IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBVIE, INC, Plaintiff, v. PAYER MATRIX, INC., Defendants.	Case No. 1:23-cv-02836 Hon. Jorge L. Alonso

MOTION OF AIMED ALLIANCE ET AL.
FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

Aimed Alliance and the health policy and patient advocacy organizations set forth in the Appendix (together, "*Amici*"), hereby respectfully move for leave to file an *amici curiae* brief in opposition to Defendant's motion to dismiss (and in response to certain representations made therein), and in support of Plaintiff's motion for preliminary injunction, modified as requested herein to require the parties to take appropriate measures to ensure that no patient is abruptly cut-off from access to their medication without adequate notice. Plaintiff consents to this motion. Defendant does not consent. In support of the motion, *Amici* state as follows:

1. Federal district courts "have discretion to permit amicus curiae briefs." *Luckett v. Wintrust Fin. Corp.*, No. 22-cv-03968, 2023 WL 4549620, at *5 (N.D. Ill. July 14, 2023) (citing *Nat'l Org. for Women, Inc. v. Scheidler*, 223 F.3d 615, 616 (7th Cir. 2000)); *see also Protect Our Parks v. Chicago Park Dist.*, No. 1:18-cv-03424 (N.D. Ill. Jan. 17, 2019), ECF No. 78 (granting and discussing prior grant of leave to file briefs as *amici curiae* in support of and in opposition to a motion to dismiss or for judgment on the pleadings).

2. No rule governs *amicus* appearances in the district courts, but Federal Rule of Appellate Procedure 29 provides that a motion for leave to file an amicus brief should state (1) "the movant's interest," and (2) "the reasons why the amicus brief is beneficial and aids in the disposition of the case." Fed. R. App. P. 29(b). The Seventh Circuit permits amicus participation when "the amicus has a unique perspective, or information, that can assist the court of appeals beyond what the parties are able to do." *Nat'l Org. for Women, Inc.*, 223 F.3d at 617; *see also Prairie River Network v. Dynegy Midwest Generation, LLC.*, 976 F.3d 761, 763 (7th Cir. 2020) (Scudder, J., in chambers) (explaining that "in deciding whether to accept an *amicus* brief, the court looks at whether the submission will assist the judges by presenting ideas, arguments, theories, insights, facts, or data that are not found in the briefs of the parties" (internal quotation marks omitted)).

3. Under this standard, *Amici* should be granted leave to file their brief. First, *Amici* have a strong interest in this case. *Amici* are non-profit patient advocacy organizations with a common mission to promote and protect the rights of health care consumers, caregivers, and providers. *Amici* support those living with rare, chronic, or complex health conditions by amplifying their voices, concerns, and lived experiences to policy makers, while also supporting patient navigation within the health care and health insurance systems. A detailed list of *Amici* appears in the Appendix.

4. As both Plaintiff and Defendant recognize, the claims asserted and relief sought in this case directly and intimately concern the interests of health care consumers and will impact consumers' access to necessary specialty medications. As advocates for patients and health care consumers, *Amici* seek to provide a consumer-focused perspective that can help ensure that the Court better understands how uninsured and underinsured consumers rely on third-party assistance

and the public harm caused by Defendant and similar alternative funding programs. *Amici* also have an interest in proposing a modification to the injunctive relief sought by Plaintiff that would protect patients by requiring the parties to take appropriate measures to ensure that no patient is abruptly cut-off from access to their medication without adequate notice, as discussed in more detail in the proposed brief. A court in another district granted a motion by *Amicus* Aimed Alliance and associated organizations leave to file a brief as *amici curiae* in opposition to a motion to dismiss claims filed by pharmaceutical manufacturer Johnson & Johnson against a company that engages in conduct similar to that engaged in by Defendant in this case. *See Johnson & Johnson Health Care Sys., Inc. v. Save On SP, LLC*, No. 2:22-cv-02632, 2023 WL 415092, at *8 n.5 (D.N.J. Jan. 25, 2023) (granting motion for leave to file amicus brief because it "contributed to the Court's understanding of the public harm from Defendant's Program").

5. Second, *Amici*'s brief will aid this Court in the disposition of this case by providing the Court with a unique perspective and unique information not available from the parties. Plaintiff, a pharmaceutical manufacturer, asserts claims and seeks injunctive relief based, in part, on the alleged effect of Defendant Payer Matrix's conduct on health care consumers and providers. *See, e.g.*, Mem. in Support of Mot. for Preliminary Injunction, ECF No. 23, at 1 (contending that Payer Matrix's "fraudulent scheme must stop before it causes further irreparable harm to … the patients who rely on [AbbVie's free-drug program] for their medicines"); *id.* at 41 (arguing that an injunction would be in the public interest because "Payer Matrix's conduct harms specialty drug patients in Illinois and across the United States"). Yet, in its motion to dismiss, Payer Matrix, also a for-profit company, opposes the claims and requested relief in part by describing itself as a "patient advocacy service," and contends that dismissal is appropriate because "[t]his dispute does

not implicate any consumer protection concerns" and that AbbVie's requested remedy "would not serve the interests of patients." Mot. to Dismiss, ECF No. 73, at 2, 9, 12.

6. Unlike the parties to this litigation, *Amici* are non-profit patient advocacy organizations who represent health care consumers. *Amici* thus can "assist the [Court] beyond what the parties are able to do" by providing the "unique perspective" of health care consumers and "information" about whether Payer Matrix is a legitimate patient advocacy service and how and Payer Matrix's conduct affects patients and their ability to access specialty medications. *See Nat'l Org. for Women, Inc.*, 223 F.3d at 617. These "insights … are not found in the briefs of the parties" and will "assist the [court]" in determining—at least preliminarily—whether to credit the parties' competing assertions regarding the nexus between Plaintiff's claims and consumers. *See Prairie River Network*, 976 F.3d at 763.

7. *Amici* represent a wide variety of consumers with chronic diseases, providers, caregivers, and others who have been directly impacted by alternative funding programs like Payer Matrix. As such, and drawing on their substantial experience and knowledge in this area, *Amici*'s brief provides an important perspective concerning consumers' reliance on patient assistance programs ("PAPs") to access their medically necessary treatments and the serious health consequences that arise when consumers are unable to access their treatments or are forced to switch treatments for financial rather than medical reasons. It also outlines how Defendant misleads and deceives health care consumers, how these programs discriminate against low-income employees, and how Defendant jeopardizes the long-term sustainability of PAPs for uninsured and underinsured individuals. This perspective is critical for the Court to determine whether Defendant's conduct has a nexus to consumers and whether granting an injunction is in

the public interest. The attached *amici curiae* brief can help answer these questions in the affirmative.

CONCLUSION

For the foregoing reasons, Aimed Alliance and fellow *Amici* respectfully request that the Court grant their motion for leave to file the proposed *amici curiae* brief, which is attached hereto as Exhibit 1.

Dated: August 24, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 24, 2023, I electronically filed the foregoing document with the clerk of the court for the Northern District of Illinois, using the electronic case filing system of the court. The electronic case filing system sent a "Notice of E-Filing" to the attorneys of record in this case.

/s/ Michael L. McCluggage

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBVIE, INC, Plaintiff, v. PAYER MATRIX, INC., Defendants.	Case No. 1:23-cv-02836 Hon. Jorge L. Alonso

NOTICE OF MOTION

PLEASE TAKE NOTICE that on **Tuesday, September 5, 2023** at **9:30 a.m.** or as soon thereafter as counsel may be heard, we shall appear before the Honorable Jorge L. Alonso, or any judge sitting in his stead in Courtroom 1903, at the United States District Court for the Northern District of Illinois, Eastern Division, 219 S. Dearborn Street, Chicago, Illinois, 60604, and present the **Motion of Aimed Alliance et al. for Leave to File Brief as Amici Curiae**, a copy of which is hereby served upon you.

Dated: August 24, 2023

Respectfully submitted,

By: */s/ Michael L. McCluggage*

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/s/ Michael L. McCluggage

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
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ABBVIE, INC, Plaintiff, v. PAYER MATRIX, INC., Defendants.	Case No. 1:23-cv-02836 Hon. Jorge L. Alonso

[PROPOSED] *AMICI CURIAE* BRIEF OF AIMED ALLIANCE ET AL. IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS AND IN SUPPORT OF PLAINTIFF'S REQUEST FOR PRELIMINARY INJUNCTION

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STATEMENT OF INTEREST

Amici curiae ("*Amici*") are non-profit patient advocacy organizations with a common mission to promote and protect the rights of health care consumers, caregivers, and providers. *Amici* support those living with rare, chronic, or complex health conditions by amplifying their voices, concerns, and lived experiences to policy makers, while also supporting patient navigation within the health care and health insurance systems. A detailed list of *Amici* appears in the Appendix.

The claims asserted and relief sought in this case directly and intimately concern the interests of health care consumers and will impact consumers' access to necessary specialty medications. As advocates for patients and health care consumers, *Amici* seek to provide a consumer-focused perspective that can help ensure that the Court understands how uninsured and underinsured consumers rely on third-party assistance and the public harm caused by Payer Matrix and similar alternative funding programs. As explained herein, Payer Matrix's alleged conduct misleads consumers as to their prescription drug coverage benefits and obligations, increases consumers' overall health care costs, and causes delays in accessing necessary medications. *Amici* also have an interest in proposing a modification to the injunctive relief sought by Plaintiff that would protect patients by requiring the parties to take appropriate measures to ensure that no patient is abruptly cut off from access to their medication without adequate notice, as discussed below.

BACKGROUND

I. Payer Matrix Is Not an Authentic Patient Advocacy Organization.

Managing one's health or the health of a loved one is a deeply personal experience. Patients often depend on their trusted health care providers to provide personalized care and select the best treatments for their specific needs and lifestyle. However, as health plans, pharmacy benefit managers, and companies like Payer Matrix devise new and complex ways to limit health care spending and maximize profits, patients, caregivers, and families impacted by benefit utilization and other

cost control tactics have increasingly turned to patient advocacy organizations for help with navigating treatment coverage and denials. This is especially true for newly diagnosed individuals who may otherwise be unfamiliar with navigating the health insurance system. True patient advocacy organizations*, like amici,* work tirelessly in the best interests of patients, caregivers, and families to overcome challenges in accessing medically necessary treatments.

Despite calling itself a "patient advocacy" organization (Mem. in Support of Mot. to Dismiss at 2), Payer Matrix has little in common with organizations like *amici*. By calling itself a patient advocacy service, Payer Matrix misleads consumers, the public, and this Court, as to who it is advocating on behalf of. Payer Matrix is a for-profit business that serves its own profit-maximizing interests and those of its clients—employer-sponsored health plans. *See* Payer Matrix, *Comprehensive Cost Management for Specialty Medications*. Payer Matrix is an "alternative funding program" whose sole purpose is to find ways to shift specialty medication payment obligations away from the plans and onto others, securing for itself a lofty payday in the process. Compl. ¶ 13.

While patient cost-sharing may sometimes be reduced through Payer Matrix's scheme of misrepresenting patients as not covered by commercial insurance, this is merely a coincidence, not Payer Matrix's purpose. This lack of concern for consumers is further demonstrated by the fact that Payer Matrix's program causes delays in access to treatments, interferes with treatment adherence, and otherwise harms consumers, and that such delays and harms do not affect Payer Matrix's profits. Furthermore, as explained herein, Payer Matrix coerces enrollees to participate in its program, which involves disclosure of highly personal information, such as income and health status. For consumers, this mandated participation in Payer Matrix's program does not provide them with a benefit that would otherwise be unavailable—again demonstrating Payer Matrix is not providing a service to benefit patients or bringing value to their care, but rather is acting in the

interests of itself and its plan clients. In short, these and other actions of Payer Matrix described throughout this brief show that, unlike authentic patient advocacy organizations, the company does not legitimately advocate for patients' needs and lived experiences. *See* Letter from 34 Patient Advocacy Organizations to Payer Matrix (Aug. 17, 2023).

II. Essential Health Benefits and Patient Assistance Programs.

An essential health benefit (EHB) is an important designation under the Patient Protection and Affordable Care Act (ACA). Under the ACA, health plans must cover ten types of EHBs, one of which is prescription drugs. *See* CMS, *Information on Essential Health Benefits (EHB) Benchmark Plans.* Federal law requires that all cost-sharing (e.g., copayments and coinsurance) paid by or on behalf of the patient for in-network EHBs must be counted towards meeting the patient's deductible and annual out-of-pocket limit. 42 U.S.C. § 18022. This requirement applies to large group and employer sponsored health plans when employers voluntarily choose to cover an EHB, such as prescription drugs. Aimed Alliance & CHLPI, *Letter to CCIIO* (Ex. A).

Despite the ACA providing important affordability protections in the form of limits on patient cost-sharing, many consumers with complex and chronic conditions still struggle to afford their medications. This is particularly true for uninsured and underinsured individuals. Uninsured individuals are those with no health insurance coverage; in contrast, underinsured individuals have insurance, but their health care costs constitute a substantial percentage of their household income (depending on the program, a minimum of between 10 and 30 percent, based on Medicare status and other criteria), making it difficult for them to afford their health care needs. *See, e.g.*, GoodRx, *Uninsured vs. Underinsured: What's the Difference?*; *see also* Choudhry et al., *Drug Company–Sponsored Patient Assistance Programs: A Viable Safety Net?*, Health Aff (Millwood), 827–34 (2009); Young et al., *How many people have enough money to afford private insurance cost sharing?*, KFF (Mar 10, 2022). Thus, to access medically necessary treatments prescribed by their

health care providers, underinsured individuals covered by private plans and uninsured individuals may rely on various types of third-party financial assistance to help access their medications.

One type of third-party financial assistance offered to uninsured and underinsured individuals is a Patient Assistance Program ("PAP"). PAPs typically provide "free" products to uninsured or underinsured consumers. Compl. ¶¶ 33, 49. In addition to PAPs offered by drug manufacturers such as AbbVie, there are also independent PAPs that help provide access to free products for consumers, or other types of financial assistance. Whether run by a drug manufacturer or an independent entity, each PAP has its own eligibility requirements. However, these programs typically require an individual to be underinsured or uninsured, meet specific income criteria, and satisfy certain health status requirements. Individuals whose commercial insurance covers a specialty drug typically are not eligible to receive PAP benefits. In short, PAPs are created for individuals with *true financial necessity,* without sufficient health care coverage, who otherwise would be forced to forego treatment without access to these programs.

III. Alternative Funding Programs Exploit Financial Assistance Programs Intended for Financially In-Need Health Care Consumers.

Alternative funding programs exploit PAPs by diverting PAP resources from the uninsured and underinsured persons for whom PAPs are intended to consumers already covered by commercial insurance. This scheme is fundamentally deceptive in its inception and in its execution and is completely unnecessary for the *insured consumers* it targets.

When a consumer who is insured by a health plan that has partnered with an alternative funding program attempts to fill their prescriptions, typically either the health plan or the alternative funding program will tell the consumer that if they enroll in the alternative funding program, they will receive their specialty medication for $0. Teamsters Local 731 Health and Welfare Funds, *Important Notice Regarding Benefit Changes*. However, the consumer is told, if they do not wish

to enroll in the program, they will be responsible for a 100 percent coinsurance, or the entire cost of the prescription drug – and this payment will not count towards their deductible or annual out-of-pocket limit. *See, e.g.*, Payer Matrix, *Payer Matrix Program Overview*; UFCW National Health and Welfare Fund, *Specialty Drugs – Fund Enhancement as of July 1, 2021*. Alternative funding programs and partnered plans justify these statements by falsely claiming that specialty drugs are non-EHBs and thereby excluded from all ACA cost-sharing protections. Confronted with this coercive scheme, consumers feel they are left with no other choice than to enroll in the program.

Once the consumer has enrolled, the alternative funding program and the plan move to the next phase of their scheme. Because alternative funding programs partner with *employer-sponsored health plans,* every PAP application submitted by, or with the assistance of, such a program is on behalf of patients **who have insurance coverage for their treatments**. These are not the underinsured or uninsured individuals PAPs are intended to support, and typically these enrollees should be ineligible for assistance under PAP terms because they do in fact have prescription drug coverage. To evade this eligibility requirement, the alternative funding program tells the health plan to automatically "deny" coverage for the enrollee's prescribed medication. This automatic denial is used to make the employee appear underinsured to satisfy the PAP eligibility criteria. Aimed Alliance, *Alternative Funding Programs* (2023) (Ex. B); Optum, *Alternative funding: Real savings or problems?*

Once the plan denies coverage, the alternative funding program then reaches out to the plan enrollees to obtain their personal information and submit the individual to the PAP.[1] Ex. B. On the

[1] Some alternative funding vendors may also illegally import medication from outside the United States and/or also try to exploit other manufacturer assistance resources that are available. However, because the Complaint does not discuss illegal importation or vendors' misuse of copay assistance, we have not addressed those issues in the brief.

PAP applications, the alternative funding program falsely states that the specialty drugs have been excluded from coverage by the enrollee's health plan. *See, e.g.*, Compl. ¶ 19. The alternative funding program does not disclose that if the PAP determines that an enrollee is not eligible for the program, the medication will be covered by the health plan as a typical pharmacy benefit. *See* Ex. B; Teamsters Local 731 Health and Welfare Funds, *supra.* This back and forth can confuse consumers and cause delays between when a consumer is denied financial assistance and when the needed medication is processed back through the plan.

ARGUMENT

I. Payer Matrix Harms and Deceives Health Care Consumers and Providers.

Payer Matrix causes an abundance of harm to consumers with chronic, complex, and rare conditions, misleading and deceiving these consumers for the gain of Payer Matrix and its employer-sponsored plan clients.

A. Payer Matrix harms patients by failing to disclose critical information about its scheme.

Advocates and lawmakers have long called for greater transparency in the U.S. health care system, including around the requirements, criteria, and rationales for cost containment measures used in prescription drug coverage. Chambers & Neumann, *A Next Frontier in Health Care Transparency: Health Plan Drug Coverage Policy,* HealthAffairs (Apr. 7, 2021). Transparency benefits the public by allowing patients and physicians to better understand how their access to care is determined, ensure accountability for improper denials, and encourage rigor in drug coverage policy discussions. *Id.* Despite the benefits of transparency, Payer Matrix consistently fails to disclose relevant information that could inform a consumer's decision to enroll in its program.

First, Payer Matrix misleadingly presents itself as a patient advocacy organization. As explained above, Payer Matrix is not a patient advocacy organization, as it "advocates" on behalf of

employer sponsored health plans and itself. Calling itself a patient advocacy organization in consumer messaging is misleading because it gives enrollees the impression that the company is acting in their best interests, rather than its own profit-maximizing interests and the interests of its plan clients. Moreover, Payer Matrix does not disclose to consumers that if it successfully sources their medication, it takes 30 percent of any "savings" achieved based on what the plan would have paid had an alternative source not been secured. Compl. ¶ 13. For Payer Matrix, the more people it successfully enrolls in a financial assistance program, the higher its revenues. This business model incentivizes Payer Matrix to do whatever it takes to increase enrollment volume—including fraudulent acts alleged in Plaintiff's Complaint—without particular concern as to whether enrollment could negatively impact enrollees by delaying medication access or interfering with treatment compliance. Compl. ¶ 146. While Payer Matrix alleges these omissions are simply "a general failure[s] to disclose," Mem. in Support of Mot. to Dismiss at 17-18, this fails to recognize that by calling itself a "patient advocacy" organization, Payer Matrix is making the affirmative representation that it is advocating on behalf of patients. This type of affirmative misrepresentation seems to be the exact type of statement that even Payer Matrix recognizes violates Illinois law. (*See id.*)

Second, Payer Matrix does not disclose to consumers how using Payer Matrix to enroll in Plaintiff's PAP could violate the PAP's terms and conditions. For example, in the FAQ provided to enrollees, Payer Matrix instructs enrollees on how to respond to manufacturers that call to confirm whether the enrollee's plan covers their specialty drug, including by providing "talking points" stating the drug is not covered. *Payer Matrix Program Overview*, *supra.* However, it does not appear that Payer Matrix explains to enrollees that they are ineligible for PAP assistance or that they should disclose to the manufacturer that the medication *will be* covered by the plan if the PAP program discovers that he or she is ineligible for assistance.

Furthermore, when Plaintiff engaged in more direct measures to limit Payer Matrix's enrollment of insured individuals in its PAP, Payer Matrix did not inform consumers how it would begin actively concealing its involvement in these applications. Compl. ¶ 21. Using *consumers' information* to submit applications that actively concealed Payer Matrix's involvement places consumers in a precarious position in which they are unintentionally violating the program terms, and potentially subjecting themselves to legal consequences related to such fraudulent conduct and improper receipt of benefits from these programs. Had Payer Matrix disclosed this information, consumers may have refused to participate in the program.

Health care consumers who are newly diagnosed with a chronic condition are particularly susceptible to being exploited by Payer Matrix. When consumers receive a new diagnosis, they begin coping with the emotional, logistical, and financial implications of their diagnosis. Thus, many newly diagnosed individuals are unlikely to even ask how this program has received access to their needed medication in the first place. Payer Matrix exploits this vulnerability by immediately applying consumers to the PAP as soon as they attempt to fill a specialty drug, without fully disclosing important details about the potential repercussions of participating in its scheme.

Payer Matrix's program also creates confusion and anxiety among impacted consumers about their insurance status and even about their ability to continue in employment with their current employer. More than half of all Americans have low health insurance literacy and lack understanding of basic terms such as coinsurance and copayment. Edward et al., *Significant Disparities Exist in Consumer Health Insurance Literacy: Implications for Health Care Reform*, Health Lit. Res. Proj (Oct. 2019). There are, moreover, significant disparities in health insurance literacy based on demographic factors such as ethnicity, income level, education level, and age. *Id.* Alternative funding programs worsen these understanding gaps and exacerbate these

disparities by creating additional layers of complexity that make it harder and more stressful for consumers to navigate an already confusing system to access the care they need.

Lastly, Payer Matrix misleads consumers as to the cost of their health care by misrepresenting the cost of their prescription drugs. For example, under one avenue, the consumer is responsible for a 100 percent coinsurance, or cost of the drug, if they do not participate in the Payer Matrix program; under another avenue, their medication has $0 cost-sharing as the result of an alternative funding source; and, under a third avenue, in which no alternative funding source is available, the specialty drug returns to the typical plan cost-sharing tiers. Teamsters Local 731 Health and Welfare Funds, *supra.* Essentially, this scheme creates three different costs all for the same individual with the same prescription drug, paying the same premium in each scenario. By creating three different costs, Payer Matrix misleads consumers as to the actual cost of their care, impairs consumers' ability to understand how their health care cost could impact their employer, and limits consumers' ability to have an active voice in local, state, and federal conversations relating to health care affordability and reform. *See* 815 ILCS 510/2 (a)(11).

In sum, Payer Matrix's alleged conduct is contrary to the public interest because it is not transparent about how its scheme operates, and it misleads consumers by failing to disclose important information that could inform consumers' decisions on whether to participate in a scheme that directly impacts the accessibility and affordability of their medications.

B. Payer Matrix's conduct interferes with patients' ability to access their treatments and the patient provider-relationship.

In addition to complicating access to prescribed medications through the process described above, Payer Matrix's program also interferes with the patient-provider relationship by urging health-care providers and/or patients to change medications for financial, rather than medical, reasons. When a stable patient is required to change treatments for financial reasons, they are more

likely to experience negative health consequences, such as medical complications and symptom relapse. *See* Nguyen et al., *Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review* (2016); Nat'l Infusion Ctr. Ass'n, *What is non-medical switching?*; Compl. ¶ 130.

When AbbVie began denying patients affiliated with Payer Matrix admission into its PAP in 2023, Payer Matrix began falsely telling these patients and their health care providers that the patients no longer had coverage for AbbVie's drugs, but they did still have coverage for other specialty drugs (i.e., ones for which Payer Matrix still could utilize a different manufacturer's PAP), thereby misleading providers to prescribe alternative treatments for their patients. Compl. ¶ 130. Of course, a provider who places their patient's interest first will prescribe an alternative treatment to help manage the patient's symptoms rather than the patient having no treatment at all. *Id.* However, for patients who are stable on an effective treatment, switching medications can have serious adverse effects. For instance, one study of 800 patients with cardiovascular disease found that when patients were forced to change medications for financial rather than medical reasons, 60 percent experienced complications from the new medication, 40 percent found the new medication not as effective, and 10 percent experienced a hospitalization as a result of the switch. P'ship to Advance Cardiovascular Health, *Non-Medical Switching & Cardiovascular Health* (July 2021). Ultimately, requiring health care providers to make this choice jeopardizes the patient's health stability solely for the purpose of permitting Payer Matrix to exploit more financial assistance.

C. Payer Matrix interferes with patient's timely access to treatments.

Payer Matrix also unnecessarily complicates and slows an already complex drug fulfillment system. When a health plan partners with Payer Matrix, it requires the patient's prescription to be sent to the plan for coverage, then to a pharmacy benefit manager for denial, and then to Payer Matrix. Once the prescription is with Payer Matrix, it then reaches out to the enrollee to

receive their personal information, and then applies the individual to the PAP for consideration. If the consumer is denied enrollment into the PAP, the prescription is sent back to Payer Matrix, which then sends the prescription back to the pharmacy benefit manager and health plan for coverage. *See* Aimed Alliance, *Alternative Funding Program Infographic* (Ex. D). Understandably, this multi-stakeholder process can result in delays from when the prescription is submitted to when it is ultimately covered by the health plan or alternative source. For health care consumers, this can mean waiting weeks or even months for access to their medically necessary treatments, when the treatments would have been provided quickly but for Payer Matrix's interference. Compl. ¶ 90. Without prompt access to their medications, consumers can experience symptom relapse, irreversible disease progression, development of co-occurring conditions, or even death.

D. Payer Matrix discriminates against low-income individuals.

In addition to requiring that an individual is uninsured or underinsured to receive PAP assistance, PAPs also have household income limitations. These requirements are designed to ensure that finite PAP resources benefit the truly in-need patients, i.e., lower-income uninsured or underinsured households. Thus, even if Payer Matrix succeeds in deceiving the PAP that the plan's commercially insured members are uninsured, the PAP will only deem lower-income plan members eligible, forcing them to continue with the Payer Matrix program. Higher income individuals whose applications are denied from the PAP after income screening, by contrast, will receive their medications under the health plan's regular pharmacy benefit. Optum, *supra*.

This creates a system that discriminates against lower-income patients, requiring them to continue to go to a PAP to receive their medication, while higher-income earners on the same plan can (after first undergoing the unnecessary and cumbersome enrollment process created by Payer Matrix) receive their medication as a typical pharmacy benefit. This discriminatory design is particularly unfair considering both low-income and high-income earners pay the same health plan

premiums. This ultimately results in each individual having different experiences with respect to medication coverage and access (e.g., access delays, assistance not counting towards deductibles). Such discrimination based on financial status is against the public interest as it perpetuates inequities within our health care system and disparities in health outcomes.

E. Payer Matrix's scheme threatens public health by eroding EHB protections.

Payer Matrix's business model is premised upon disregarding EHB protections set forth in the ACA and its implementing regulations. Ex. A. As explained above, alternative funding providers encourage plan customers to improperly designate certain medications as non-EHB, thereby excluding these drugs from the ACA's protections and annual limits on cost-sharing.[2] However, as Aimed Alliance explained in a September 13, 2021, letter to the federal government, this model mischaracterizes federal laws and regulations on EHBs and is inconsistent with how the U.S. Department of Health and Human Services intends for EHBs to be covered and defined by plans. *Id.* Moreover, it contradicts the intent of the ACA's EHB mandate and cap on annual out-of-pocket expenses which, together, provide meaningful coverage, protect consumers from unaffordable costs, and ensure consumers are not bankrupted due to their medical needs.

By exploiting what it considers a "loophole" in the ACA, Payer Matrix perpetuates a precarious roadmap for how a similar rationale could be used to erode other EHB protections. For example, Payer Matrix could encourage health plans to adopt the benchmark with the fewest covered services for "maternal and newborn care" and deem all additional maternal and newborn care services non-EHBs. This type of erosion is dangerous for women who experience high-risk pregnancies and need more visits, tests, or ultrasounds than those provided in the benchmark plan. *See*

[2] While some alternative funding programs explicitly state their program operates under the non-EHB loophole, or that specialty drugs are "covered non-EHBs," Payer Matrix does not. However, this non-EHB loophole *is the only ground* upon which Payer Matrix could claim that a patient's 100 percent cost-sharing requirement will not count towards their annual out-of-pocket limit.

generally Centers for Disease Control, *Maternal Mortality Rates in the United States, 2021* (discussing impact of maternal mortality rate crisis on Black, Hispanic, and non-white women).

The large-scale ramifications of Payer Matrix's program cannot be ignored. By permitting this action to proceed and enjoining Payer Matrix's conduct, this Court can help ensure that similar programs are not empowered to continue to disregard patient protections throughout all EHBs.

F. Payer Matrix threatens patients' health stability by jeopardizing the sustainability of financial assistance programs.

Financial assistance programs help patients afford certain medically necessary treatments and meet their deductibles and annual out-of-pocket maximums. Given the steady rise in enrollees' cost-sharing obligations imposed by their health plans, patients with chronic conditions increasingly rely on financial assistance programs to afford their medications. Kollet Koulianos & Keri Norris, *Copay assistance should count as part of patients' cost sharing for medications,* STAT News (June 30, 2021). When consumers are unable to afford their prescription drugs and other health care expenses, they may become nonadherent to their treatment plans. Non-adherence can include stopping treatments altogether, rationing medications by skipping doses, or limiting medication usage. This can lead to poor health outcomes, including relapses in symptoms and hospitalization, which can increase overall health care costs. This is a major reason why financial assistance programs have become so important to patients.

PAPs are not bottomless wells for health plans to tap into to reduce the financial burden on employer-sponsored health care. As previously stated, PAPs are created for individuals with *true financial necessity* who otherwise would be forced to forego treatment without these programs. Compl. ¶ 33. It is unrealistic to assume manufacturers will continue to support financial assistance programs in perpetuity if patients for whom these programs were not intended to support continue to divert resources away from the intended individuals. By submitting applications to PAPs for

insured individuals, Payer Matrix jeopardizes the viability and sustainability of these important safety-net programs. If these programs cannot be sustained in a way that provides consumers who rely on them with meaningful assistance, then the health of these patients is ultimately at risk.

II. Payer Matrix Engages in Unfair and Deceptive Trade Practices.

The Illinois legislature passed the Consumer Fraud and Deceptive Business Practices Act with the intent of creating state-based protections against "unfair or deceptive trade practices," akin to the federal protections established in Section 5(a) of the Federal Trade Commission Act (FTC Act). *See* 815 ILCS 505/2. Thus, when determining whether the alleged conduct is an unfair trade practice under the ILCS 505, the Court may consider whether this is the type of conduct the FTC Act is intended to protect consumers from. Illinois Legal Aid Online, *Deceptive Trade Practices under the UDTPA and FTC*; FTC, *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*; CFPB Consumer Laws and Regulations, *Unfair, Deceptive, or Abusive Acts or Practices.* Aimed Alliance strongly believes alternative funding programs broadly, and Payer Matrix's program specifically, are unfair trade practices in violation of the FTC Act. Aimed Alliance has raised these concerns with the FTC on multiple occasions, including through a 2022 comment opportunity and a 2023 letter to the FTC on alternative funding programs. Aimed Alliance, *Aimed Alliance Comment to FTC* (May 25, 2022); Aimed Alliance, *Letter to FTC* (June 14, 2023) (Ex. C).

III. Amici Request that the Court Modify Plaintiff's Proposed Injunction to Require Notice to Impacted Consumers.

Plaintiff requests an injunction prohibiting Payer Matrix from "contacting patients and health care providers and relying on sham specialty drug exclusions to falsely claim that patients no longer have insurance coverage for AbbVie's specialty drugs and must be switched to a new medication or making any other misrepresentations about AbbVie's drugs or its PAP to patients,

health care providers, employers, plan sponsors, and other third parties." Mem. in Support of Mot. for Prelim. Inj. at 4–5. *Amici* ask this Court to modify the requested injunction to require the parties to take appropriate measures to ensure that no patient is abruptly cut off from access to their medication without adequate notice.

Amici understand that the earliest an injunction would be granted is in 2024. Given that January marks the beginning of the plan year for most consumers, individuals and their providers may be contacted beginning January 1 and informed that they must change treatments due to a lack of coverage as alleged in Plaintiff's complaint. Thus, if an injunction is enacted after January 1, and Payer Matrix has already engaged in discussions with consumers and their health care providers, these individuals will need to be notified that the prior statements made by Payer Matrix regarding coverage inadequacy were inaccurate. At minimum, this notice should include a brief explanation of the reasons why Payer Matrix will no longer be involved in how the patient accesses their medication and information on how they can communicate with their health plan about continued access to and coverage of their treatments.

Amici firmly believe that an injunction will safeguard PAPs from exploitation and ensure they remain available for the individuals for whom they were intended. These suggested notice requirements are not intended to impair or limit the Court's ability to enjoin Payer Matrix's conduct. Instead, they are designed to ensure that consumers impacted by Payer Matrix are made aware of Payer Matrix's misrepresentations about their treatment coverage.

CONCLUSION

For the foregoing reasons, *Amici* request that the Court deny Defendant's Motion to Dismiss and grant Plaintiff's Motion for a Preliminary Injunction, modified as proposed herein.

Dated: August 24, 2023

Respectfully submitted,

By: */s/ Michael L. McCluggage*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 24, 2023, I electronically filed the foregoing document with the clerk of the court for the Northern District of Illinois, using the electronic case filing system of the court. The electronic case filing system sent a "Notice of E-Filing" to the attorneys of record in this case.

/s/ Michael L. McCluggage

Appendix

List of *Amici*

1. **ADAP Advocacy's** mission is to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for persons living with HIV/AIDS. ADAP Advocacy works with advocates, community, health care, government, patients, pharmaceutical companies, and other stakeholders to raise awareness, offer patient educational programs, and foster greater community collaboration.

2. **Advocacy & Awareness for Immune Disorders Association (AAIDA)** educates and advocates for patients living with all immune dysregulation disorders and overlapping conditions and physicians who treat them. AAIDA is well-versed with alternate funding programs and aim to make the public more aware of their deceptive tactics regarding patient treatments and costs.

3. **Aimed Alliance** is a 501(c)(3) not-for-profit health policy organization whose mission is to protect and enhance the rights of health care consumers and providers. Aimed Alliance advances policies to ensure that consumers and health care providers, can make informed and individually appropriate decisions without third-party interference from health insurers and their agents. Aimed Alliance leads and participates in policy-focused coalition activities to advance its mission. Aimed Alliance's organizational positions are established by its independent board of directors in accordance with its public interest mission.[1]

4. **Any Positive Change Inc.** focuses on people who use drugs and maximizing health and wellbeing as they determine for themselves.

5. **Cancer*Care*** is the leading national organization providing free, professional support services and information to help people manage the emotional, practical, and financial challenges of cancer.

6. **Coalition of State Rheumatology Organizations (CSRO)** has advocated for 20 years for improved patient access to treatment of rheumatologic conditions, and Payer Matrix has continually created barriers to care for rheumatology patients.

7. **Color of Crohn's and Chronic Illness (COCCI)** is a national patient advocacy organization whose mission is to improve the quality of life for BIPOC who are affected by IBD, Digestive Disorders and associated Chronic Illnesses, through Community, Research, Education, and Advocacy. A key pillar in our advocacy agenda is access to

[1] AbbVie Inc. is a commercial supporter of Aimed Alliance. All of Aimed Alliance's commercial supporters are listed on the Aimed Alliance website.

treatments; we believe that alternative funding programs such as those involved in this lawsuit have a significant negative impact on patients and their ability to access treatments for their GI conditions.

8. **Community Access National Network (CANN)** is a 501(c)(3) national nonprofit organization (formerly incorporated under the "Ryan White CARE Act Title II Community AIDS National Network") focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking. CANN's coalition-based work is done on behalf of the patient advocacy groups, pharmaceutical partners, and government agencies. ensuring patients receive accurate information from payors and the fullest benefit of manufacturer patient assistance programs is critical to advancing patient health outcomes and reaching public health goals.

9. **Connecticut Oncology Association** is a not-for-profit professional society for oncology professionals caring for cancer patients in the state of Connecticut. Alternate funding programs are adversely affecting patients, draining funds from funds set aside for needy patients, and causing patients to abandon their needed medications due to disruption in their insurance coverage. We are vehemently against any possible delay of this lawsuit.

10. **Gaucher Community Alliance's (GCA)** mission is to support patients with Gaucher disease and their families through peer-to-peer support and education, advocacy, patient and family resources, and networking. Through mutual self-help and peer-to-peer connections, the GCA wants to ensure that no families shall face this disease alone. GCA has consistently heard from our community that PBM actions cause hardship and adverse medical consequences. Our treatments are high cost and often involve pharmaceutical assistance as the only way for our patients to access treatment. As more and more insurance companies' contract with PBMs and enact co-pay accumulators, patient advocacy efforts are increasingly needed to work on a state-by-state basis to support state bills to ban the practice and informing and involving our community in supporting favorable state and federal actions.

11. **Global Healthy Living Foundation** is a 501(c)(3) nonprofit organization whose mission is to improve the quality of life for people with chronic illnesses (such as arthritis, osteoporosis, migraine, psoriasis, asthma, alopecia, inflammatory bowel disease, and cardiovascular disease) by advocating for improved access to health care at the community, state, and federal levels, and amplifying education and awareness efforts within its social media framework. We are concerned with any scheme that interferes with patients' abilities to access needed therapies in a timely fashion.

12. **Healthy Men Inc.'s** mission is to help make healthcare more "Guy-Friendly" and empower men to take charge of their own healthcare and wellness.

13. **Hemophilia Federation of America** is a community-based, grassroots advocacy organization that assists, educates, and advocates for people with hemophilia, von Willebrand disease, and other rare bleeding disorders. People with bleeding disorders have complex, lifelong medical needs. Most depend on ongoing use of prescription specialty medications to treat or avoid debilitating bleeding episodes that can lead to advanced medical issues or even death.

14. **HIV and Hepatitis Policy Institute** is a nonprofit organization dedicated to promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. The patients we represent rely on the prescription medications their providers prescribe to remain healthy and alive. Many people with or at risk of HIV or have hepatitis B or C rely on drug manufacturer patient assistance programs to access their prescriptions. Payor Matrix specifically targets several HIV and hepatitis drugs on their list of medications for which they seek "alternative funding."

15. **Infusion Access Foundation** is a community of patients and advocates united to protect access to provider-administered treatments, such as infusions and injections. As a 501(c)(3) nonprofit, our mission is to expand access to these therapies and help patients live their best, healthiest lives. We support patients across all disease states and advocate for policies and regulations that will increase access, equity, and affordability. The Infusion Access Foundation's work revolves entirely around the patient experience, which is why we support ending the deceptive and unethical behavior by alternative funding programs, including Payer Matrix.

16. **Lupus and Allied Diseases Association** was founded in 1978 and is a non-profit organization led by people with lupus and allied diseases who are dedicated to ensuring that the patient perspective is included and recognized as an equal stakeholder in the healthcare, regulatory and public policy arenas and across the research continuum. It is our goal to improve access to care and quality of life by fostering collaboration among stakeholders and by wielding the patient voice as a catalyst to advance innovative advocacy, education, awareness, and biomedical research initiatives that will identify causes, advance better diagnostics, and discover superior treatments, and cures. As patients ourselves, who know firsthand the challenges of dealing with serious medical conditions on a daily basis, we strongly support establishing essential patient protections that are affordable and improve access to vital therapies.

17. **Massachusetts Society of Clinical Oncologists** is dedicated to improving cancer care and treatment and is recognized by the Massachusetts Medical Society and the American

Society of Clinical Oncology as the voice for cancer physicians and in the state.

18. **Missouri Oncology Society** collaborates with internal and external organizations to support our mission of improving patient outcomes and the treatment of cancer in the State of Missouri. Our interest in this lawsuit is to ensure that patients are protected from deceptive alternative funding programs that may bar or delay access to treatment, interfere with the patient-provider relationship, or discriminate against low-income individuals.

19. **National Bleeding Disorders Foundation** (formerly National Hemophilia Foundation) is a patient advocacy organization on behalf of people with inherited blood and bleeding disorders.

20. **National Consumers League (NCL)** is America's leading pioneering consumer advocacy organization, representing consumers and workers on marketplace and workplace issues since our founding in 1899. Specialty medicines are used to treat complex, chronic conditions like cancer and rheumatoid arthritis; they are drugs often offered to some of the sickest patients. While they represent a mere 2 percent of prescriptions, they add up to half of the estimated $500 billion spent each year in the U.S. on drugs. Thus, specialty drugs are hefty contributors to self-funded employers' health plan costs. (Source: optum.com) One "solution" offered by third party vendors peddling AFPs is to remove coverage of specialty drugs from the employer's formulary. This immediately renders those employees "uninsured" as far as coverage for their needed drugs goes. The AFP vendor then matches the newly uninsured employee with a patient assistance program offered by drug manufacturers and other charitable foundations. The patient's co-pay is fully covered by the assistance program, the employer saves money, and the vendor takes a cut of the savings. We think this so-called solution is underhanded and dangerous for patients.

21. **National Infusion Center Association (NICA)** is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of provider-administered medications. In the last year and a half, NICA's members – infusion providers – have reported an increase in patients receiving letters from alternative funding program entities. These letters make the patient an offer that can't be refused: enroll in a new program or pay for 100% of the specialty drug cost out-of-pocket. The alternative funding program entity refuses to work with the patient's provider or anyone other than the patient directly, which is unusual, since providers usually help patients navigate the complex barriers and requirements around accessing specialty drugs. Affected patients have expressed confusion over having to enroll in a separate program in addition to their insurance plan and concern about handing over private health and financial information to an unknown company soliciting them by mail. When a patient ignores these letters for those reasons, they risk missing their next treatment, given the length of time needed to fully enroll and receive patient assistance or, upon

denial, coverage. Because these entities jeopardize patient access to necessary medications, NICA has a keen interest in ending the deceptive and unethical behavior by alternative funding programs, including Payer Matrix.

22. **National Oncology State Network** is a nonprofit action organization established by state leaders collaborating on emerging state issues in order to strengthen cancer care and policy across the country. Alternate funding programs are adversely affecting patients, draining funds from funds set aside for needy patients, and causing patients to abandon their needed medications due to disruption in their insurance coverage.

23. **The AIDS Institute** is a 501(c)(3) non-profit organization that advocates for increased access to health care for people living with and at risk for HIV, viral hepatitis, and other chronic illnesses.

24. **Triage Cancer** is a national, nonprofit organization that provides free education on the legal and practical issues that may impact individuals diagnosed with cancer and their caregivers, through events, materials, and resources. Triage Cancer is interested in this lawsuit because of its implications on patient access to care and the financial burden these policies can impose on patients and their families.

Exhibit A

AIMED ALLIANCE

September 13, 2021

Jeff Grant
Acting Deputy Administrator & Director and Deputy Director
Center for Consumer Information & Insurance Oversight
Jeffrey.grant1@cms.hhs.gov

Jeff Wu
Deputy Directory of Policy
Center for Consumer Information & Insurance Oversight
Jeff.Wu@cms.hhs.gov

Re: Essential Health Benefits Scheme

Dear Mr. Grant and Mr. Wu:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. The Center for Health Law and Policy Innovation of Harvard Law School ("CHLP") advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses and disabilities.

It has recently come to our attention that some companies that are partnering with insurers and misleading patients by calling themselves "patient services hub centers" are likely violating the Patient Protection and Affordable Care Act ("ACA"). Thus, we are asking that the Center for Consumer Information and Insurance Oversight:

(1) Confirm our interpretation that if a health plan, including an employer-sponsored health plan, covers a prescription drug, drug is considered an essential health benefit ("EHB");
(2) Determine that patient services hub centers are violating the ACA and its implementing regulations; and
(3) Take enforcement action against these companies if they are violating the ACA or provide a frequently asked questions ("FAQ") on the issue.

Finally, we request a virtual meeting to discuss this matter further.

I. Patient services hub centers have created a new industry that exploits a loophole in ACA

We are concerned that companies that refer to themselves as "patient services hub centers" ("Hub Centers") are misinterpreting EHB protections in the ACA to the detriment of patients. A "hub" generally acts as an intermediary between various members of the distribution chain and the consumer.[1] There are a variety of hub models; however, "patient services hub centers" typically

[1] https://www.pharmaceuticalcommerce.com/view/2015-hub-services-report

refers to hubs that contract with drug manufacturers to provide services to patients so that patients can access their medications and adhere to their treatment plan.[2] Here, Hub Centers, such as SaveonSP, are partnering with insurance companies and pharmacy benefit managers (PBMs) to administer a program in which they claim to have found a legal loophole to EHB protections.[3] The ACA's EHB requirement ensures that a certain minimum number of medications in each class and category of drugs are covered and subject to annual maximum out-of-pocket limits on cost-sharing.[4] These protections help to ensure that consumers can access and afford medically necessary therapeutics. However, SaveonSP's program (described as "a non-essential health benefits copay assistance solution" and a "copay offset program from specialty medication")[5] "utilizes plan-design changes to identify select drugs as non-essential health benefits, enabling maximum savings and reducing plan and member costs" for employer-sponsored health plans.[6] Under this program, specialty medications listed on SavonSP's drug list are available for a $0 copay for plan enrollees who sign up.[7] Once the plan enrollee is enrolled in SaveonSp's plan, the plan collects the maximum amount of copay assistance from the manufacturer and does not count that copay assistance toward the plan enrollee's deductible, essentially serving as a copay maximizer program.[8]

However, if the enrollee does not sign up, the enrollee is responsible for a much higher copay.[9] SaveonSP states that the copays "may vary based on the manufacturer allowed amounts for a particular specialty prescription drug."[10] In other words, copay amounts are determined based upon the maximum value that a manufacturer has set for a copay assistance program. The copays for several medications, for example, are set at $7,500 per fill.[11] That copay does not count towards the plan enrollee's deductible, or the annual maximum out-of-pocket limit as established by the ACA. Instead, the plan enrollee is responsible for that copay for the entirety of the plan year, unless they enroll in SaveonSp's program.[12] Therefore, a monthly medication with a $7,500 copay could cost a plan enrollee $90,000 per year if they do not sign up. That is $81,450 over the annual limit for individuals and $72,900 over the limit for family health plans.[13]

SaveonSP has argued that it is permitted to charge plan enrollees more than the ACA maximum out-of-pocket limit because it has determined that the specialty drugs on its list are "covered" but not EHBs.[14] SaveonSP has come to this conclusion based on two arguments. First, it claims that specialty medications are not one of the ten categories of EHBs.[15] Second, it argues that

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[2] https://www.pharmaceuticalcommerce.com/view/finding-the-hub-in-specialty-pharma-services
[3] https://www.express-scripts.com/corporate/solutions/lowering-costs#saveonsp
[4] https://www.drugchannels.net/2020/02/latest-express-scripts-data-slow-drug.html
[5] https://www.express-scripts.com/corporate/solutions/lowering-costs#saveonsp
[6] https://www.express-scripts.com/corporate/solutions/lowering-costs
[7] https://www.strsoh.org/news/health-care/2021/saveonsp-program-added-for-some-specialty-medications.html
[8] https://www.iona.edu/offices/human-resources/employee-benefits/health-insurance/saveonsp-variable-copayments-certain
[9] https://www.strsoh.org/news/health-care/2021/saveonsp-program-added-for-some-specialty-medications.html
[10] https://www.strsoh.org/_pdfs/health-care/saveonsp.pdf
[11] https://www.strsoh.org/_pdfs/health-care/saveonsp.pdf
[12] https://www.strsoh.org/news/health-care/2021/saveonsp-program-added-for-some-specialty-medications.html
[13] https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/
[14] https://www.iona.edu/offices/human-resources/employee-benefits/health-insurance/saveonsp-variable-copayments-certain
[15] https://www.aps.edu/human-resources/benefits/documents/2021-summary-of-benefits/express-scripts-summary-of-benefits

an insurer is only required to cover the same *number* of drugs within a class and category as the state's benchmark health plan. Therefore, any additional medications that a plan covers within those classes and categories are not considered an EHB and not subject to the ACA's out-of-pocket maximums.[16]

II. The EHB Scheme Violates the ACA and Its Implementing Regulations

SaveonSP's scheme violates the ACA and its implementing regulations because employer-sponsored health plans that choose to offer prescription drugs must comply with the ACA annual limits on cost-sharing, with certain exceptions that do not apply here.[17]

A. Specialty medications are prescriptions drugs—an EHB

SaveonSP argues that the "specialty medications" subject to its program do not fit within the existing 10 categories of EHBs.[18] However, prescriptions drugs is one of the categories of EHBs.[19] While the ACA does not define the term "prescription drugs," the ACA regulation governing prescription drugs as an EHB refers to "FDA-approved drugs."[20] The FDA defines a "prescription drug" as "any human drug required by Federal law or regulation to be dispensed only by a prescription. . . ."[21] Likewise, the plain meaning of the word "prescription drug" is a "drug that can be obtained only by means of a [health care practitioner's] prescription."[22] Moreover, the ACA regulations only mention one class or category of drugs that health plans may choose not to cover as an EHB—drugs intended for abortion.[23] Each of the specialty medications listed in SaveonSP's drug list requires a prescription in order to be dispensed or administered.[24] None of them appear to be for abortion.[25] Therefore, all of the specialty medications subject to SaveonSP's program fit within the EHB category of "prescription drugs."

B. Covered prescription drugs are EHBs and must count toward annual cost-sharing limits

Under the ACA, all EHBs, including prescription drugs, are subject to the annual limits on cost-sharing, unless an exception exists.[26] Cost-sharing includes deductibles, coinsurance,

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[16] https://www.express-scripts.com/corporate/articles/reducing-specialty-drug-costs
[17] 42 U.S.C §18022(b); 42 C.F.R. §156.122
[18] https://www.aps.edu/human-resources/benefits/documents/2021-summary-of-benefits/express-scripts-summary-of-benefits
[19] 42 U.S.C §18022(b); 42 C.F.R. §156.122
[20] 42 C.F.R. 156.122(a). This regulation states that in order for prescription drugs to be considered an EHB, the plan must use a pharmacy and therapeutic (P&T) committee that meets certain standards. These standards include a review of new and existing FDA-approved drugs. As such, the term "prescription drugs" likely refers to FDA-approved drugs.
[21] 21 C.F.R. 205.3(e)
[22] https://www.merriam-webster.com/dictionary/prescription%20drug
[23] 42 C.F.R. 156.122(b)
[24] https://www.ccsoh.us/site/handlers/filedownload.ashx?moduleinstanceid=8821&dataid=32394&FileName=SaveOn%20Drug%20list%20July%201%202021.pdf
[25] https://www.ccsoh.us/site/handlers/filedownload.ashx?moduleinstanceid=8821&dataid=32394&FileName=SaveOn%20Drug%20list%20July%201%202021.pdf
[26] https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf at p. 4 Exceptions include ng coverage is for premiums, balance billing for non-network, or spending on non-covered services

copayments, and similar charges.[27] Employer-based plans are not required to offer EHBs.[28] However, if an employer-sponsored plan chooses to offer an EHB, the EHB coverage must comply with ACA requirements.[29]

ACA regulations state a health plan provides essential health benefits for prescription drugs only if it "covers ***at least the greater*** of (1) one drug in every USP category and class; or (2) the same number of prescription drugs in each category and class as the benchmark plan."[30] By using the "at least the greater" language, the regulation sets a ***minimum*** standard of what a plan must cover to offer prescription drugs as an EHB rather than an upper limit. This interpretation is consistent with other provisions within the same regulation. For example, the regulation provides that a health plan must offer appropriate means for an individual to request and receive appropriate clinical prescriptions that are not covered under the general plan (i.e., an exception request).[31] The exception provision says that the plan "must treat the excepted drug(s) as an essential health benefit, including by counting any ***cost-sharing toward the plan's annual limit on cost-sharing***. . . ."[32] It would be inconsistent for excepted drugs to be considered an EHB while other drugs that are covered by the plan are not considered EHBs. Similarly, in discussing charging different cost-sharing amounts for obtaining a covered drug at a retail pharmacy, the regulation says, ***"all cost sharing will count toward the plan's annual limitation on cost sharing,"*** again conveying that all covered drugs are to be treated as EHBs for the purpose of calculating the annual cost sharing limitation.[33]

Moreover, HHS has confirmed this interpretation, at least as it applies to small and individual group plans. In the Notice of Benefit and Payment Parameters for 2016 ("NBPP 2016"), HHS stated that "plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB. Therefore, if the plan is covering drugs beyond the number of drugs covered by the benchmark, ***all of these drugs are EHB and must count towards the annual limitation on cost sharing***."[34] This position was also reaffirmed by HHS in the NBPP 2020.[35]

Employer-sponsored health plans that use the services of Hub Centers like SaveonSP provide voluntary coverage of prescription drugs. All covered drugs offered by these plans are EHBs, and therefore, such plans are required to comply with the ACA's annual limit on cost-sharing. However, SaveonSP and other Hub Centers are incorrectly defining EHBs by misconstruing the "at least the greater" language to mean that only the minimum number of medications must be covered as an EHB, and therefore, the remainder of the medications are not considered EHB.[36] This interpretation is incorrect because the regulation explicitly provides a manner for non-benchmark medications to be considered an EHB. Moreover, the operation of SaveonSP's policy goes directly against the language of the statute that states "***all cost sharing will***

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[27] 42 U.S.C §18022(c)
[28] https://www.cms.gov/cciio/resources/files/downloads/ehb-faq-508.pdf
[29] https://www.cms.gov/cciio/resources/files/downloads/ehb-faq-508.pdf
[30] 42 C.F.R. 156.122
[31] 42 C.F.R. 156.122
[32] 42 C.F.R. 156.122
[33] 42 C.F.R. 156.122
[34] govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf at p. 69 (emphasis added).
[35] https://www.federalregister.gov/documents/2019/04/25/2019-08017/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020
[36] https://www.drugchannels.net/2020/02/latest-express-scripts-data-slow-drug.html

count toward the plan's annual limitation on cost sharing."[37] Thus, if an individual is prescribed a covered medication, the medication must be considered an EHB and subject to the cost-sharing limits.

C. Employer-sponsored plans can define an EHB so long as the definition complies with pre-established definitions and guidance, statutes, and regulations.

Hub Centers, such as SaveonSP, are using an impermissible definition of "EHB" that is inconsistent with U.S. Department of Health and Human Services ("HHS") guidance.

In 2011, HHS issued guidance defining EHBs.[38] This guidance provided that under the ACA, large group health plans and self-insured health plans are not required to offer EHBs.[39] However, as stated above, if they do choose to offer an EHB, ACA limits on cost-sharing apply to them.[40] HHS also stated that such plans could impose certain limits on benefits "that do not fall within the definition of EHB."[41] However, the guidance stated that large group health plans and self-insured plans may only modify the definition of EHB in a manner "that is ***authorized by the Secretary of HHS***."[42] Furthermore, the guidance said that the Departments of Labor, Treasury, and HHS "intend to use their enforcement discretion and work with those plans that ***make a good faith effort*** to apply an authorized definition of EHB."[43]

In 2014, HHS amended the definition of EHB, authorizing a narrow carve-out for EHB coverage requirements in self-insured and large group plans.[44] The carve-out permitted plans to exclude the cost of name brand prescriptions towards the out-of-pocket maximum when a medically appropriate generic version is available.[45] The guidance did not define any other carve-outs, nor did it leave room for inferences regarding additional exceptions that could be derived from this narrow exclusion. Therefore, HHS has only authorized one deviation to the standard definition of EHB (i.e., excluding brand drugs if a generic exists). However, SaveonSp's definition of EHB is based on the number of drugs offered in a state's benchmark health plan. HHS has not released any guidance permitting this interpretation.

SaveonSP and similar Hub Centers also do not appear to be acting in good faith. SaveonSP's argument that a "specialty medication" is not an EHB is not remotely reasonable given that "prescription drugs" is a category of EHBs and all medications within SaveonSP's drug list require a prescription. Additionally, SaveonSP's policies are blatantly inconsistent with HHS's intent as established in the NBPP 2016 and NBPP 2020.[46] Additionally, as noted, HHS has never

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[37] 42 C.F.R. 156.122
[38] https://www.cms.gov/cciio/resources/files/downloads/essential_health_benefits_bulletin.pdf at p. 3.
[39] https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf at p. 4.
[40] https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf (stating that self-insured and large group plans "are permitted to impose non-dollar limits, consistent with other guidance, on EHB as long as they ***comply with other applicable statutory provisions.***")
[41] https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf
[42] https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf
[43] https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf
[44] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19#ftn8
[45] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19#ftn8
[46] https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf; https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf

released any guidance permitting such an interpretation of an EHB. Instead, SaveonSP appears to be attempting to exploit a perceived loophole by excluding medications from annual cost-sharing requirements so that plan enrollees will feel pressured to sign up for a copay maximizer program. This is bad faith.

III. The SaveonSP scheme is harmful to patients

SaveonSP's scheme is harmful to patients. This program places patients in an unfair predicament in which they must choose between paying a higher out-of-pocket cost for their medication or entering into a copay maximizer program in which the value of their copay assistance is conveyed to the health plan without counting toward the patient's deductible. Although copay maximizer programs may initially be appealing to patients as they will have no up-front cost for prescriptions, these programs hurt patients in the long run, as patients are still required to meet their annual deductible but without the cost of the prescription medication contributing to that annual amount.

Copay maximizers can also perpetuate health disparities among minority populations. In 2021, a National Hemophilia Foundation survey found that 65 percent of respondents would face difficulties in accessing their treatments if copay assistance programs are not directly contributed to their out-of-pocket expenses.[47] This study also found that one-third of individuals who were unable to afford their treatments when the copay assistance ran out were people of color.[48] Maximizer programs like SaveonSP's will only contribute to the perpetuation of healthcare disparities as patients might be able to afford some of their medications but be unable to afford other medications or necessary supplemental care due to remaining high deductibles.[49]

IV. Conclusion

For the reasons provided above, Aimed Alliance and CHLP request that CCIIO confirm our interpretation that Hub Centers, such as SaveonSP violate the ACA and its implementing regulations, and take enforcement action against these companies and/or provide an FAQ confirming our interpretation. We request a virtual meeting to discuss this matter further with you.

Sincerely,

Stacey Worthy
Counsel, Aimed Alliance

Phil Waters
Staff Attorney, The Center for Health Law and Policy Innovation of Harvard Law School

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[47] https://www.hemophilia.org/news/covid-19-exacerbates-treatment-affordability-challenges-health-inequities
[48] https://www.hemophilia.org/news/covid-19-exacerbates-treatment-affordability-challenges-health-inequities
[49] https://www.hemophilia.org/news/covid-19-exacerbates-treatment-affordability-challenges-health-inequities. *See also* https://www.mmm-online.com/wp-content/uploads/sites/2/2018/09/AccumulatorAdjustmentProgramsThroughPatientsEyes.pdf

Exhibit B

AIMEDALLIANCE

ALTERNATIVE FUNDING PROGRAMS:
The Cost Saving Measure that Could Cost You

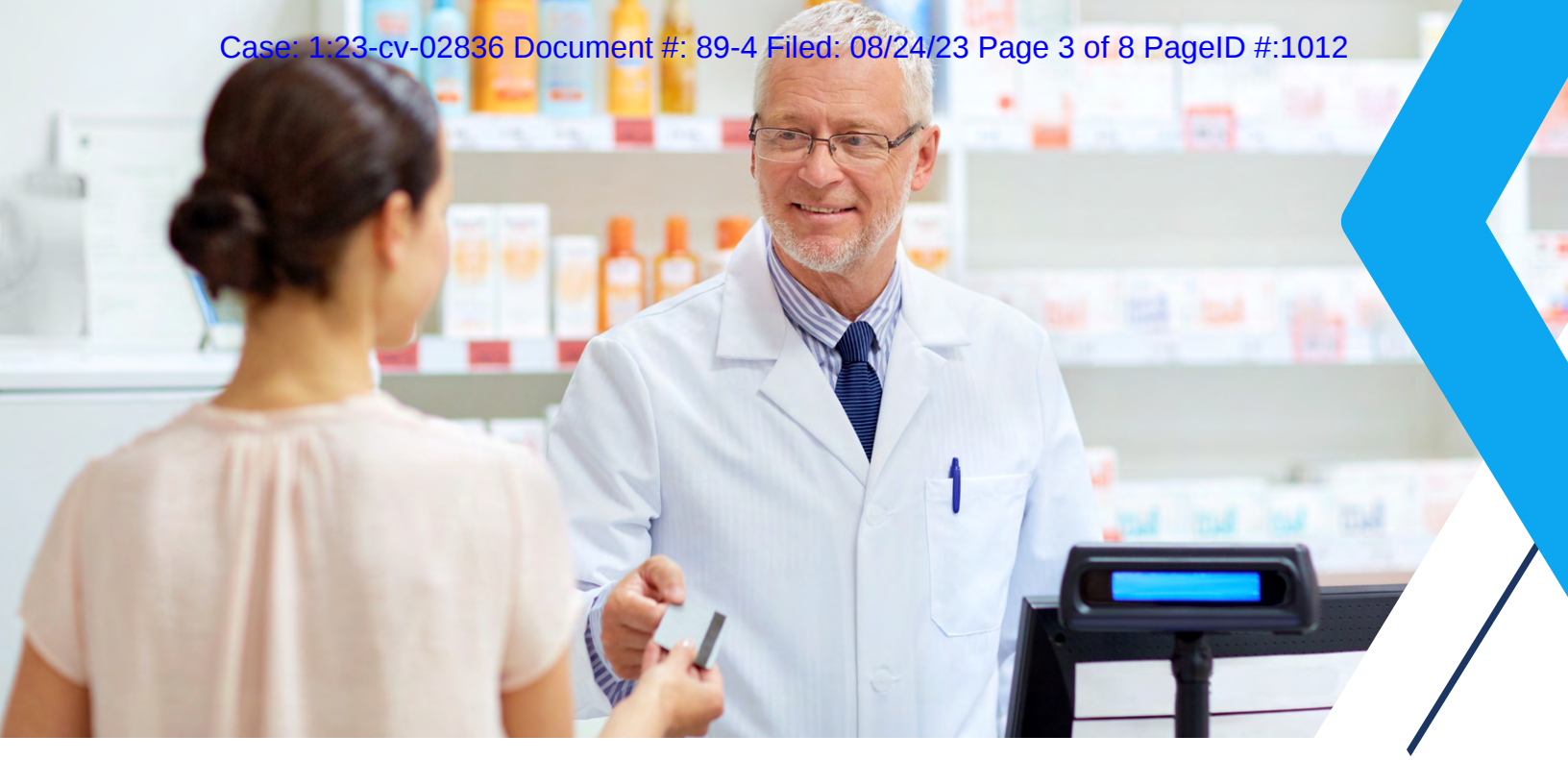
Typically, most prescription drugs require some form of cost-sharing from individuals with commercial insurance. For many individuals, cost-sharing obligations can be difficult to afford, especially for those who are prescribed more than one medication. A 2022 survey found that 6 in 10 respondents reported taking at least one prescription drug, and 25 percent reported taking four or more prescription drugs.[1] The same survey found that 20 percent of respondents taking one to three medications could not afford their health plans' cost-sharing requirements. This number increased to 32 percent for those who take four or more prescription drugs.[2] Some individuals who are unable to afford their medications may be forced to switch, ration, or abandon their treatments. Stopping treatments when not directed to do so by a health care professional can increase the risk of disease progression and hospitalizations.[3]

Consumers who cannot afford their cost-sharing obligations may be eligible for third-party financial assistance. Third-party assistance can come in many forms, including manufacturer copay assistance programs, charitable assistance programs, and financial assistance from friends and family.

Manufacturer copay assistance programs are for individuals with commercial insurance. A manufacturer copay assistance program can pay for some or all of an individual's cost-sharing for their medication. For example, if a health plan enrollee with a $100 copay participates in a manufacturer copay assistance program, the program could contribute $50 and the enrollee could pay the remaining $50.[4]

Charitable assistance programs can be used when an eligible individual is either underinsured or uninsured.[5] Eligibility requirements vary and can include diagnosis criteria, household income, family size, and medical expenses.[6] Some charitable assistance programs provide a medication directly to the consumer while others may provide some form of direct financial assistance.

Individuals enrolled in Medicare and Medicaid are not eligible for manufacturer copay assistance program because use of these programs violates the federal Anti-Kickback Statute.[7]



HEALTH PLANS WANT TO EXPLOIT FINANCIAL ASSISTANCE PROGRAMS

Typically, assistance from manufacturer and charitable programs will count towards the participating individual's cost-sharing obligations at the pharmacy counter, as well as their deductible and annual limit on cost-sharing. However, some health plans have adopted copay accumulator policies that accept third-party assistance on behalf of the consumer but do not count it toward the individual's annual limit on cost-sharing. As health plans have recognized that copay accumulator policies allow them to "double dip" by collecting revenue from both the assistance program and the consumer, more health plans have implemented these policies.

To further exploit this financial assistance, health plans have contracted with third-party specialty medication programs to help enroll health plan enrollees in financial assistance programs, irrespective of each enrollee's financial needs. One type of third-party specialty medication program is known as an alternative funding program.

WHAT IS AN ALTERNATIVE FUNDING PROGRAM?

When a health plan partners with an alternative funding program, the health plan defines all specialty medications as a non-essential health benefits (non-EHB).[8] By defining specialty medications as a non-EHB, health plans inform enrollees that they must either enroll with the alternative funding program or be responsible for 100 percent of the cost of the medication.[9] Because this medication is defined as a non-EHB, any cost paid for the medication by or on behalf of the enrollee will not count towards their deductible or annual limit on cost-sharing.[10] Given this coercive program design, plan enrollees are essentially required to enroll with the alternative funding program.

Once enrolled with the alternative funding program, the health plan automatically denies coverage for the enrollee's prescription medication.[11] The alternative funding program then steps in and obtains the enrollee's personal information such as household size and annual income to determine the type of third-party financial assistance the plan enrollee may be eligible for. Unlike typical non-EHB programs, which primarily enroll plan enrollees in manufacturer copay assistance programs, alternative funding programs determine whether enrollees are eligible for **manufacturer copay assistance programs, charitable assistance programs, and international importation programs.**[12]

If an individual is eligible for a manufacturer copay assistance program, the health plan will inflate the cost of the prescription drug to the maximum amount of manufacturer copay assistance available for the year. If the enrollee is eligible for a different program such as international importation, then enrollee will receive their medication through that source. However, if the enrollee is not eligible for any part of the alternative funding program, then the prescription will be sent back to the health plan for coverage and the medication will be covered like a regular pharmacy benefit.[13]

These programs are structured very similarly to non-EHB programs, which are sometimes referred to as "maximizer" programs. To learn more about these programs and how they define specialty medications as a non-EHB, read Aimed Alliance's non-EHB fact sheet.

CONSEQUENCES OF ALTERNATIVE FUNDING PROGRAMS

To ensure that individuals do not switch, ration, or abandon their medications due to cost alone, consumers have access to financial assistance programs. The financial value of this assistance is intended to benefit consumers not only by reducing costs at the pharmacy counter, but also by counting toward their annual limits on cost-sharing. However, when enrolled in an alternative funding program, the health plan accepts financial assistance on behalf of the enrollee but does not count the assistance toward meeting the enrollee's annual limit on cost-sharing. As a result, consumers are required to unnecessarily pay thousands of dollars more to meet their annual cost-sharing requirements. Further, copay assistance is not unlimited; it is subject to an annual cap. Once all available copay assistance is exhausted, it becomes increasingly difficult for enrollees to pay their copays, satisfy their deductibles, and reach their annual limits on cost-sharing. If a consumer is required to switch health plans mid-year but has exhausted all available copay assistance while enrolled under their previous plan, they will not be able to rely on copay assistance under the new plan the remainder of the year.

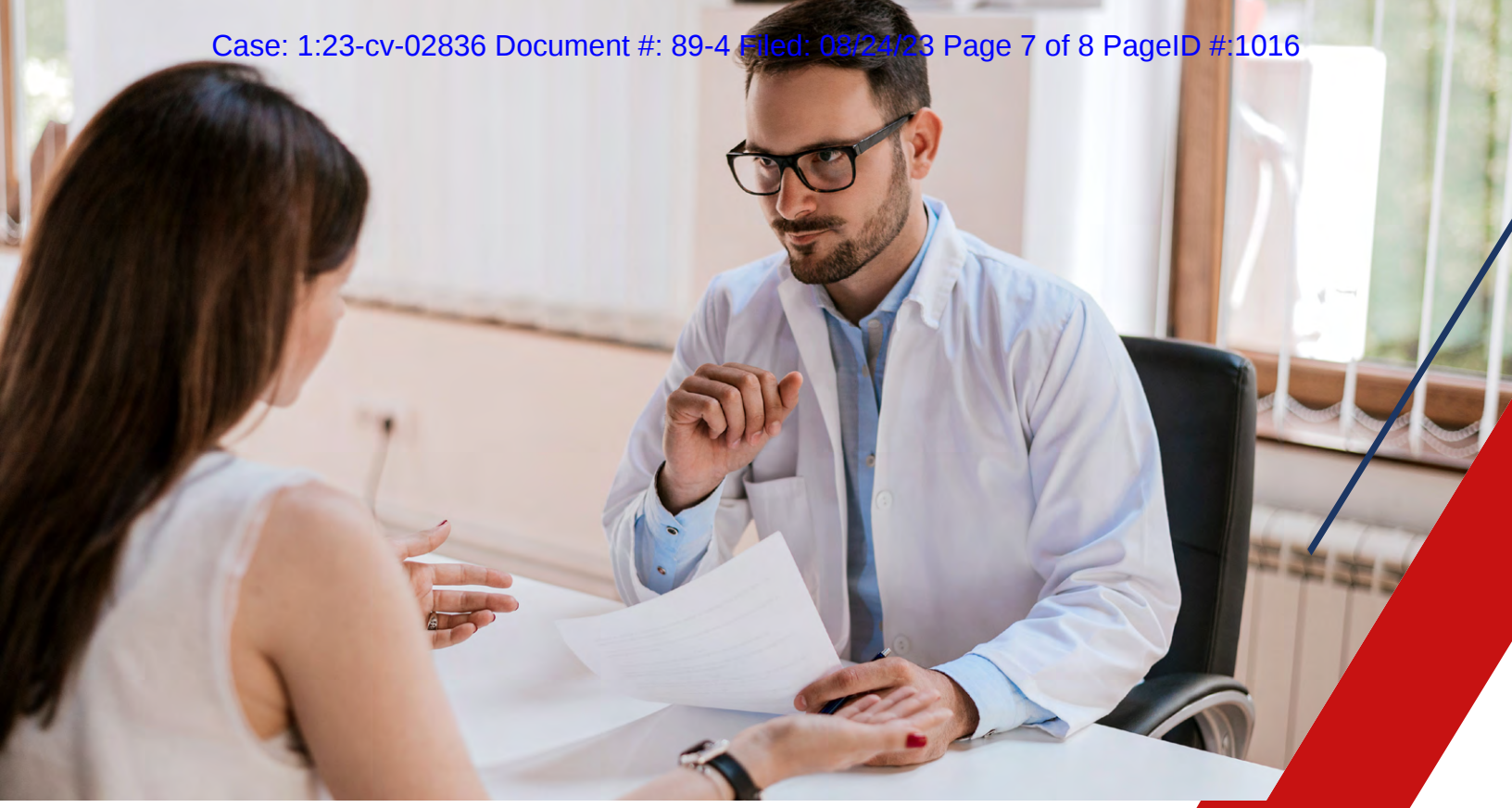
Moreover, when alternative funding programs force consumers who are able to afford their cost-sharing obligations to enroll in financial assistance programs, they jeopardize the availability of funds to support consumers who are actually *in financial need*. For example, charitable assistance programs are intended for individuals who are uninsured or underinsured, not for individuals who have adequate health insurance and are able to cover the cost of their medication but prefer not to do so. By exploiting such programs, alternative funding programs jeopardize the sustainability of important safety net programs intended for financially in-need consumers. As a result, charitable assistance programs could significantly decrease the number of consumers they can help. For some consumers, this may mean being forced to forego treatment due to unaffordability.

Lastly, alternative funding programs can mandate consumers import their medications from outside the United States. This could be problematic given that federal law prohibits the importation of drugs that have not been approved by the U.S. Food and Drug Administration (FDA), including "foreign versions" of FDA approved drugs.[14] Congress implemented this prohibition to help ensure that the domestic drug supply is safe and effective for consumers.[15] Regardless of whether a new drug is manufactured in the United States or in a foreign country, the drug must comply with federal law prior to being marketed in the United States. For example, it must be approved by the FDA, produced in FDA-inspected plants operating in accordance with current good manufacturing practices, and labeled with all required information.[16] As such, any entity that imports prescription drugs for human use into the United States must ensure that the drug satisfies these requirements.[17]

While importing unapproved prescription drugs is illegal, FDA's policy on importing prescription drugs for personal use recognizes that there may be circumstances in which the FDA may exercise enforcement discretion with respect to illegal importation.[18] The personal use policy, set forth in FDA's Regulatory Procedures Manual and endorsed under the FDCA, provides that *an individual* may be permitted to import an unapproved prescription drug for personal use if:

- The product is not used to treat a serious condition, such as the use of an over-the-counter treatment (OTC); or the product is used to treat a serious condition; and
- The product is needed to treat the serious condition and the medication is not available in the United States;
- There is no commercialization or promotion of the drug to U.S. residents;
- The drug does not represent an unreasonable risk;
- The individual importing the drug affirms in writing that the product is for personal use;
- The quantity is not more than a 3-month supply; and either: (1) the consumer provides contact information for the U.S. doctor providing treatment with the drug; or (2) the consumer provides evidence that the product is for continuation of a treatment begun in a foreign country.

However, the types of personal importation that the FDA anticipated when it developed this policy is far from what occurs with alternative funding programs. The FDA intended this policy to apply to importation by individuals, not large health plans attempting to lower their prescription drug costs. Thus, importation of prescription drugs by alternative funding programs likely falls outside of what FDA considers permissible conduct. If this practice is illegal, it raises questions about consumers' potential legal risks with respect to enrolling and participating in these programs.



WHAT CAN BE DONE TO HELP PROTECT PATIENTS?

Contact your elected officials and tell them to take action to protect consumers from alternative funding programs. State and federal legislatures need to be aware of these programs. Your story can play an important role in educating policymakers and lawmakers about why they must take action to prevent implementation of these programs. If you would like to share how you have been impacted by an alternative funding program, please email Aimed Alliance at policy@aimedalliance.org.

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14. The federal Food, Drug, and Cosmetic Act (FDCA) prohibits importing non-FDA approved drugs, including "foreign versions" of Food and Drug Administration (FDA) approved drugs. HHS, HHS Task Force on Drug Importation, http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf; FDA, CDER Small Business and Industry Assistance: Import and Export of Human Drugs and Biologics, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/cder-small-business-and-industry-assistance-import-and-export-human-drugs-and-biologics; FDA, Personal Importation, https://www.fda.gov/industry/import-basics/personal-importation#whatis .
15. HHS, HHS Task Force on Drug Importation, http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf; FDA, CDER Small Business and Industry Assistance: Import and Export of Human Drugs and Biologics, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/cder-small-business-and-industry-assistance-import-and-export-human-drugs-and-biologics; FDA, Personal Importation, https://www.fda.gov/industry/import-basics/personal-importation#whatis .
16. HHS, HHS Task Force on Drug Importation, http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf;
17. Id.
18. Id.

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Exhibit C

AIMED ALLIANCE

June 14, 2023

Lina Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
antitrust@ftc.gov

Re: Non-EHB, Alternative Funding Programs, and Unfair Trade Practices

Dear Chairwoman Khan:

Aimed Alliance is a 501(c)(3) not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to bring to your attention an unfair trade practice that is harming consumers with chronic health conditions. In particular, we are writing to discuss how third party companies are **partnering with health plans to implement non-essential health benefit (non-EHB) and alternative funding schemes. These profit-maximization schemes unfairly force patients who are prescribed specialty medications to enroll in programs that improperly take advantage of financial assistance available to such patients.**

Given the authority of the Federal Trade Commission (FTC) to protect consumers from unfair trade practices, we are requesting a meeting with your office to discuss the FTC's role in protecting consumers from non-EHB and alternative funding schemes.

I. Background

When patients cannot afford their prescriptions medications, eligible patients may rely on financial assistance from non-profit organizations, drug manufacturers, and other sources (referred to collectively as financial assistance) to help meet their health plan's cost-sharing requirements (e.g., copayments). This is especially true of vulnerable patients with serious, rare, complex, or chronic conditions who are prescribed specialty drugs for which there are no generic alternatives. Typically, this financial assistance should be applied to the patient's deductible and annual out-of-pocket limits. However, in recent years, health plans and pharmacy benefit managers (PBMs) have increasingly implemented what are known as "copay accumulator programs."[1] Under copay accumulator programs, the health plan or PBM accepts financial assistance intended for the consumer's benefit; yet, those dollars are not counted toward the consumer's deductible or annual

[1] Spondylitis Association of America, *Copay Accumulators Programs: What They Are And How They Might Impact Your Out-Of-Pocket Costs*, https://spondylitis.org/spondylitis-plus/copay-accumulator-programs-what-they-are-and-how-they-might-impact-your-out-of-pocket-costs/ .

out-of-pocket limit.[2] In other words, copay accumulator programs are used to capitalize on financial assistance for the benefit of the plan and to the detriment of the patient.

Recently, health plans have expanded this practice to further exploit financial assistance by contracting with third-party vendors to manage their specialty medication benefits through non-EHB[3] and alternative funding schemes.[4] Our understanding is that these vendors' fees are based on either a percentage of the cost savings achieved, or the amount of financial assistance secured.[5] PBMs actively market these partnerships to health plans as a solution for lowering plan costs.[6] However, these schemes are unfairly structured to exploit financial assistance and force patients who are prescribed specialty medications to enroll in these schemes. Although these programs are often pitched by PBMs, to our knowledge these third-party companies are independent companies and not legal subsidiaries of any PBM or health plan.

A. Non-EHB Schemes

An essential health benefit (EHB) is an important designation under the Patient Protection and Affordable Care Act (ACA). Under the ACA, health plans must cover ten types of EHBs, one of which is prescription drugs.[7] Federal law requires that all cost-sharing paid by or on behalf of the patient for in-network EHBs must be counted towards meeting the patient's deductible and annual out-of-pocket limit.[8] However, under non-EHB schemes, specialty drugs are inappropriately deemed as non-EHBs—even for individuals with serious, rare, complex, or chronic conditions whose medically necessary treatments truly are essential. As such, these schemes allow the third-party program to capitalize on the maximum amount of financial assistance available without applying the assistance toward the patient's deductible or annual out-of-pocket limits.[9]

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[2] SaveonSP, *Employers FAQ*, https://saveonsp.com/employers/; PrudentRx, The PrudentRx Copay Program Frequently Asked Questions, at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf.

[3] Examples include SaveonSP, PrudentRx, and PillarRx.

[4] Examples include PayorMatrix, SharkRx.

[5] MMIT, *Industry Experts Question Alternative Funding Companies that Carve Out Some Specialty Drugs, 'Abuse' Charities*, https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding-companies-that-carve-out-some-specialty-drugs-abuse-charities/.

[6] ExpressScripts, SaveonSP, https://www.express-scripts.com/corporate/solutions/lowering-costs#saveonsp; See also, Human Resources County of San Luis Obispo, *Save on Specialty Medications with Express Scripts SaveOnSP*, https://www.slocounty.ca.gov/Departments/Human-Resources/Department-News/Save-on-Specialty-Medications-with-Express-Scripts.aspx; While these outside companies are marketed as unrelated partners to PBMs, these schemes have been pitched to plans by a PBM and not by representatives of the third-party companies See e.g. *IPBC and SaveonSP Training – 20210216*, https://vimeo.com/513414094 (SaveonSP is pitched to health plans by an ExpressScripts representative); see also New Mexico Retiree Health Care Authority, *Annual Meeting of the Board of Directors*, https://www.nmrhca.org/wp-content/uploads/2021/07/2021-7-15-Board- Book.pdf.

[7] See generally, CMS, Information on Essential Health Benefits (EHB) Benchmark Plans, https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.

[8] 42 U.S.C. § 18022 – Essential health benefits requirements.

[9] *See generally*, CMS, Information on Essential Health Benefits (EHB) Benchmark Plans, https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.; SaveonSP, https://saveonsp.com/.

When a health plan partners with a non-EHB program, the health plan or non-EHB vendor first notifies consumers about the program's coercive details when the consumer is attempting to fill certain specialty medication prescriptions. Consumers are told that they will receive their specialty medication for $0 or at a low-cost if they enroll in the program.[10] While consumers may be presented with the "choice" to enroll in the specialty medication program, these non-EHB schemes are coercively structured to ensure enrollment. Specifically, these programs tell patients that if they do not wish to enroll in the program then they will be responsible for a coinsurance payment—which can run between 30 to 70 percent—and this payment will not count towards their deductible or annual out-of-pocket limit.[11] As a result, patients are left with no other choice than to enroll in these third-party programs to avoid unmanageable coinsurance payments.

The program's low or $0 copay is created by determining the maximum amount of financial assistance available annually for a specialty medication and then dividing that amount by 12 to determine the amount of monthly assistance available.[12] Once the amount of available monthly assistance is determined, health plans are advised to set the monthly copay to at least the monthly amount of financial assistance available.[13] After this calculation is made, the non-EHB program contacts the consumer to obtain the consumer's personal information for the purpose of applying for a manufacturer copay assistance program. For consumers already enrolled in a manufacturer copay assistance program, the consumer is automatically integrated into the non-EHB program, often without prior notification.[14]

B. Alternative Funding Schemes

Third-party vendors have taken non-EHB schemes one step further by implementing what are known as alternative funding programs. These schemes operate almost identically to non-EHB schemes—health plans and PBMs partner with third-party companies to manage specialty medication benefits while imposing the same coercive enrollment structure and excluding financial assistance from counting towards the patient's deductible and annual out-of-pocket limit.[15] However, alternative funding schemes are distinguishable from non-EHB programs because alternative funding schemes target a broader range of financial assistance. While non-EHB schemes primarily target manufacturer copay assistance programs, alternative funding schemes typically also target assistance from foundations, non-profits, or other charitable sources. Additionally, some even source medications from outside the United States, which is illegal under

[10] *IPBC and SaveonSP Training* – 20210216, https://vimeo.com/513414094.
[11] *Id.*; PrudentRx, PrudentRx *Copay Program Frequently Asked Question*, https://www.pcsb.org/cms/lib/FL01903687/Centricity/Domain/200/Member%20FAQ-%20The%20PrudentRx%20Copay%20Program.pdf.
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] CareFactor, *PaydHealth Program*, (see attached PDF).

federal law except under very limited circumstances.[16]

Typically, financial assistance programs from charities and foundations have income-eligibility requirements that many patients do not qualify for; yet the vendor nevertheless applies for such assistance on the patients' behalf even if the application will ultimately be denied. Under alternative funding schemes, some program materials state "if a member does not qualify for a program then the medication will go back through the [PBM] and be processed under the plan[']s prescription benefit."[17] This back and forth can be confusing for consumers and cause delays between when a consumer is denied financial assistance and when the needed medication is processed back through the plan.[18] For consumers with complex and chronic conditions, delays in accessing medically necessary treatments can result in patients continuing to experience symptoms without relief; further deterioration of their health; and other long-term health consequences.

II. The FTC Has Authority To Regulate Unfair Trade Practices By Third-Party Companies Engaging in Non-EHB and Alternative Funding Programs

The FTC has authority to investigate, gather information on, and prosecute business conduct that affects commerce.[19] Moreover, the FTC only needs a "reason to believe" that a violation of the FTC Act has occurred to issue a complaint setting forth the alleged violation.[20] It is a violation of the FTC Act to engage in an "unfair or deceptive practices in or affecting commerce."[21] The FTC's scope of authority is broad and has limited exceptions to when conduct is outside its jurisdiction.

The FTC has explained that its authority can be limited based on the (1) businesses' status or (2) activity in question.[22] First, the FTC is prohibited from regulating certain entities such as banks, credit unions, and some non-profit organizations.[23] This exemption is *solely* based on the status of these organizations.[24] Alternative funding programs are not an exempt entity based on status.[25] Although some alternative funding programs identify themselves as "patient advocacy"

[16] *Id.*; FDA, *ElextRx and Health Solutions, LLC*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023.
[17] CareFactor, *PaydHealth Program*, (see attached PDF).
[18] *Id.*
[19] FTC, *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, https://www.ftc.gov/about-ftc/mission/enforcement-authority .
[20] *Id.*
[21] FTC Act Section 5(a).
[22] FTC, *Opinion 03-1*, (Aug. 19, 2003), https://www.ftc.gov/legal-library/browse/advisory-opinions/opinion-03-1-1
[23] *Id.*
[24] *Id.*
[25] 15 U.S.C.§ 45 (a)(2).

companies,[26] a term typically associated with non-profits that support patients and caregivers,[27] these programs are for-profit companies.

Second, certain activities are exempt from the FTC's authority. Specifically, the McCarran-Ferguson Act exempts activities that constitute "the business of insurance" but only to the extent that such activities are regulated by state law.[28] This limitation is narrow and does not prohibit the FTC from exercising its authority over certain practices engaged in by insurance companies, but rather the limited conduct identified as the "business of insurance."[29] Moreover, in 2020 Congress passed the *Competitive Health Insurance Reform Act*, which removes the "business of insurance" exemption from federal anti-trust laws.[30] While the *Competitive Health Insurance Reform Act,* does still permit certain conduct to be exempt from the FTC's jurisdiction, the McCarran-Ferguson Act should not impair the FTC's ability to regulate these companies. Moreover, even if the McCarran-Ferguson Act applied, the conduct of non-EHB and alternative programs does not constitute the "business of insurance."

A. Non-EHB and Alternative Funding Schemes Do Not Constitute the Business of Insurance

In *Union Labor Life Insurance Co. v. Pireno*, the Supreme Court explained that, under the McCarran-Ferguson Act, a three-part factual inquiry is necessary to evaluate whether a particular activity constitutes the business of insurance.[31] Specifically, the alleged conduct must be assessed to determine if the activity (1) has the effect of transferring or spreading a policyholder's risk; (2) is an integral part of the policy relationship between the insurer and the insured; and (3) is a practice limited to entities within the insurance industry.[32] This inquiry requires a factual analysis of the activities in question, and no single element of the inquiry is determinative.[33]

1. Non-EHB and alternative funding schemes do not spread a policyholder's risk

In making its ruling in *Pireno*, the Supreme Court relied on *Group Life & Health Ins. Co. v. Royal Drug Co.*, 440 U. S. 205 (1979). In *Royal*, the petitioner was an insurance company that offered policies entitling insured persons to purchase prescription drugs for $2 each from any

[26] PR Newswire, *Leading Patient Advocate Slams AbbVie's Moves to Deny Vital Drugs to Needy Patients,* (May 23, 2023), https://www.prnewswire.com/news-releases/leading-patient-advocate-slams-abbvies-moves-to-deny-vital-drugs-to-needy-patients-301831464.html .
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[29] *Id.*; Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119 (1982).
[30] Public Law No: 116-327, https://www.congress.gov/bill/116th-congress/house-bill/1418/text.
[31] *See* Union Labor Life Insurance Co. v. Pireno, 458 U.S. 119, 129 (1982).
[32] *Id.*
[33] *Id.*

pharmacy participating in a pharmacy agreement with the insurer.[34] Policyholders were also allowed to purchase prescription drugs from a nonparticipating pharmacy, but in the event they did they would have to pay full price for the drugs, and would be reimbursed by the insurer for only a part of that price.[35] Nonparticipating pharmacies filed an antitrust action alleging that the insurer and three participating pharmacies conspired to fix prescription drug prices and encourage policyholders to boycott nonparticipating pharmacies.[36] The trial court granted the insurer and participating pharmacies' motion for summary judgment on the ground that the agreements were exempt from the antitrust laws under the McCarran-Ferguson Act because the agreements were the "business of insurance," regulated by Texas. The Court of Appeals reversed. The Supreme Court ultimately held that the alleged conduct did not constitute the business of insurance.

In holding that the pharmacy agreements did not constitute the business of insurance, the Court reasoned that a core element of insurance is the underwriting or spreading of risk between the insurer and the policyholder.[37] However, the pharmacy agreements did not serve that purpose because they were merely arrangements for the purchase of goods and services by the insurer to enable the insurer to minimize its costs and maximize its profits.[38] The Court intended to make it clear that simply contracting with a health plan to help the health plan *as a business* would not qualify the contracting company to be engaging in the "business of insurance".

Similarly, non-EHB and alternative funding schemes are not mechanisms for underwriting or spreading risk. As explained in a Congressional Research Service Report,

> A function of insurance is to spread risk across a group of people. This is achieved in health insurance when people contribute to a common pool (risk pool) an amount at least equal to the expected cost resulting from use of covered services by the group as a whole. In this way, the actual costs of health services used by a few people are spread over the entire group. This is the reason why insuring larger groups is considered less risky—the more individuals participating in a risk pool, the less likely that the serious medical experiences of one or a few persons will result in catastrophic financial loss for the entire pool.[39]

Insurers understand that individuals prescribed specialty medications often have chronic, rare, or serious conditions, and therefore expect such patients to be more likely to utilize covered services compared to certain other groups in the risk pool (e.g., individuals without such

[34] 440 U.S. 205
[35] 440 U.S. 205.
[36] 440 U. S. 209.
[37] 440 U.S. 214 (citing *SEC v. Variable Annuity Life Ins. Co.,* 359 U.S. 65 (1959) (holding that when a company bears no risk it cannot be considered the business of insurance)).
[38] 440 U. S. 214.
[39] https://crsreports.congress.gov/product/pdf/RL/RL32237

conditions). Insurers spread this known risk across the risk pool when it calculates premiums to be charged to those enrolled in its health plans.

As such, non-EHB and alternative funding schemes are not used to spread risk; rather, their sole purpose is to contain insurers' costs, maximize insurers' profits, and drive the vendors' revenues. These programs utilize financial assistance available to enrollees to subsidize and reduce the financial burden of coverage among enrollees who tend to be higher utilizers of covered items and services. As noted by the Court in *Royal*, " . . . cost-savings arrangements may well be sound business practice, and may well inure ultimately to the benefit of policyholders in the form of lower premiums, but *they are not the business of insurance*."[40] (emphasis added).

Additionally, the vendors in these non-EHB and alternative funding schemes do not share any risk with the health insurers they partner with. These programs "procure high cost" specialty treatments through avenues such as manufacturer copay assistance programs; charitable assistance programs; or international importation.[41] When alternative funding programs source the medication from a third-party, any cost-sharing required is paid by the consumer and the health plan, not the alternative funding program. Moreover, if a medication is unable to be sourced from an alternative funding method, the medication is covered under the plan's regular pharmacy benefit. Thus, regardless of whether the alternative funding program procures the medication, the vendor maintains no risk because the plan not the alternative funding source will always pay the cost.

In sum, non-EHB and alternative funding programs do not serve the core purpose of insurance—spreading risk. Rather, like the pharmacy agreements in *Royal*, their primary purpose is to reduce plan costs and maximize profits by sourcing certain specialty medications from manufacturer copay assistance programs; charitable assistance programs; or through international importation.

2. Non-EHB and alternative funding schemes are not an integral part of the policy relationship between the insurer and the insured

In *Pireno,* Union Labor Life Insurance Co. (ULL) entered an arrangement with New York State Chiropractic Association (NYSCA), a chiropractic trade group, whereby NYSCA's Peer Review Committee would help ULL evaluate whether claims were reasonable and necessary. A chiropractor sued ULL after ULL frequently referred to the Committee for review his treatments of ULL policyholders and his charges for such treatments. The Committee sometimes deemed such treatments unreasonable or charges unreasonable. The chiropractor alleged that ULL had used the Committee's review process as the vehicle for a conspiracy to fix the prices that chiropractors would be permitted to charge for their services. The district court dismissed his claim, concluding that the peer review practices were the business of insurance and thus exempt from antitrust

[40] Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119 (1982).
[41] ShaRX, *Sourcing Hope Through Advocacy,* https://www.sharxplan.com/about-sharx/ .

scrutiny. The court of appeals reversed.

The Supreme Court held that the peer review practices at issue were not the business of insurance. The Court rejected the argument that the peer review process directly involved the interpretation and enforcement of the insurance contract and therefore should satisfy part two of the three-part factual inquiry. Instead, the Court held that ULL's use of the Committee was not an integral part of the policy relationship between insurer and insured.

The Court compared the Committee arrangement to the pharmacy agreements at issue in *Royal*. In that case, the pharmacy agreements were "between [the insurer] and pharmacies engaged in the sale and distribution of goods and services other than insurance." Similarly, ULL's use of the Committee was "a separate arrangement between the insurer and third parties not engaged in the business of insurance." Furthermore, the Court stated:

> As in *Royal Drug*, petitioners have shown, at the most, that the challenged peer review practices result in 'cost savings to [ULL] which may be reflected in lower premiums if the cost savings are passed on to policyholders.' To grant the practices a[n] exemption on such a showing 'would be plainly contrary to the statutory language, which exempts the business of insurance and not the business of insurance companies.'[42]

The third-party vendors contracted by insurers under non-EHB and alternative funding schemes are not insurance companies themselves. As explained above, our understanding is that they are independent companies and not legal subsidiaries of any PBM or health plan. As such, these companies are similar to the Committee in *Pireno*, in that they provide services pursuant to an agreement that is distinct from the contract between the insurer and policyholder; with such services being intended to result in cost savings for the insurer. At the same time, non-EHB and alternative funding schemes are even less intimately tied to the policy relationship between the insurer and insured compared to a review committee that has the final say on coverage of a treatment, se these vendors simply use consumers' information (e.g., prescription type, name, type of insurance coverage, income) to seek out alternative sources of funding for specialty medications, including by applying for third-party financial assistance on consumers' behalf. As such, these activities are purely administrative and can be more accurately described as the business of insurance companies than the business of insurance.

3. Non-EHB and alternative funding schemes are not limited to parties within the insurance industry

Like the pharmacies in *Royal* and the review committee made up on chiropractors in *Pireno*, the vendors that contract with health insurers and PBMs to implement these non-EHB and alternative funding schemes are not insurers themselves. Indeed, certain alternative funding

[42] Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119 (1982)

programs self-identify as a "non-insurance solution . . . to help procure . . . drugs . . . through multiple avenues."[43] Therefore, non-EHB and alternative funding schemes involving these independent third-party service providers are not limited to parties within the insurance industry.

However, even if these vendors can be considered parties within the insurance industry, this factor alone is not dispositive. As explained by the Supreme Court, no singular part of the three-part inquiry is determinative with respect to whether a practice is the business of insurance. Therefore, even if non-EHB and alternative funding schemes are deemed as involving only parties within the insurance industry, the other two factors analyzed above overwhelmingly support the conclusion that these schemes are not the business of insurance.

B. Alternative funding programs are not regulated by state law

There is no applicable state law that would prevent the FTC from acting on alternative funding programs' unfair business practices. While several states have passed insurance laws prohibiting copay accumulators, these laws do not apply to the practices at issue here.[44] State laws that prohibit copay accumulator programs simply require health insurers that collect pharmaceutical manufacturer and other third-party assistance on behalf of a consumer to count such assistance towards the consumer's deductible and annual out-of-pocket limit. These insurance laws do regulate how alternative funding programs market these schemes, contract with insurers and PBMs, or enroll consumers into copay assistance programs or other financial assistance programs.

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III. Non-EHB and Alternative Funding Schemes Are Unfair Practices under the FTC Act

Under Section 5(a) of the FTC Act, the FTC has authority to prevent corporations from using "unfair or deceptive acts or practices in or affecting commerce."[45] For the FTC to have jurisdiction over the conduct at issue, the business practice must be either deceptive or unfair; it is not required to be both deceptive and unfair.[46] The FTC has authority to regulate unfair practices when the Commission has "reason to believe" a violation has occurred.[47] A practice is unfair where the practice (1) causes or is likely to cause substantial injury to consumers; (2) cannot be reasonably avoided by consumers; and (3) is not outweighed by countervailing benefits to consumers or competition.[48]

Based on our analysis, non-EHB and alternative funding schemes are unfair as defined by

[43] ShaRX, *About Us,* https://www.sharxplan.com/about-sharx/.
[44] Aimed Alliance, *Copay Accumulators,* https://aimedalliance.org/copay-accumulators-enacted-laws/ .
[45] FTC, A Brief Overview of the Federal Trade Commission Investigative, Law Enforcement, and Rulemaking Authority, https://www.ftc.gov/about-ftc/mission/enforcement-authority .
[46] *Id.*
[47] *Id.*
[48] FTC, Federal Trade Commission Act: Section 5: Unfair or Deceptive Acts or Practices, at p. 8, https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf

the FTC Act. Therefore, we urge the FTC to investigate these practices and take appropriate enforcement action to protect consumers.

A. Non-EHB and alternative funding schemes cause or are likely to cause substantial injury to consumers

A substantial injury occurs when a consumer experiences a genuine harm.[49] The FTC applies an objective test to determine if a genuine harm has occurred.[50] Emotional distress is usually insufficient, however, a financial injury will satisfy the genuine harm requirement.[51]

Non-EHB and alternative funding schemes cause consumers to experience financial losses. When a consumer is forced to enroll in the third-party company program under either a non-EHB or alternative funding scheme, any financial assistance the consumer receives will not count towards meeting their deductible or annual out-of-pocket limit.[52] As a result of the assistance not being counted towards the consumer's deductible or annual out-of- pocket limit, the individual is required to pay thousands of additional dollars before they reach their deductible and annual out-of-pocket limit. In other words, because the assistance is accepted for the plan's benefit and not counted towards the consumers deducible or annual out- of-pocket limit, consumers lose the full financial benefit of the financial assistance. As such, these schemes cause consumers to experience genuine financial harm.

B. Consumers cannot reasonably avoid enrolling in these programs

The FTC has found that a practice is not unfair if a consumer can reasonably avoid the injury.[53] However, a practice may be considered unfair if the consumer is coerced into purchasing unwanted products or services.[54]

As explained in Section I above, non-EHB and alternative funding schemes are structured to coerce consumers to enroll in the third-party company's program. These schemes present consumers with two bad options, either of which leads to financial injury over time. If consumers enroll in these programs, they receive their medications at a lower upfront cost; however, their financial assistance will be collected for the benefit of the plan and not count towards their deductible or annual out-of-pocket limit. As a result, they will have to pay significantly more out

[49] *Id.*
[50] FTC, The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection, https://www.ftc.gov/news-events/news/speeches/ftcs-use-unfairness-authority-its-rise-fall-resurrection.
[51] *Id.*
[52] SaveonSP, Employers FAQ, https://saveonsp.com/employers/; PrudentRx, The PrudentRx Copay Program Frequently Asked Questions, at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf; CareFactor, PaydHealth Program, https://www.wchcs.org/Downloads/Paydhealth%20general%20letter%20for%20EMPLOYEES.pdf.
[53] FTC, Federal Trade Commission Act: Section 5: Unfair or Deceptive Acts or Practices, at p. 8, https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf .
[54] *Id.*

of pocket before these amounts are satisfied. If they do not enroll, then they are required to pay between a 30 to 70 percent coinsurance and, on top of that, the coinsurance *still will not* count towards their deductible or annual out-of-pocket limit.[55] As a result, most consumers are forced to choose the lesser of two evils—enrollment. In short, there is no reasonable way for consumers who are prescribed a specialty medication that is managed by a third-party program to avoid financial injury.

C. Allowing non-EHB and alternative funding schemes to collect financial assistance and not count this assistance towards deductibles and annual out-of- pocket limits does not benefit consumers or competition

Lastly, for a practice to be unfair, its overall net effect on consumers must be negative, and any harm incurred by the consumer cannot be outweighed by an alternative benefit to consumers or competition.[56] Non-EHB and alternative funding schemes do not have an underlying benefit to consumers or competition that would outweigh the net harm experienced by consumers forced to enroll in these programs.

While plans, PBMs, and the partnering companies operating these schemes would likely argue that consumers receive a net benefit because they receive their medications for a low-cost or for $0, this argument ignores the fact that in the larger picture of the plan year, these programs cost patients thousands of additional dollars per year as they work to meet their deductible and annual out-of-pocket limit. For example, the AIDS Institute estimated that when an individual patient is subject to a copay accumulator program, the individual can pay over $7,000 a year in *additional* health care costs.[57] As a result, the short term benefit of paying less at the pharmacy counter for a specialty drug does not outweigh the additional financial pressures that consumers experience as a result of not having assistance counted toward their deductibles and annual out-of-pocket limits. As such, the long-term financial harm outweighs any short-term benefit under these programs, and the overall net impact of these programs is negative for consumers.

Moreover, these programs can also place consumers in a legally precarious position with pharmaceutical companies and federal agencies. For instance, Johnson & Johnson recently filed a lawsuit against SaveOnSP, a company that implements non-EHB programs. In its complaint, Johnson & Johnson alleges that the SaveOnSP program interferes with the contractual relationship

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[55] SaveonSP, Employers FAQ, https://saveonsp.com/employers/; PrudentRx, The PrudentRx Copay Program Frequently Asked Questions, at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf; CareFactor, PaydHealth Program, https://www.wchcs.org/Downloads/Paydhealth%20general%20letter%20for%20EMPLOYEES.pdf; PaydHealth, Select Drugs and Product Program Questions & Answers, https://mennonitevillage.org/wp-content/uploads/2021/03/Select-Drugs-and-Products-Program_HR-FAQ-2020-03.pdf.

[56] FTC, *The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection* (May 30, 2003), https://www.ftc.gov/news-events/news/speeches/ftcs-use-unfairness-authority-its-rise-fall-resurrection.

[57] AIDS Institute, *Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness*, at p. 9 (2023), https://aidsinstitute.net/documents/TAI-Report-Copay-Accumulator-Adjustment-Programs-2023.pdf.

between Johnson & Johnson and the consumers to whom it provides copay assistance. Specifically, Johnson & Johnson argues that its patient assistance program prohibits consumers from enrolling in any other assistance program, and that SaveOnSP forces consumers to violate this agreement by requiring consumers to enroll in the SaveOnSP program which it considers another assistance program.[58] While Johnson & Johnson has not yet sued any consumer who participates in its copay assistance programs for breach of contract, programs like SaveOnSP's open consumers up to this possibility. Additionally, in its recent lawsuit against Payer Matrix, AbbVie has alleged that Payer Matrix uses consumer information to fraudulently apply to AbbVie's copay assistance and charitable assistance program, despite their financial assistance programs explicitly prohibiting the use alternative funding programs.[59] By using consumers' information to apply to these programs, these alternative funding programs create a risk that charitable assistance programs could bring legal claims against consumers for participating in such schemes. Finally, alternative funding programs that import prescription drugs from outside of the United States could subject consumers to violations of federal law. Federal law prohibits the importation of prescription medications from outside the United States, with limited exceptions.[60] The FDA has stated these programs are not a permissible exception to the general prohibition on importation. As such, alternative funding programs create legal risk for consumers when they import prescription drugs on consumers' behalf.[61]

In summary, we strongly believe that non-EHB and alternative funding schemes satisfy the definition of an unfair practice under the FTC Act. Therefore, Aimed Alliance encourages the FTC to take appropriate enforcement action against these programs.

IV. Conclusion

In conclusion, we would greatly appreciate an opportunity to meet with your office and discuss these unfair trade practices that impair patient access to necessary treatments. Thank you for your time and consideration.

Sincerely,
Ashira Vantrees
Counsel

[58] Johnson & Johnson v. SaveOnSP, *Complaint*, https://www.drugchannelsinstitute.com/files/22-cv-02632.pdf.
[59] AbbVie v. Payor Matrix, *Complaint*, https://drugchannelsinstitute.com/files/Abbvie-vs-PayerMatrix-23-cv-02836.pdf.
[60] Aimed Alliance, *Letter to FDA Importation of Prescription Drugs from Outside the United States and Canada*, https://aimedalliance.org/wp-content/uploads/2023/03/Aimed-Alliance-Letter-to-FDA-February-2023.pdf.
[61] Food and Drug Administration, *Warning Letter: Elect Rx and Health Solutions LLC.*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023#:~:text=ElectRx%20contracts%20with%20public%20and,enrolled%20employees%20with%20prescription%20drugs.

Exhibit D

ALTERNATIVE FUNDING PROGRAMS

1 Plan enrollee has commercial health insurance

2 Commercial health insurance partners with a third-party specialty medication program

3 Commercial health insurance removes all or a majority of specialty medication from coverage

4 Health insurance requests third-party specialty medication program to manage all specialty medications

5 Plan enrollee receives a prescription for a specialty medication that is managed by the third-party specialty program

6 Plan enrollee is informed they must enroll in the third-party specialty medication program to receive their specialty drug

Enrolls in Program

Does Not Enroll in Program

The enrollee will be responsible for 100% coinsurance which will not count towards their annual limits on cost sharing

7 Third party specialty medication program obtains enrollee's personal information to determine if the plan enrollee can receive their specialty medication from:

1. a manufacturer copay assistance program
2. a charitable assistance program
3. an international pharmacy

If plan enrollee is eligible to receive their medication from one of the three sources they get their medication from those programs

Any third party contributions received do not count towards meeting the enrollee's annual limits on cost-sharing

If not the prescription is sent back to the plan and covered like a regular pharmacy benefit under the plan terms

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