September 1, 2023

Amy Turner
Director
Office of Field Administration
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210-0002

Re: Follow-Up Letter to June 1, 2023 Meeting and Documents Provided on Alternative Funding Programs

Dear Director Turner,

Thank you again for providing patient advocacy groups with the opportunity to both meet with representatives of the Department of Labor (DOL) and provide documents and other materials evidencing our grave concerns with alternative funding programs.

The undersigned organizations, representing millions of patients living with serious, chronic health conditions who rely on specialty prescription medication to treat and/or manage their disease, submit this letter to expound upon the June 1, 2023 discussion among patient groups and the DOL as well as to provide context to the supporting materials previously provided.

## *I. Discrimination Based on a Health Factor Under HIPAA*

**Conversation Recap:** During the June 1, 2023 meeting with the Department of Labor (DOL), advocacy organizations explained and raised concerns that alternative funding programs (AFPs) implemented by group health plans discriminate against participants and beneficiaries based on health factors. We noted that AFPs specifically target and solely apply to individuals with serious, chronic health conditions prescribed specialty medications and do not apply to similarly situated participants or beneficiaries not prescribed specialty medications. We also explained that by directing and imposing AFP benefit restrictions or limitations only on participants and beneficiaries prescribed specialty medications, charging these individuals the same premium as similarly situated participants and beneficiaries not subject to these benefit restrictions or limitations equates to charging more for coverage based on a health factor.

**Potentially relevant rules/laws:** The Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits group health plans from determining plan benefits on specific health factors and pre-existing conditions.[1] Specific health factors include health status, physical and mental illnesses, claims experience, receipt of health care, medical history, genetic information, and

[1] DOL, *FAQs on HIPAA Portability and Nondiscrimination Requirements for Employers and Advisors,* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/hipaa-compliance.pdf

disability.[2] HIPAA also prohibits an individual from being charged more for coverage than any similarly situated individual is being charged based on any health factor.[3] While group plans may exclude or limit coverage for a specific condition, types of treatments, or experimental or medically unnecessary treatments, these exclusions are *only* permissible when applied uniformly to all similarly situated individuals.[4]

**Examples from documents provided:**

14. HYL_WhitePaper_SpecialtyRX_White_Paper (warning that removing coverage of certain medications or categories of medications could violate HIPAA, which prohibits health plans from discriminating against individuals based on health status-related factor)

33. HIPAA Nondiscrimination FAQ (explaining that HIPAA prohibits discrimination in group health plan eligibility, benefits, and premiums, based on specific health factors, including medical condition, claims experience, medical history, evidence of insurability, disability, health status, genetic information, and receipt of health care)

## *II. Fiduciary Duty Violations*

**Conversation Recap:** Employees who pay to participate in their employer group health plan have a reasonable expectation that their employer will use their payments and manage the plan and its assets with the goal of providing them with benefits. This expectation aligns with one of many fiduciary responsibilities owed by plan sponsors to employees.[5] Unfortunately, and in direct contradiction of their fiduciary responsibilities, employers implement AFPs to avoid providing benefits to participants and beneficiaries so that the plan can reap the benefit of saving money. As discussed in our June 1, 2023 meeting, AFPs impose harmful barriers and limitations on participants' and beneficiaries' access to specialty medications in violation of fiduciary responsibilities including, but not limited to:

- Providing inaccurate, incomplete, untimely, and/or misleading plan information to participants and beneficiaries;
- Claiming the plan excludes coverage of specialty medications but failing to provide plan documents detailing non-coverage;
- Implementing automatic denials of prior authorization without reviewing and making a determination on the merits of the request;

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[2] DOL, *FAQs on HIPAA Portability and Nondiscrimination Requirements for Employers and Advisors,* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/hipaa-compliance.pdf

[3] DOL, *FAQs on HIPAA Portability and Nondiscrimination Requirements for Employers and Advisors,* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/hipaa-compliance.pdf

[4] DOL, *FAQs on HIPAA Portability and Nondiscrimination Requirements for Employers and Advisors,* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/hipaa-compliance.pdf

[5] 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

- 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;
- Making statements to participants and beneficiaries that implementing an AFP does not change the participants' or beneficiaries' process for accessing specialty medications,
- 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 patient assistance programs (PAPs) as a prerequisite to accessing specialty medications,
- Providing participants and beneficiaries with illegally imported, non-FDA approved medications that pose a health and safety risk to participants and beneficiaries;
- 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 to participants and beneficiaries;
- Delaying participants' and beneficiaries' timely access to specialty medications by requiring a denial of eligibility from PAPs before reversing the plan's previous non-coverage decision and approving coverage of the specialty medication as a medical necessity, potentially causing negative health consequences to participants and beneficiaries;
- Delaying participants' and beneficiaries' timely access to specialty medications by requiring a denial of eligibility from PAPs before approving the plan's previous automatic denial of prior authorization without reviewing and making a determination on the merits, potentially causing negative health consequences to participants and beneficiaries;
- Providing participants and beneficiaries with less than the full course of treatment prescribed by the clinician, potentially causing negative health consequences to the participants and beneficiaries; and
- Mismanaging participants' and beneficiaries' premium (i.e., plan assets) payments held in trust.

**Potentially relevant rules/laws:** 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*."[6]

Moreover, the United States Supreme Court in Varity Corp. v. Howe stated "[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.'"[7]

[6] 29 U.S.C. § 1104; 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.
[7] Varity Corp. v. Howe, 516 U.S. 489 (1996), https://supreme.justia.com/cases/federal/us/516/4.89/

In addition to the fiduciary duty to act solely in the interest of the plan participants and their beneficiaries and with the exclusive purpose of providing benefits to them, plan sponsors also have the fiduciary responsibility to:

- Carry out their duties prudently;
- Follow the plan documents (unless inconsistent with ERISA);
- Hold the plan assets (if the plan has any) in trust; and
- Pay only reasonable plan expenses.[8]

The policies and practices used in the implementation of AFPs raise potential violations of the following fiduciary duties:

- The fiduciary's failure to act prudently in implementing an AFP that prioritizes achieving plan savings over providing participants and beneficiaries with benefits;
- The fiduciary's failure to follow the terms of plan documents when claiming non-coverage or automatically denying prior authorization; and
- The fiduciary's 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.[9]

**Examples from documents provided:**

6. Compliance-Issues-with-Alternative-Funding (outlining how a group health plan fiduciary that uses participant contributions to pay for expenses not covered by the plan is a breach of its fiduciary duty under ERISA)

7. Council Bill No. 6299- Agreements, Pharmacy Services and Business Associate, SHARx (noting that the Client is considered the plan administrator and named fiduciary of the plan benefits for purposes of ERISA)

9. EmpiRx – Drug Excluded and Patient 100% Responsible (explaining in a letter to a patient, that the prescription drug benefit was not covered, the member copay is 100% the cost of the claim, and the copayment is excluded from the out-of-pocket maximum)

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[8] U.S. Department of Labor, 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

[9] *DOL, Fiduciary Responsibilities, https://www.dol.gov/general/topic/retirement/fiduciaryresp; American Society of* Pension Professionals & Actuaries, *What Expenses Can Be Paid from Plan Assets?,* https://www.asppa.org/news/browse-topics/what-expenses-can-be-paid-plan-assets; 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

13. Holocomb (explaining that patients are being told that they are not actually insured and providers are experiencing uncertainty regarding patients' benefit coverage when it was assumed that they were fully insured under their employer's benefit plan)

39. BCBS Kansas Blog Post about Potential Harms of AFPs (explaining that AFPs that exclude specialty drugs from coverage and then use PAPs for funding expose employers and employees to numerous ERISA and IRS-related complicated risks and violations)

### *III. Deceptive and Fraudulent Business Practices*

**Conversation recap:** Included among the bulleted items illustrating AFPs' fiduciary duty violations in Section II of this letter are several strong-arm and deceitful tactics used by AFPs against targeted participants and beneficiaries which enable plans to avoid paying for specialty medications. As discussed at the June meeting, participants and beneficiaries receive written notification that their specialty medication is either no longer covered under the plan or has been denied prior authorization – which may or may not be true. The notification is typically made as a blanket statement without the benefit of supporting documentation. Patient advocates are aware of instances where medication alleged to be excluded is still covered under the plan and where prior authorization denials were made without the request ever being considered on the merits. In most cases where a participant or beneficiary fails to qualify for the PAP, coverage for the "excluded" specialty medication is reconsidered and approved through the medical necessity exceptions process and a previous "default" denial of prior authorization is subsequently approved.

Participants and beneficiaries are pressured into complying with AFP requirements by being told that failure to do so will result in their being responsible for the full cost of the specialty medication and, even if paid, none of those expenses will not count toward their out-of-pocket cost-sharing responsibilities.

In many instances, AFPs require participants and beneficiaries to provide sensitive information and documents, including a power of attorney, tax returns, and answers to financial and personal inquiries. Third party AFP vendors tell participants and beneficiaries how to answer PAP application questions on coverage issues, i.e., instruct them to state that they do not have coverage for their prescription medication whether or not that is true. AFP vendors have also used the executed power of attorney to complete the PAP applications on behalf of the participant or beneficiary.

As discussed throughout this letter, AFPs impose significant harms on targeted participants and beneficiaries (those that qualify for a PAP, those that fail to qualify for a PAP, and those that do not agree to participate) that are not imposed on similarly situated participants and beneficiaries not prescribed specialty medications. These harms may include, but are not limited to, delaying access to specialty medications, providing less than the prescribed full course of treatment, exposing participants and beneficiaries to illegally imported, non-FDA approved medications, requiring participants and beneficiaries to provide false information on PAP applications, imposing significant financial costs on participants and beneficiaries who do not agree to participate, requiring participants and beneficiaries to sign a power of attorney, and being obligated to provide

tax returns and other personal information and documents simply to access specialty medications necessary to treat their condition.

**Potentially relevant rules/laws:** An act or practice is deceptive if it is material and would likely mislead consumers acting reasonably under the circumstances.[10] A practice is unfair if it causes or is likely to cause substantial consumer injury which consumers cannot reasonably avoid, and which is not outweighed by benefits to consumers or competition.[11]

**Examples from documents provided:**

2. 2020 - Paydhealth - SATTP Overview.pdf. (characterizing the change in coverage of specialty medications as a "non-material update")

6. Compliance-Issues-with-Alternative-Funding (explaining that to obtain funding, representations are made that the individual has no insurance for specialty drugs and, since plans provide for reimbursement if assistance is not provided by an alternative funding source, such representations could be considered misleading or fraudulent)

8. CS_Specialty-Carve-Out.pdf (misleadingly marketing that "third-party vendors say that carving-out specialty medications from the total pharmacy benefit is a win-win situation for everyone")

21. Quill - Letter #L10444 - Alternative Funding Vendors to FTC.pdf (explaining how AFVS are advising health plans to exclude coverage for specialty drugs and are creating the fraudulent appearance of noncoverage by telling consumers that they their drug will not be covered unless they cooperate with the AFV's fraudulent scheme and apply for coverage through the PAP and that if coverage is unsuccessful through the PAP, their employer will reinstate their coverage)

### *IV. Discrimination Under the ACA*

**Conversation recap:** Patient advocacy groups understand that self-funded and large group plans are not required to provide coverage for the ACA's ten categories of essential health benefits (EHBs). However, self-funded or large group plans that choose to cover one or more categories of EHBs must comply with the ACA's requirements for EHBs. The communities we advocate on behalf of have serious, chronic health conditions that require prescription drugs referred to as specialty drugs or specialty medications to treat their condition. The restrictions and limitations on access to medications specifically target and solely apply to participants and beneficiaries with serious, chronic health conditions who use doctor-prescribed specialty medications.

**Potentially relevant rules/laws:** Existing regulations require plans providing EHBs to not employ plan designs that discriminate against people with chronic illnesses or disabilities.[12] Plan designs

[10] *See* Federal Trade Commission Policy Statement on Deception, appended to *Cliffdale Assocs., Inc.,* 103 F.T.C. 110, 174-83 (1984).
[11] *See* 15 U.S.C. 45(n); Federal Trade Commission Policy Statement on Unfairness, appended to *Int'l Harvest Co.,* 104 F.T.C. 949, 1070-76 (1984).
[12] 45 C.F.R. § 156.125(a)

that make drugs specific for a chronic condition hard to access (such as through significant cost sharing) may inappropriately discriminate against people living with those conditions.

**Examples from documents provided:**

17. Payer Matrix - Client Savings Analysis 2020 - 2022.pdf (reporting that 29% of plan savings were generated from Hemlibra and 22% from Humira)

26. Magellan specialty-alternative-funding-solutions (claiming that the AFP only "benefits," or targets, members with chronic illnesses)

30. Understanding_Alternative_Funding_for_Specialty_Medication_eBook (explaining how people diagnosed with conditions like lupus, hemophilia, and cancer may rely on specialty medications, the drugs which APV target)

32. HA_UnderstandingYourRxBenefits with Magellan and Paydhealth.pdf (warning patients, if they "have been prescribed a qualified specialty drug, [they] must engage with Paydhealth before the pharmacy can fill your prescription")

## *V. Illegal Importation*

**Conversation recap:** As mentioned in the *Fiduciary Duty Violations* section of this letter, patient advocacy groups also have grave concern about AFPs that provide participants and beneficiaries with illegally imported, non-FDA approved medications. While AFPs may or may not disclose to participants and beneficiaries that their drug may be sourced from overseas, participants and beneficiaries have no control over where AFPs get the medication. In addition, any AFP notification to participants and beneficiaries that medications may be sourced from overseas does not make such action legal. Illegally imported, non-FDA approved medications pose potentially serious health risks to participants and beneficiaries. The FDA recognizes this risk, stating in a warning letter to one AFP vendor that "[t]his distribution scheme is particularly concerning, as employees are likely inclined to trust that they will receive safe and effective drugs through their employer's "insurance" plan and may not question their legitimacy."[13]

**Potentially relevant rules/laws:** The introduction of unapproved new drugs and misbranded drugs into interstate commerce violates sections 301(a), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)].

**Examples from documents provided:**

13. Holocomb (explaining that specialty carve-out vendors are engaging in wholesale importation of massive quantities of prescription drugs because "a blind eye is turned on the practice because drugs in the United States are too costly, and the importation is justified because of the savings on drug cots to employers and employees")

[13] U.S. Food and Drug Administration, Warning Letter, ElectRX and Health Solutions, LLC, March 2, 2023, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023

14. HYL_WhitePaper_SpecialtyRX_White_Paper (warning that the practice of importing medications from other countries to leverage international cost savings is considered illegal by many regulatory bodies, noting that the FDA states that any drugs purchased for consumption in the U.S. must be approved by the FDA for both use and sale, and explaining that the practice of promoting insourcing medications from other countries is considered illegal by all state boards of pharmacy)

39. BCBS Kansas Blog Post about Potential Harms of AFPs (warning that AFPs are known for sourcing prescriptions from unlicensed, unsafe pharmacies located outside the United States, which is not only against the law, but also can be dangerous or even deadly).

## *VI. Discrimination Based on Income*

**Conversation Recap:** In addition to AFPs discriminating on the basis of a health factor and effectively charging targeted participants and beneficiaries more for coverage, AFPs also discriminate against low-income employees. Despite low-income and high-income employees paying the same premiums, thus entitling them to the same benefits under the plan, AFPs leverage PAP income eligibility requirements to force low-income employees to access their specialty medication via PAPs instead of regular plan-funded channels – all for the express purpose of saving the plan money. This income-based distinction creates an inequitable system that discriminates against lower-income employees by charging them the same premium as higher-income colleagues for coverage of fewer and lower quality benefits. In addition, lower-income participants and beneficiaries forced to access medications through an AFP may be subject to additional and potentially dangerous burdens and barriers not imposed on higher-income participants such as longer delays in accessing their medication and the risk of being provided illegally imported, non-FDA approved medications that pose a health and safety risk.

**Potentially relevant rules/laws:** IRS Code Section 105(h) prohibits plans from discriminating in favor of highly compensated individuals (HCI) as to eligibility to participate *and* benefits provided under the plan.[14] An HCI is defined as an individual who is one of the five highest paid officers, a shareholder who owns more than 10 percent in value of the stock of the employer, or among the highest paid 25 percent of all employees. Section 105(h) applies to group plans including self-funded plans under the Employee Retirement Income Security Act (ERISA).[15] A plan can be discriminatory in favor of HCIs on its face or in application.[16]

While there is no bright-line test for determining if a plan is discriminatory, a health plan that imposes different criteria for health plan eligibility and benefits in favor of HCIs will likely be

[14] 26 CFR § 1.105-11(c)(2)-(3).
[15] 26 CFR § 1.105-11(d); IRS, *Affordable Care Act Nondiscrimination Provisions Applicable to Insured Group Health Plans*, https://www.irs.gov/pub/irs-drop/n-11-01.pdf.
[16] 26 CFR § 1.410(b)-4(c)(3)(i)-(ii); 26 CFR § 1.410(b)-4(c)(2)(iii); When determining if a plan is discriminating in favor of HCI's, the DOL must review plan terms for all employees, except those that have not completed three years of service; are under the age of 25; are part-time or seasonal employees; are collectively bargained employees; or non-residents

considered discriminatory.[17] Alternative funding schemes are structured in way that only higher-income employees, including HCIs, are eligible to receive their medication through the plan, while lower-income employees are directed to obtain their medication through the PAP or be responsible for the entire coinsurance.

**Examples from documents provided:**

6. Compliance-Issues-with-Alternative-Funding-V1.01 (explaining that alternative funding is usually limited to lower income individuals, and if alternative funding is procured for participants with lower income, plan benefits could be skewed toward highly compensated employees to an impermissible degree, or one which results in taxation to highly compensated employees)

8. CS_Specialty-Carve-Out.pdf (explaining that needs-based funding requires income verification, and "in certain white-collar industries, many members may fall beyond the maximum income thresholds, especially when many specialty utilizers are, on average, more seasoned employees in higher level positions")

23. ARORx enrollee packet.pdf (explaining that when employees do not qualify for PAP due to income, the AFP typically maximizes copay assistance at a local pharmacy or PBM mail order, or fills the drugs through international mail order pharmacy)

36. Paydhealth-FAQs_Final.pdf (explaining that the AFP qualification criteria include the size and income of the household)

### *VII. Improper Use of Plan Funds*

**Concerns:** An issue of concern not addressed during the June meeting is, that by prioritizing plan savings over the duty to act solely in the interest of plan participants and beneficiaries and with the exclusive purpose of providing benefits to them, plan sponsors may reap such significant financial savings from AFPs that they fail to spend the required 85% of premiums and rebates on health care claims/clinical care and quality improvement measures. Likewise, the cost of implementing AFPs may result in plans exceeding the 15 percent maximum contribution allowed for administrative and marketing expenses, and profits. This may occur if: (1) plans' administrative payments to third-party AFP vendors, whether derived from a percentage of the plans' savings and/or a flat fee, is greater than 15 percent of premiums and rebates, (2) plans' profits achieved from AFPs requiring targeted participants and beneficiaries to get their medication from PAPs instead of spending premiums to pay for those benefits is greater than 15 percent of premiums and rebates, or (3) a combination of the two.

[17] If a health is determined to be discriminatory, the amount reimbursed to a highly compensated individual which constitutes an excess reimbursement is not excludable from such individual's gross income under section 105(b). To determine if a health plan benefit is discriminatory, the DOL must conduct a fact-based inquiry into each situation (26 CFR § 1.410(b)-4(c)(ii)).

**Potentially relevant rules/laws:** ERISA sets standards for the administration and operation of employee benefit plans, including health plans.[18] Under ERISA, fully or partially self-funded group health plans have legal and ethical obligations to plan enrollees, known as fiduciary duties.[19] Under the fiduciary duty requirements, plan sponsors have specific limitations on how plan premiums and rebates can be used.[20] Large group plans are required to spend 85 percent of premiums and rebates on health care claims/clinical care and quality improvement measures.[21] Only the remaining 15 percent can contribute to administrative and marketing expenses, and profits.[22]

Clinical care refers to the actual treatment of a patient's condition.[23] Quality improvement measures include "quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives."[24] Alternative funding programs do not meet either of these definitions.[25]

**Examples from documents provided:**

5. Complaint.filed version_AbbVie.pdf (explaining that when AFPs succeed in passing off a patient as "uninsured" and get them enrolled in a PAP, the AFP then charges the employers for each medicine distribution that the patients receive for free, calculating the amount it charges the employers as approximately 30 percent of the "savings" generated for the employer)

6. Compliance-Issues-with-Alternative-Funding (explaining that when alternative funding is successfully arranged, the employer is billed by the AFP based on percentage of savings generated)

7. Council Bill No. 6299- Agreements, Pharmacy Services and Business Associate, SHARx (clarifying that SHARx is "not in any way be deemed to be an insurer" and that the fee for enrollment in SHARx is $37,800)

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[18] U.S. Department of Labor, Employee Retirement Income Security Act (ERISA), https://www.dol.gov/general/topic/retirement/erisa (last visited Jun. 8, 2023); 29 U.S.C. § 1104.
[19] U.S. Department of Labor, *Understanding Your Fiduciary Responsibilities* (Sept. 2010), 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.
[20] Kaiser Family Foundation, *Medical Loss Ratio Rebates,* https://www.kff.org/private-insurance/issue-brief/medical-loss-ratio-rebates/; U.S. Centers for Medicare & Medicaid Services, *Medical Loss Ratio*, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Medical-Loss-Ratio (last visited Jun. 8, 2023); [20] U.S. Department of Labor, *Technical Release No. 2011-04, Guidance on Rebates for Group Health Plans Paid Pursuant to the Medical Loss Ratio Requirements of the Public Health Service Act* (Dec. 2, 2011)( clarifying that if the handling of rebates as plan assets must comply with ERISA's fiduciary standards, including acting in the best interests of plan participants and beneficiaries); U.S. Department of Labor, *Understanding Your Fiduciary Responsibilities.*
[21] Kaiser Family Foundation, *Medical Loss Ratio Rebates,* https://www.kff.org/private-insurance/issue-brief/medical-loss-ratio-rebates/.
[22] Kaiser Family Foundation, *Medical Loss Ratio Rebates,* https://www.kff.org/private-insurance/issue-brief/medical-loss-ratio-rebates/.
[23] *Clinical,* Dictionary.com.
[24] HHS, *Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection Affordable Care Act,* https://www.federalregister.gov/documents/2010/12/01/2010-29596/health-insurance-issuers-implementing-medical-loss-ratio-mlr-requirements-under-the-patient
[25] Alternative funding programs do not allege they provide clinical care.

We appreciate DOL's examination of AFPs implemented by group health plans and their related practices which, as discussed above, we believe violate several rules and laws that impose significant burdens and barriers on patients. We would like to schedule a follow-up meeting to discuss the concerns raised in this letter and answer any questions. Please reach out to Kim Czubaruk, JD, Associate Vice President of Policy, Cancer*Care* (kczubaruk@cancercare.org) or Kollet Koulianos, MBA, Senior Payer/Provider Consultant, National Bleeding Disorders Foundation (formerly National Hemophilia Foundation) (kollet@p3hbc.com) to identify a convenient date and time.

Sincerely,

Cancer*Care*
National Bleeding Disorders Foundation
Aimed Alliance
Arthritis Foundation
Association for Clinical Oncology
Cystic Fibrosis Foundation
EveryLife Foundation for Rare Diseases
Hemophilia Federation of America
National Organization for Rare Disorders (NORD)
National Psoriasis Foundation
PAN Foundation
Sickle Cell Disease Association of America
The AIDS Institute