

March 15, 2024

Chairwoman Virginia Foxx
House of Representatives
Committee on Education and the Workforce

Re: The Committee on Education and the Workforce Request for Information on Employer-Sponsored Insurance and Employee Retirement Income Security Act (ERISA)

Dear Representative Foxx:

The undersigned organizations represent patients, providers, and caregiver communities; and non-profit health policy organizations invested in improving and protecting health care access for consumers.

I. Introduction and Overview of Alternative Funding Programs (AFPs)

The Employee Retirement and Income Security Act (ERISA) was originally passed to govern how employers managed public pension benefits, and to ensure these benefits were protected from mismanagement.¹ ERISA was only later expanded to provide broader protections to employees' health insurance benefits.² However, under both the original intent and expanded mandate of ERISA, the ultimate aim of this legislation is to protect employees' right to access the benefits they have been promised by their employer.³

The responsibility to enforce ERISA requirements is shared between multiple agencies including the Department of Labor (DOL), the Internal Revenue Service (IRS), and the Department of Health and Human Services (HHS).⁴ Unfortunately, the complexity of this joint oversight arrangement has sometimes resulted in gaps, allowing health plans to exploit ambiguities in the law to the detriment of beneficiaries and health care consumers.

One recent development enabled by lack of oversight action is the proliferation of alternative funding programs (AFPs) among ERISA plans. Alternative funding programs are operated by third-party vendors that contract with ERISA health plans to manage employee access to specialty drugs. Under these schemes, the ERISA health plan either excludes select high-cost drugs from coverage or subjects specialty drugs to a strict – and often unreasonable – prior authorization process which unduly hampers access to these medications. Enrollees who use any of the drugs included in the program are offered a “choice” to enroll in the program or forfeit any coverage for the drug in question.⁵

If the employee or plan participant enrolls in the program, the AFP then attempts to source the drug from outside of the health plan, usually through a Patient Assistance Program (PAP)

¹ <https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/history-of-ebsa-and-erisa#:~:text=ERISA%20was%20the%20culmination%20of,of%20employees%20and%20their%20families.>

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ https://aimedalliance.org/wp-content/uploads/2024/02/AFP-White-Paper_FINAL.pdf

operated by a pharmaceutical manufacturer to help people who are truly uninsured or underinsured gain access to high-cost prescription drugs. The AFPs goal of initially carving out or denying prior authorization for the drug is to make the enrollee appear underinsured to meet the PAP's eligibility requirement. In exchange for the AFP's role in procuring the prescription drug from the PAP, the employer will pay the AFP vendor a fee, usually between 30 and 50 percent of the plans savings achieved as a result of not covering the cost of the prescription drug. If the AFP is unable to source the drug through a PAP or other means outside of the plan, the enrollee may then be able to get coverage through the plan or they may be left without access to critical treatment⁶

While these programs may appear beneficial on their face, in practicality these programs create discriminatory benefits for high-cost prescription drug needs; deprive consumers of the benefit of their health care premiums; and can delay timely access to medically necessary treatments for severe and life-threatening conditions. The proliferation of AFPs and the havoc they wreak for patients and providers is indicative of a need for ERISA reform to ensure that employer health benefits are administered to the benefit of their enrollees. With that in mind, the undersigned organizations sincerely appreciate the opportunity to comment on how Congress can reform and improve ERISA to ensure employers are incentivized to offer comprehensive benefits and protect employee's ability to access care.

II. Fiduciary Duty Requirements

Under current law, ERISA plans have a fiduciary duty to act solely in the interest of the plan participants; carry out their duties prudently; follow the plan documents (unless inconsistent with ERISA); hold any plan assets in trust; and to pay only reasonable plan expenses.⁷ In recent years, health plans have increasingly deviated from these obligations, acting in the employer's interest rather than the employees', resulting in unnecessary delays in access to treatments, discriminatory benefit designs, and improper benefit denials.

A. Definition of fiduciary, its use, and fiduciary obligations under ERISA

Under ERISA Section 404(a)(1), plan sponsors have a fiduciary duty to "discharge[their] duties . . . solely in the interest of the participants and beneficiaries and for the exclusive purpose of . . . providing benefits to participants and their beneficiaries."⁸ In *Vanity Corp v. Howe*, the United States Supreme Court further clarified that this obligation was truly intended to focus on *the beneficiary* not the plan's interest by stating: "[t]o participate knowingly and significantly in deceiving a plan's beneficiaries in order to save the employer money at the beneficiaries' expense is not to act 'solely in the interest of the participants and beneficiaries.'"⁹

Thus, employees who pay to participate in their employer group health plan have a reasonable expectation that their employer will use their pay and manage the plan and its

⁶ <https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/before-abbvie-lawsuit-payer-matrixs-cbo-defended-companys-business-model-2/>

⁷ [Fiduciary Responsibilities | U.S. Department of Labor \(dol.gov\)](#)

⁸ ERISA Section 404(a)(1),

⁹ *Vanity Corp. v. Howe*, 516 U.S. 489 (1996).

assets with the goal of providing them with health benefits.¹⁰ Unfortunately, and in direct contradiction of their fiduciary responsibilities, employers have recently begun to implement AFPs to avoid providing the promised benefits to participants and beneficiaries, so the plan can spend less on providing health care benefits. Prioritizing employer cost-savings at the expense of consumers is the exact breach of fiduciary duty the Supreme Court was concerned about in *Vanity Corp. v. Howe*.¹¹

The policies and practices used in the implementation of AFPs raise potential violations of the following fiduciary duties: (1) failure to act prudently when implementing an AFP that prioritizes achieving plan savings over providing participants and beneficiaries with benefits; (2) failure to follow the terms of plan documents when claiming non-coverage or automatically denying prior authorization; and (3) failure to pay only reasonable plan expenses when paying third-party vendors to engage in transactions to save the plan money rather than providing benefits to participants and beneficiaries.¹² Other conduct that may violate fiduciary duty requirements include, but is not limited to:

- Implementing automatic denials of prior authorization without reviewing and making a determination on the merits of the request;
- Claiming the plan excludes coverage of specialty medications and failing to provide plan documents detailing non-coverage;
- Sending or authorizing written notifications to participants and beneficiaries stating the plan's third-party vendor is a patient advocate acting solely in the best interest of participants and beneficiaries, when the third-party's sole responsibility is to reduce prescription drug costs for the ERISA health plan;
- Requiring participants and beneficiaries to sign a power of attorney as a prerequisite to accessing specialty medications;
- Requiring participants and beneficiaries to provide financial and other personal information as a prerequisite to accessing specialty medications;
- Requiring participants and beneficiaries to misrepresent their insured status on applications to PAPs as a prerequisite to accessing specialty medications,
- Providing participants and beneficiaries with prescription drugs that are imported from outside the United States, that do not follow the FDA's requirements for international importation, posing health and safety risks to them;
- Providing participants and beneficiaries with less than the full course of treatment prescribed by the clinician, potentially causing negative health consequences for them;
- Making inaccurate statements to participants and beneficiaries that implementing an AFP does not change their process for accessing specialty medications,
- Delaying participants' and beneficiaries' timely access to specialty medications by requiring the completion and submission of applications and supporting materials to PAPs, potentially causing negative health consequences

¹⁰ DOL, Employee Benefits Security Administration (EBSA), *Understanding Your Fiduciary Responsibilities Under A Group Health Plan*, <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/understanding-your-fiduciary-responsibilities-under-a-group-health-plan.pdf>

¹¹ https://aimedalliance.org/wp-content/uploads/2024/02/AFP-White-Paper_FINAL.pdf

¹² ERISA Section 404(1)(a).

- Mismanaging participants' and beneficiaries' premium (i.e., plan assets) payments held in trust; and
- Providing inaccurate, incomplete, untimely, and/or misleading plan information to participants and beneficiaries.

Recommendations:

1. *Congress should strengthen or clarify “in the interest of participants and beneficiaries” to include not only financial interest of the whole but also the medical interests of those beneficiaries. Exclusionary practices that restrict a beneficiary’s ability to receive evidence-based, medically necessary treatment are not in their best interest. We would also ask that Congress apply the standard of what a prudent person would expect when defining coverage requirements related to the fiduciary responsibility of trustees and plan sponsors.*
2. *Congress should require all parties involved with plan design implementation, operation, and oversight to owe a fiduciary duty to plan participants and beneficiaries. This includes trustees, plan sponsors, administrators, TPAs, insurance broker-agents, pharmacy benefit managers, and any other third-party entity involved in the process of securing or operationalizing benefits on behalf of a member.*
3. *Congress must ensure that all parties acting on behalf of an ERISA plan are held to the same fiduciary requirements as the plan trustees. Without this, third parties such as AFP vendors and pharmacy benefit managers are able to undermine the fiduciary protection requirements, leaving plan beneficiaries without the coverage they believed they had when they enrolled the plan. Extending fiduciary duty requirements to third parties also deters entities from imposing large and unnecessary “cost avoidance fees” on the plan that have no benefit to plan beneficiaries.*
 - a. *Currently only plan trustees are held to the fiduciary responsibility. Because these trustees are typically volunteers and have full time jobs elsewhere, they rely on outside agents, brokers, and vendors to assist with plan design and operation. These vendors are not currently held to the same fiduciary responsibility and this lack of pass-through accountability increases risk for trustees who may be unfamiliar with all of the minutia that could create significant personal risk for them. By allowing the fiduciary requirements to apply to all those in the process, it ensures that assets are truly being managed for the benefit of plan participants.*
 - b. *Fiduciary duties should not fall on beneficiaries as they have no ability to change plan design, implementation, or operation. Moreover, plan beneficiaries generally already seek the most affordable treatments to manage their conditions. Under these circumstances it would be unfair to state a beneficiary who requires a higher-cost prescription drug is breaching their fiduciary duty owed to the plan because their health care needs are more expensive. While we do feel that it is the responsibility of all Americans to be good healthcare consumers, current plan designs including single sourcing and vertical integration take that ability away from the end consumer.*

III. Direct and Indirect Compensation

An overarching aim of the Consolidated Appropriations Act, 2021 (CAA) is to require transparency in an historically opaque health care system. In addition to helping manage health care spending, transparency also helps ensure that employees (and their family members) are receiving the high-quality and comprehensive coverage and access to care that they deserve in return for their health care premiums. With the proliferation of AFP vendors and their direct influence on enrollees' access to care and treatment, the CAA must ensure that employees and beneficiaries, as well as the plan, benefit equally from the greater transparency related to direct and indirect compensation.

Under the CAA, "covered service providers," such as brokers and consultants who contract with a covered plan and are reasonably expected to receive compensation in excess of \$1,000 or more, must disclose this information to their clients.¹³ Importantly, the clarification states that the "covered service providers" disclosures extend to the indirect and direct compensation of their affiliates and subcontractors - irrespective of which entity will actually perform the services.¹⁴ We thank Congress for including the compensation paid to affiliates and subcontractors requiring affiliates and subcontractors to be subject to these disclosure requirements, since this will at least minimize what were invisible or unaccounted for transactions that left employers and employees (and their beneficiaries) alike vulnerable to overspending and increased costs.

Undisclosed direct and indirect compensation paid for nondescript services adds to the cost of care for employees and their beneficiaries and enables the furtive implementation of services that may negatively impact, and even target, patients with serious, complex, and chronic health conditions. Employees are confused by the relationship between these AFP vendors and their employer plan, especially since they may not have advanced notice and/or understanding of the AFP arrangement prior to the vendor reaching out to them. There is great inconsistency and ambiguity on what employees and their beneficiaries are told about if or how they must work with the vendor to get their medication, or possibly be left responsible to pay for the full cost of their medication with nothing counting toward their deductible or out-of-pockets limits.

While the undersigned organizations support the expanded transparency relating to direct and indirect compensation, we believe that there remain significant gaps related to unaccountable costs to employers, employees, and the health care system as a result of AFP compensation incentives. We ask that the Content of Disclosure requirements address both the cost *and impact on affordability* to ensure that these reporting requirements have a direct impact on plan payers and beneficiaries. Additional details required in the Content of Disclosure will also help all stakeholders learn more about the costs related to all of the entities in their healthcare chain.

Recommendations:

1. *Require that the plan fiduciaries make available to all employees and their beneficiaries the full content of all reports received by the plan fiduciary(ies) on direct and indirect compensation per the terms of the CAA;*

¹³ https://nabip.org/media/6779/broker_compensation_group_112921.pdf

¹⁴ https://nabip.org/media/6779/broker_compensation_group_112921.pdf

2. *Require all CAA reports on direct and indirect compensation be prominently displayed in writing where employees and their beneficiaries can obtain the reports and that information on how and where to access the reports on direct and indirect compensation is provided to employees and beneficiaries*
3. *Require all CAA reports on direct and indirect compensation to be referenced in the documents provided to enrollees for open enrollment, including how and where to access the reports.*

A. Scope of Reporting Requirements for Direct and Indirect Compensation

The CAA defines “brokerage and consulting services” as those involved in the (1) selection of insurance products, including dental and vision; (2) recordkeeping services; (3) selection of medical management vendors; and (4) benefit administration, including dental and vision.¹⁵ The selection of insurance products and services includes, but is not limited to: stop loss insurance, pharmacy benefit manager services, wellness services, transparency tools and vendors, group purchasing organizations, preferred vendor panels, disease management vendors, compliance services, employee assistance programs, third party administrations, and development of plan design.¹⁶

While there has not always been full transparency of the direct compensation received by a covered service provider, there has historically been little if no transparency of the *indirect compensation* that creates significant and unaccountable costs to employers, employees, and the health care system. The Content of Disclosure requirements are crucial to capturing a comprehensive understanding of the players and the money flow. It is especially important that the CAA requires disclosure of indirect compensation, as well as a description of the arrangement between the payer and service provider, affiliate or subcontractor, and what services are being provided.

We especially emphasize the inclusion of the parenthetical “but not limited to” after both the list of “brokerage and consulting services” and “all products and services related to the health plan” included in the Content of Disclosure. For too long the opaqueness of the system enabled, and even encouraged, entities to fall outside of scrutiny by calling themselves by another name or creatively describing their services. In addition, requiring a description of any formula used to derive bonuses and other alternate forms of compensation is important to close gaps in accountability and promote transparency. We believe that the “but not limited to” allows these reporting requirements to respond to an evolving health care system.

Lastly, the CAA’s requirement that the covered service provider give the plan fiduciaries notice or written disclosure of the direct and indirect compensation from the various defined entities no later than a date “reasonably in advance of” when the contract is entered, extended, or renewed is important to prevent ad hoc entities from interfering with the transparency of the process and driving up costs. Under current guidance, covered services providers are given discretion to consider what is a “reasonable” timeline for providing this information.

¹⁵ https://nabip.org/media/6779/broker_compensation_group_112921.pdf

¹⁶ https://nabip.org/media/6779/broker_compensation_group_112921.pdf

Recommendations:

- 1. To ensure transparency data is appropriately and timely reported, the DOL should consider any notice that is less than 30-days prior to contract enactment or amendment unreasonable.*

Ultimately, we applaud the steps that the CAA has implemented to provide transparency and accountability from covered service providers, affiliates, or subcontractors with regard to compensation from brokerage and consulting services in their selection, placement, enrollment, and servicing of all products related to the health plan. However, the CAA should require plan fiduciaries to make available the full content of these disclosures to all employees and plan beneficiaries sufficiently before enrollment. Transparency and accountability as called for by the CAA cannot be achieved if employees and plan beneficiaries are not provided timely access to this information.

IV. Reporting Requirements

Electronic disclosures are essential to ensuring that consumers understand the type of health insurance they are purchasing, its benefits, and limitations. Therefore, it is critical that DOL, IRS, and HHS enforce health plan obligations to notify participants and beneficiaries, within a reasonable time and using plain language, of changes in plan design and benefits. We also ask for further clarification regarding how consumers can challenge plan changes.

A. Electronic Disclosures to Plan Beneficiaries

Currently, plan administrators under ERISA are required to disclose (1) plan rules; (2) financial information; and (3) documents on the operation and management of the plan.¹⁷ In addition, plans must provide a summary of plan benefits including an overview of the benefits available under the plan, and how to file a claim for benefits. A new summary of benefits must be provided whenever there is a change to plan terms during the plan year.

For consumers to be able to understand these documents, the summary of plan benefits must be provided promptly and in an understandable and reader-friendly manner. Today, the summary of plan benefits is often intentionally vague, resulting in consumers not having the necessary information to properly understand what services and treatments in-fact are covered by the plan.

For example, when an employer-sponsored health plan partners with an AFP, they rarely disclose that partnering with the AFP means that certain prescription drugs are removed from the plan's prescription drug benefit coverage. For instance, one plan document from 2022 Open Enrollment states:

“[The AFP] for the upcoming year will be a new plan to control prescription costs. This will place an additional burden on some employees using certain brands/types of drugs, but it is necessary to attempt to control the costs of the plan.

¹⁷ <https://www.dol.gov/general/topic/health-plans/planinformation#:~:text=The%20Employee%20Retirement%20Income%20Security,documents%20on%20the%20operation%20and>

This new addition will be put in place as of January 1, 2022, for some of the specialty drugs, but will start November 1st for most prescriptions. The plan is called [company name]. They will be partnering with [employer] to reduce the cost of your high dollar prescription drugs.

[The AFP] will be working directly with the employee in order to obtain alternative funding through the manufacturer, foundations and grants. There are a number of drugs on the list that some of our employees are currently receiving. We expect to see a significant reduction in the amount charged for these specialty prescriptions. A Care Coordinator will be assigned to work directly with each employee requesting qualifying prescriptions.”¹⁸

The above plan disclosure does not state that the consumer will **be required** to work with the AFP because certain prescription drugs have been carved out from coverage or considered non-essential health benefits. Thus, this vague language impairs peoples’ ability to understand what benefits their health plan is offering, misleading them to sign up for a plan during open enrollment which may not offer the benefits they need.

Moreover, in some cases consumers have reported being unaware that their health plan has contracted with a new third party to manage their benefits. Thus, when contacted by the AFP, they ignore requests for information out of concern that these third parties are health care scammers – especially as they are asking for sensitive and personal information not usually required by a health insurer. Furthermore, many AFPs identify themselves as “patient advocacy” organizations, alleging they are working in the best-interest of the consumer.¹⁹ But this misrepresents their purpose, which is to reduce the employer’s prescription drug spend by enrolling as many people who use high-cost drugs as possible into manufacturer patient assistance programs, without regard to the impact of delays or negative health complications for consumers. AFPs should be required to publicly disclose their financial incentives and purpose, to prevent misleading plan enrollees.

In addition, when working with an AFP, the employer-sponsored health plan does not disclose how health data will be shared with and used by these third-party companies. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), health plans are considered covered entities responsible for protecting consumer’s health data.²⁰ HIPAA data protection obligations also extend to “business associates” of a covered entity such as subcontractors that help process claims, administer health plan benefits, or manage medical records.²¹

¹⁸[https://docs.bartonccc.edu/humres/HRBenefits%20and%20Discounts/Benefits/Health%20Plan%20Open%20Enrollment%20Links/Health%20Plan%20Announcement-FT%20Employees%20\(21-22\).pdf](https://docs.bartonccc.edu/humres/HRBenefits%20and%20Discounts/Benefits/Health%20Plan%20Open%20Enrollment%20Links/Health%20Plan%20Announcement-FT%20Employees%20(21-22).pdf)

¹⁹ aimedalliance.org/wp-content/uploads/2023/08/Response-to-Payer-Matrix_Final-8.17.23.pdf

²⁰ <https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html#:~:text=In%20addition%2C%20business%20associates%20of,services%20to%20the%20covered%20entity>

²¹ <https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html#:~:text=In%20addition%2C%20business%20associates%20of,services%20to%20the%20covered%20entity>

Recommendations:

- 1. If the practice of mandating enrollees to work with third-party alternative funding vendors is deemed permissible under federal law, health plans should be required to clearly disclose in open enrollment documents that plan enrollees are required to work with the third-party to access certain specialty drugs, and clearly state the consequences when a consumer refuses to participate in the alternative funding program.*
- 2. Health plans should be required to disclose the financial incentives third-party companies receive for working with the plan to manage specialty drug benefits. Third-party entities should be prohibited from identifying as misleading names, including “patient advocacy” companies or programs, when the third-party has a financial interest in benefit administration that is not dependent on beneficiary health outcomes.*
- 3. All business associates contracting with employer-sponsored health plans - including AFPs – should be held to the same data protection requirements as covered entities. Moreover, these programs should have an obligation to inform consumers (1) how their data is being shared; (2) when they will be notified that their data is or has been shared; and (3) how they will be notified if there is a breach of their data.*

V. ERISA Advisory Council

The ERISA Advisory Council (Council) is a 15-member council that provides feedback on policies and regulations impacting employee benefit plans governed by ERISA.²² Members of the Council are appointed for three-year terms and must represent the following fields: employee organizations; accounting; actuarial counseling; corporate trust; insurance; investment counseling; and investment management.²³ Similar to the Council, the Medicare Payment Advisory Committee (MedPAC) has 17 members who are responsible for advising Congress on issues affecting the Medicare program.²⁴ MedPAC members are also appointed for three-year terms and must represent diverse experience and expertise in the financing and delivery of health care services.²⁵

Given the branches of government the Council and MedPAC are respectfully situated, it would not be possible for the Council to provide the same breadth of work as MedPAC. However, there are elements of the MedPAC structure and reporting we believe would greatly increase Congress’ and DOL’s understanding of how employer-sponsored health plans are operating and the impact that has on enrollees.

²²<https://www.dol.gov/newsroom/releases/ebsa/ebsa20240305#:~:text=The%2015%2Dmember%20council%20provides,year%20terms%20representing%20nine%20fields.>

²³<https://www.dol.gov/newsroom/releases/ebsa/ebsa20240305#:~:text=The%2015%2Dmember%20council%20provides,year%20terms%20representing%20nine%20fields.>

²⁴ <https://www.medpac.gov/what-we-do/>

²⁵ <https://www.medpac.gov/what-we-do/>

A. Expanding Role of ERISA Advisory Counsel

The Council's scope is simultaneously broad and narrow. While ERISA itself touches on a range of benefits, as currently composed, the Council does not have the capacity or expertise to provide reports and recommendations on issues affecting health benefits. Health insurance has largely been an afterthought during the enactment and implementation of ERISA, with most of the Council's attention focused on ERISA's retirement plan provisions. This is demonstrated through the DOL's primary authority in implementing and enforcing ERISA and the basic standards for governing plan fiduciaries' actions. Similarly, the Council's role is to provide reports and recommendations to DOL, not to HHS, which enforces various rules for other types of private health insurance, nor Congress. Focusing the Council's efforts primarily on pension benefits is detrimental to American workers.

Unlike other federal health and insurance laws, which tend to set a regulatory floor on which states may build upon, ERISA contains provisions broadly preempting states from regulating employer health plans, even when no federal rules otherwise apply. This relatively hands-off approach to regulating health plans has created an environment where there is minimal oversight of employer-sponsored health plan actions that now are negatively impacting enrollees.

Unlike the Council, MedPAC is commissioned as an independent, non-partisan legislative branch agency, established to advise Congress on issues affecting the Medicare program. In addition to advising Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC provides information on access to care, quality of care, and other issues affecting Medicare. MedPAC also issues two reports annually and submits comments on reports and proposed regulations issued by HHS. It also provides testimony and briefings for Congressional staff. Finally, MedPAC frequently meets with individuals interested in the Medicare program, including staff from congressional committees, HHS, health care researchers, health care providers, and beneficiary advocates. Ultimately, unlike the Council's orientation, MedPAC is designed to hear from consumers, respond and engage on both public and private payer concerns, and consider consumer affordability and access when providing feedback. Similar consumer-focused obligations are not imposed on the Council.

Recommendations:

- 1. Establish two separate ERISA Councils: one Council focusing solely on pensions and retirement ("ERISA Pension Council"), the second focusing on health and welfare plans ("ERISA Health Council"). These Councils may continue to advise DOL and submit written recommendations on issues regarding DOL. Dividing the Council into two entities would help address the growing complexities of our health care system without deprioritizing the important pension and retirement protections at the core of ERISA. Similarly, given the number of individuals reliant on employer-sponsored health benefits, the Council can no longer consider this a back seat issue and could benefit from a separate ERISA Health Council exclusively charged with addressing issues affecting employer-sponsored health benefits, and the employees and beneficiaries that rely on them.*

- We recommend the ERISA Health Council issue two reports (similar to MedPAC's current conduct -- one spring, one summer/fall) as the primary outlet for Council recommendations. In addition to these reports, Council members and DOL staff should seek input on employer-sponsored benefit issues through frequently meeting with individuals interested in the program, including staff from Congressional committees and HHS, health care researchers, health care providers, and beneficiary advocates.*

VI. Medical Loss Ratio Requirements and Incentives

Under the Affordable Care Act, health plans are required to spend at least 80 percent or 85 percent of premiums on medical care and health care quality improvement, while the remaining 15 or 20 percent can be spent on administrative costs and profits.²⁶ If a plan spends more than 15 or 20 percent on administrative costs and profits, it must issue a rebate to its beneficiaries.²⁷ These requirements are known as the Medical Loss Ratio (MLR).

While the MLR requirement was intended to lower overall costs by ensuring that insurance providers spend premium dollars on paying claims, vertical integration within the payer space has undermined the premise of the MLR. For example, due to vertical integration between pharmacies, health plans, and pharmacy benefit managers, plans are incentivized to charge themselves more for drugs dispensed by their fully-owned pharmacies, which allows them to increase overall profits for the plan without violating the MLR requirement.

By increasing the amount charged by the pharmacy, the MLR for the health plan is increased, thus showing a higher claim paid to premiums collected ratio. Since consumers often pay a percentage of the drug cost, this artificially inflated drug cost directly increases overall costs to the consumer and the plan.

Recommendation:

- Congress should ban vertical integration in healthcare as it significantly increases cost and decreases competition in the marketplace. Moreover, Congress should provide the Federal Trade Commission with authority to regulate these purchases and prohibit the development of these monopolies.*

VII. Specialty Drug Coverage

Specialty drugs are high-cost prescription drugs used to treat complex and chronic conditions like hemophilia, HIV, arthritis, psoriasis, and cancer.²⁸ Specialty drugs often require special handling and administration requirements and are often either infusion or injection medications.²⁹ Expanded development of specialty drugs has changed treatment options and health outcomes for a variety of conditions including Hepatitis C, HIV, cancer, and pulmonary

²⁶ <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/medical-loss-ratio>

²⁷ <https://www.cms.gov/marketplace/private-health-insurance/medical-loss-ratio>

²⁸ <https://www.healthinsurance.org/glossary/specialty-drug/>

²⁹ <https://www.healthinsurance.org/glossary/specialty-drug/>

hypertension.³⁰

However, specialty drug costs have been a significant burden on employers who are not properly positioned for catastrophic claims. Many smaller employers choose to self-insure their plans even though they are not financially prepared to take on the risk of high-cost claims. As a result, many health plans have sought new ways to reduce their exposure to the high cost of specialty prescription drugs. One recent development has been a shift to AFPs, which exclude coverage for these drugs from plans in an attempt to capitalize on the availability of patient assistance foundations intended for those who are truly uninsured. While we recognize the difficulty created by high-cost prescription drugs, it is critical to remember that these drugs enable people living with serious and chronic illness to manage their condition or that of a family member so that they can stay healthy (or avoid deterioration of their condition) and continue working. This also reduces other costs associated with deteriorating health associated with non-adherence to treatment regimens.

Ensuring that employers are educated on the risks of self-insurance and the importance of reinsurance will help mitigate some of the financial strain of an unexpected specialty claim. Utilizing broad networks accepting any willing provider can also help encourage price competition and lower overall cost of the drugs.

Throughout this letter, we have highlighted challenges from the employee perspective in accessing specialty drugs and we also recognize the challenges that employers face in determining how to afford their high costs. The AFPs we have discussed above take advantage of employer concern over this issue, costing them money and impeding access to care for their employees. We emphasize that AFPs are not an appropriate “coverage model” to address high-cost specialty drugs, but rather are discriminatory, misleading, and violate various ERISA regulations, as noted above.

Recommendations:

- 1. Congress should recognize that the AFP model violates a variety of ERISA policies and is therefore not an innovative model that should be encouraged or replicated.*
- 2. Congress should broadly support payers in contracting with specialized centers of excellence, such as hemophilia treatment centers, cystic fibrosis centers, Certified Duchenne Care Centers, and cancer centers. The best way to manage an individual’s condition – and their treatment costs – is by facilitating access to expert care.*

VIII. Conclusion

The practices highlighted above impact employee health and employer business outcomes. For instance, in 2021, a gaming company decided to prioritize employee health and well-being rather than increase workloads to achieve a deadline for a product.³¹ When ultimately releasing the product under the new timeline, the company reported that consumer experience with the product

³⁰ <https://abarcahealth.com/understanding-specialty-medications/>

³¹ <https://www.forbes.com/sites/forbeshumanresourcescouncil/2022/03/25/health-is-wealth-why-prioritizing-employee-well-being-leads-to-better-business-outcomes/?sh=107116e01bfa>

was highly positive, demonstrating a strong connection between employee experience and customer experience ultimately impacting company profits and outcomes.³²

Providing health insurance benefits also helps employers increase workplace diversity and inclusion which can ultimately impact company profits. For example, a 2018 study found that employers who supported disability inclusion in hiring practices and employment were 28 percent more profitable compared to non-inclusive companies.³³ For employees with chronic conditions and disabilities, having access to stable and affordable health care coverage can often be a key consideration when taking a job. As such, employers who provide comprehensive health benefits are more likely to create an environment in which disabled or chronic disease candidates are comfortable accepting a position within a company. This improves both workplace inclusion and company profits.

We appreciate your consideration of our perspectives and recommendations. We seek to ensure appropriate ERISA protections for employees that protect individuals' ability to participate in the workforce and support positive business outcomes in the long-term. If you have any questions, please contact Kim Czubaruk, JD, Associate Vice President of Policy, *CancerCare* (kczubaruk@cancercare.org) and Kollet Koulianos, MBA, Consultant, National Bleeding Disorders Foundation (formerly National Hemophilia Foundation) (kollet@p3hbc.com).

Sincerely,

CancerCare
National Bleeding Disorders Foundation
Aimed Alliance
The AIDS Institute
EveryLife Foundation for Rare Diseases
Alliance for Patient Access (AfPA)
Alliance of Dedicated Cancer Centers
American Kidney Fund
National Organization for Rare Disorders (NORD)
National Psoriasis Foundation
Bleeding & Clotting Disorders Institute (BCDI)
LUNGeivity Foundation
HIV + Hepatitis Policy Institute
Patient Access Network (PAN) Foundation
Arthritis Foundation
Melanoma Research Foundation
Cancer Support Community
AiArthritis
The Mended Hearts, Inc.

³² <https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/history-of-ebsa-and-erisa#:~:text=ERISA%20was%20the%20culmination%20of,of%20employees%20and%20their%20families.>

³³ <https://www.accenture.com/content/dam/accenture/final/a-com-migration/pdf/pdf-89/accenture-disability-inclusion-research-report.pdf>

ICAN, International Cancer Advocacy Network
Headache and Migraine Policy Forum
Gaucher Community Alliance
Prevent Blindness
Hemophilia Alliance
Biomarker Collaborative
Exon 20 Group
MET Crusaders
PD-L1 Amplifieds
The Sumaira Foundation
Hemophilia Federation of America
CFRI- Cystic Fibrosis Research Institute
Spondylitis Association of America
Little Hercules Foundation
The International Waldenström's Macroglobulinemia Foundation (IWMF)
Partnership to Advance Cardiovascular Health
Coalition for Hemophilia B
The Lysosomal Storage Advocacy Coalition
WAIHA Warriors
Bleeding Disorders Foundation of North Carolina
Pacific Northwest Bleeding Disorders
Georgia AIDS Coalition
Fair Health North Carolina