Biotechnology Innovation Organization
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December 5, 2022

Cynthia Pierre
Chief Operating Officer,
U.S. Equal Employment Opportunity Commission

Delivered via Federal e-Rulemaking Portal: https://www.regulations.gov

RE: Notice of Availability and Request for Comment: Equal Employment Opportunity Commission (EEOC) Draft Strategic Plan 2022–2026

Dear Cynthia Pierre:

Thank you for the opportunity to comment on the Equal Employment Opportunity Commission (EEOC) Draft Strategic Plan 2022–2026. BIO commends the Commission for carrying out its important mission to stop and remedy unlawful employment discrimination in the workplace by enforcing Federal laws that prohibit employment discrimination.

To that end, we are writing on behalf of the Biotechnology Innovation Organization (BIO) to request that EEOC investigate the removal, or "carving out" of some or all specialty drugs from an employer's drug benefit for inappropriate reliance on a drug manufacturer's patient assistance program to pay for such drugs, sometimes called "Alternative Funding Programs" (AFPs). We encourage EEOC to investigate the extent to which such activities may violate equal opportunity laws including the Americans with Disabilities Act (ADA), which prohibits employers from discriminating on the basis of disability in the provision of health insurance to their employees and the Affordable Care Act, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability, in certain health programs or activities. Appropriate and adequate health insurance coverage is especially critical for the estimated thirty million Americans living with a range of 7,000 rare or orphan diseases, whose conditions all too often result in disability. Because of the health challenges such patients face, getting the right medicine at the right time is critical. Therefore, proper enforcement of federal law protecting Americans with disabilities is also critical.

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 thirty 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 yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. Our members also administer patient assistance programs and work closely with case managers who ensure patients can get access to our therapies.

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Background on AFPs

In recent years, employers have increasingly utilized AFPs by partnering with vendors such as ImpaxRX, Paydhealth, SHARx, PayerMatrix, Rx Help Centers, Ventegra, and Script Sourcing. These third-party vendors assist employers in limiting their benefits such that certain patients, often with disabilities, effectively have no coverage for specialty medications. The vendors then, in turn, work with the patients prescribed the specialty drug or treatment to obtain their medication via patient assistance programs at manufacturers' or other charitable foundations' expense.[i]

There are several issues with this practice. Most importantly, AFPs hurt patients. In removing coverage for a specialty drug, the employer and the AFP then inappropriately exposes patients to significant delays in care, added administrative burden, and uncertainty that their medicine will be covered. These can create a range of problems for patients, including a lack of continuity in care, which can lead to worse patient outcomes.

AFPs also result in a misallocation of charitable funds. Patient assistance programs by both manufacturers and other foundations typically have low-income and non-insured status requirements in place for patients using that assistance. Thus, the AFP, by portraying a member disingenuously as uninsured or underinsured, can subvert the charitable intention of the needs-based assistance to cover the cost of the treatment now carved out of the employer's health benefit package. Thus, according to experts, commercial payers are inappropriately accessing needs-based funds from charitable foundations that were established to help underinsured and uninsured patients.[ii] Further, patients with real unmet needs must then compete for patient assistance program funds with financially sound payers and patients who would not otherwise be eligible for charitable support.[iii]

Moreover, the employers partnering with AFP third-party vendors can be unaware of how the AFPs operate and some experts have gone as far to state that the AFPs "misrepresent" their patients to the medical charities.[iv] Third party vendors' actions can result in employers cutting a full class of specialty benefits without realizing it. Sometimes, once they realize what has occurred, employers end up paying out of pocket for their employees' healthcare, after they have already paid an insurance premium, expecting subsequent coverage and care for the employee. What is more, third-party vendors' practices could potentially violate not only federal employment and benefit laws, but also false advertising laws, and a range of state insurance codes.

If a patient is not eligible to receive patient assistance due to income or other qualifying criteria, a patient with coverage featuring an AFP may simply go without the needed drug. Alternatively, experts report that in such cases, "some carve-out vendors will seek to source products from pharmacies located outside the United States."[v] This is likely not permitted under federal law and may subvert the FDA's drug safety standards.[vi] The bottom line is that AFPs are yet another party inserting themselves into the revenue stream of healthcare. They are charging the employer a share of what they are saving, without adding any value—and potentially being harmful—to patient outcomes and experience.

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The Use of AFPs Presents Troubling Precedents and May Violate Employment Law

Title I of the ADA requires an employer to provide reasonable accommodation to qualified individuals with disabilities who are employees or applicants for employment. The ADA further requires employers to provide reasonable accommodations so that employees with disabilities can enjoy the "benefits and privileges of employment" equal to those enjoyed by similarly situated employees without disabilities.[vii]

Specifically, the ADA makes it unlawful for an employer to discriminate on the basis of disability in regard to, among other things, the "terms, conditions, and privileges of employment."[viii] EEOC's regulations clarify that this extends to "[f]ringe benefits available by virtue of employment, whether or not administered by the [employer]," including health insurance plans provided by an employer to its employees.[ix] An employer therefore may not directly discriminate through the health insurance plan it provides as part of its benefits; nor may an employer enter into, or participate in, a contractual or other arrangement or relationship that has the effect of discriminating against their own qualified applicants or employees with disabilities.[x]

Thus, if an employer drops all specialty drugs from its benefit package, or even a specific specialty drug or treatment, the employer could be violating equal benefits laws for individuals with disabilities, serious disease, or rare disease who are prescribed the dropped treatments. These discriminatory practices can have a devastating impact on employees and their dependents (including children and spouses with rare diseases) who are unable to access specialty drugs and innovative cell and gene therapy treatments with limited to no other treatments being available to them.

EEOC Should Investigate Improper Use of AFPs and Update Guidance Accordingly.

BIO recommends that as part of its strategic plan, the EEOC investigate this growing and systemic form of discrimination in the use of AFPs and where necessary, partnering with other federal agencies, such as the Department of Health and Human Services, Department of Labor, the Treasury Department, and perhaps others.

Consistent with Strategic Objective I.A. and with EEOC's Systemic Program, EEOC should dedicate resources to reveal discrimination in the provision of health benefits and support its investigators and trial attorneys in pursuing enforcement action where needed. Employees and their families, who are affected by disability and rare diseases, including rare pediatric conditions, deserve to see EEOC action against discriminatory practices in their employer's health insurance.

Additionally, BIO recommends the EEOC update its 1993 ADA Guidance. Objectives II.A and II.B address EEOC's plans to update existing guidance and training materials and create new, user-friendly resources and tools to address and prevent workplace discrimination. As part of this effort, EEOC should update and modernize its 1993 ADA Guidance to reflect the emergence of specialty drugs and transformative therapies and treatments. This update should include the substantial strides in the treatment of cancer and rare diseases and

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should ensure that employers neither intentionally nor unintentionally discriminate on the basis of disability with respect to how they design and apply their health benefits packages. BIO and its member companies are happy to assist these efforts, for example, in assuring that guidance properly describes specialty drugs or supplying real-life case studies of discrimination patients in charitable programs have experienced.

Conclusion

We thank you for the opportunity to register our thoughts and concerns on how AFCs applied to employer health benefits are discriminating against Americans with disabilities and look forward to future discussions. BIO and its member companies stand ready to partner with you and assist you in investigating these matters in any way we can. Please do not hesitate to contact us with any questions at (202) 962-9200.

Sincerely.

Crystal Kuntz
Vice President,
Healthcare Policy and Research

Andy Cosgrove
Senior Director
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[i] Vivio, "ERISA and IRS Compliance Related Issues for Alternative Funding Programs," chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://viviohealth.com/wp-content/uploads/2022/06/Compliance-Issues-with-Alternative-Funding-V1.01.pdf

[ii] See, e.g., Adam Fein, " "The Shady Business of Specialty Carve-Outs," August 2, 2022, https://www.drugchannels.net/2022/08/the-shady-business-of-specialty-carve.html

[iii] See, e.g., Adam Fein, Op. Cit.

[iv] Vivio, Op. Cit.

[v] See, e.g., Adam Fein, Op. Cit.

[vi] FDA, "Is it Legal for Me to Personally Import Drugs?" January 6, 2021. https://www.fda.gov/about-fda/fda-basics/it-legal-me-personally-import-drugs

[vii] US EEOC, "Enforcement Guidance on Reasonable Accommodation and Undue Hardship under the ADA," October 17, 2002. https://www.eeoc.gov/laws/guidance/enforcement-guidance-reasonable-accommodation-and-undue-hardship-under-ada#requesting

[viii] 42 U.S.C. § 12112(a).

[ix] 29 C.F.R. § 1630.4(a)(vi).

[x] 42 U.S.C. § 12112(b)(2); 29 C.F.R. § 1630.6(a), (b). Such activities may also stand in violation of Section 1557 of the Affordable Care Act.