play in assisting employers, drug manufacturers, and other entities to manage risks and to share the costs and savings of employer-sponsored coverage of high-cost specialty drugs?

BIO strongly believes that any actions taken by employer-sponsored plans or other stakeholders to manage risks, share costs, and produce savings should never come at the expense of patients' access to clinically necessary drugs. Accordingly, the federal government's role should prioritize putting patients first and ensuring that entities do not inappropriately discriminate against patients that need adequate specialty drug coverage. Putting patients first involves banning discriminatory tactics such as AFPs that limit patient access to specialty drugs. As mentioned, AFPs mislead and deceive employers by making inaccurate claims of cost savings, when in reality, costs are inappropriately shifted to PAPs and potentially even secondary payors such as Medicaid. AFPs disproportionately target patients with complex and rare conditions that are prescribed specialty medications. These vulnerable patients are then subject to discriminatory coverage exclusions that result in treatment delays and potentially even exposure to non-FDA approved medications sourced from outside of the United States. Employers appear to be largely unaware of these risks as the adoption of AFPs has grown in recent years. In 2022, 14% of employers reported using an AFP, up from 6% in 2021.[10] The increasing prevalence of AFPs in employer-sponsored plans underscores the critical need for the federal government to protect patients from AFPs.

Similarly, the federal government should prohibit the use of accumulator adjustment programs (AAPs) which exclude the value of manufacturer cost-sharing assistance from patient deductibles and annual out-of-pocket limits on cost sharing. In doing so, AAPs increase patient nonadherence which can lead to negative health outcomes. A study by IQVIA, cited by Bloomberg Law, found that between 25% to 36% of respondents discontinued treatment when they received charges of more than $1,500 as a result of AAPs.[11] Despite these concerning outcomes, more commercial plans are implementing these programs. In 2023, 82% of commercially insured beneficiaries were enrolled in plans that have implemented AAPs and 72% were in plans that have implemented copay maximizer programs.[12] Copay maximizer programs set patient's OOP obligations to the maximum value of manufacturer copay assistance, so that the assistance does not count towards the patient's deductible and OOP maximum. We urge the Committee to remove cost-sharing barriers for patients so that patients are able to share in savings to access their life-saving medication.

[10] Fein, Adam J. "Employers Expand Use of Alternative Funding Programs- But Sustainability in Doubt as Loopholes Close." Drug Channels. January 2024.
[11] Hansard, Sara. "Lawmakers Ask HHS to Drop Copay Assistance Court Challenge." Bloomberg Law. January 2024.
[12] Fein, Adam J. "Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow." Drug Channels. February 2024.

What barriers exist in ERISA or elsewhere that prevent employers from entering into value-based arrangements with drug manufacturers for coverage of high-cost specialty drugs?

Employer-sponsored plans are strongly influenced by coverage and reimbursement frameworks and barriers set by public programs. Accordingly, legacy laws and rules within public programs that disincentivize the use of VBAs often have spill-over effects that create barriers in employer-sponsored coverage. For instance, unit-based price reporting and operating on volume rather than value inhibits the adoption of innovative payment models across all market segments. Recently, the proposed Medicaid Best Price Rule (MDRP) would require the stacking of all discounts (including commercial discounts), provided through the supply chain when calculating best price. If finalized, the "stacking" provision would have downstream implications in the commercial marketplace and subsequently impose barriers on VBAs in all markets, including employer-sponsored coverage of specialty drugs. The Committee should carefully consider how barriers to VBAs in public programs can impact coverage of specialty drugs across markets.

In addition, VBAs in the commercial market, including employer-payment arrangements, are limited by state budgetary pressures. All states are required to balance their budgets either by their Constitution or by state law. Frequently, this pressure to balance their state budgets can result in benefit cuts and restrictive policies denying many patients access to their needed specialty drugs. States facing budget constraints may be reluctant to shift to VBAs or allocate resources for the development of VBAs. However, it is critical that policymakers understand that barriers placed on VBAs due to budgetary pressures may ultimately be counterproductive. Rather, promoting VBAs and exploring reimbursement pathways to increase patient access to specialty drugs will improve overall health outcomes and generate long term savings.

What innovative coverage models are currently in use that address the high cost of specialty drugs?

The biopharmaceutical market is well positioned to test various innovative coverage models based on the unique aspects of each specialty drug. Innovative coverage models that may benefit certain specialty drugs include value-based arrangements, indication-based pricing, outcomes-based arrangements, money-back guarantees, product warranties, and other arrangements that account for long-term value, provide efficacy assurances, and align provider incentives with patient health. For certain specialty drugs, the ability to pay for a high-cost, single-administration therapy over the long term, via multiple payments, instead of one payment at the time of administration, may offer the opportunity and option for payers to decrease upfront spending. However, it is critical to note that there is no one-size-fits-all payment solution. The applicability of each coverage model varies based on the unique characteristics of each drug. Each arrangement brings a unique set of benefits or challenges to the patient, the payer, and the market of biopharmaceutical innovation. Given the complexity and varying needs for all parties, it is essential that agreements remain flexible and voluntary, which will subsequently allow for an environment that encourages innovation. BIO encourages the Committee to prioritize the flexible and voluntary nature of innovative coverage models and allow stakeholders to tailor payment innovations to the clinical and operational factors and other variables associated with each specialty drug.

II. Prohibited Transactions

The Committee seeks feedback on whether 340B discounts and pharmacy steering may constitute self-dealing and violate ERISA's prohibited transactions in certain circumstances.

Actions by covered entities under the 340B Program are prone to statutory violations, including but not limited to potential ERISA violations, due to systematic abuse of the 340B program including the lack of program oversight, a growing amount of private hospitals receiving 340B discounts for which they are not eligible, and the overall lack of scrutiny for contract pharmacy arrangements. In 2018, two-thirds of all audited covered entities were found by HRSA to have violations of program requirements.[13] In 2019, fifty-six percent of all covered entities were found by HRSA to have violations.[14] These audits found that significant violations occur in the duplicate discount area, in addition to covered entities incorrectly listing ineligible child sites in the Office of Pharmacy Affairs Information System (OPAIS), which would inappropriately enable them to receive discounts they are not entitled to. In addition, a report by GAO found that a subset of hospitals included in the study did not appear to have contracts in place that require hospitals to serve the 340B low-income population.[15] Further, GAO found that at many of those contract pharmacies, 340B discounts were not passed through to patients.[16] Greater oversight and scrutiny of contract pharmacy arrangements is necessary to curb perverse incentives that encourage potential statutory violations.

The Committee should also scrutinize the practices of self-insured 340B entities and 340B contract pharmacies that may attempt to receive greater discounted 340B drugs from their own employees' prescriptions. Due to the heightened fiduciary responsibilities of employers under ERISA, it is essential for self-insured health systems to ensure that they are fairly representing the interests of their employees rather than their own. However, it is evident that the vertical integration of self-insured health systems have contributed to perverse incentives and are susceptible to self-dealing. It has become more common that self-insured health systems are maximizing their employee's use of internal specialty pharmacies by making their pharmacy the preferred option or designating it as the exclusive specialty pharmacy in its plan's network in order to maximize 340B profits.[17] A study by the American Society of Hospital Pharmacists (ASHP) found that nearly two-thirds of the larger health system specialty pharmacies are the exclusive pharmacy within self-insured health systems' networks.[18] The steering of employees to health system-owned or affiliated 340B contract pharmacies, in order to maximize overall health system profits, may constitute self-dealing and be in violation of ERISA's prohibition transactions for fiduciaries. We encourage the Committee to investigate 340B-covered entities and contract pharmacies that may be engaging in these 340B statutory violations.

---

[13] Review of HRSA Covered Entity Audit Findings, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-18-results.html
[14] Review of HRSA Covered Entity Audit Findings. Ibid.
[15] "340B Drug Discount Program: Increased Oversight Needed to Ensure Non-governmental Hospitals Meet Eligibility Requirements," GAO Report, December 2019.
[16] "Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement." GAO Study. June 2018.
[17] Fein, Adam J. "Fresh Evidence: How Health Systems Steer Prescriptions to Their Own Specialty Pharmacies." Drug Channels. October 2021.
[18] Fein, Adam (Ibid).

III. Conclusion

BIO appreciates the opportunity to comment on the RFI. Should you have any questions, please contact us at 202-962-9200.

Sincerely,

/s/
Crystal Kuntz
Vice President
Healthcare Policy and Research

/s/
Melody Calkins
Senior Manager
Healthcare Policy