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Memorandum

Date: October 25, 2024

To: Patient Advocate Foundation

From: Stephanie L. Trunk
Hillary M. Stemple

Re: **Analysis of Charitable Patient Assistance Program Compliance with OIG Guidance Related to Co-Pay Assistance Program Eligibility Criteria**

You asked us to evaluate the ability of charitable patient assistance programs ("CPAPs") providing co-payment assistance ("Co-Pay Program(s)") to use certain eligibility criteria such as considering an applicant's eligibility status with other forms of co-payment assistance, including assistance through a manufacturer co-payment program. More specifically, you asked us to analyze: (i) the compliance risks associated with CPAPs adopting "payer of last resort" and "no double dipping" eligibility criteria[1] (described in more detail below); and (ii) whether the HHS Office of the Inspector General ("OIG") would view these requirements as violating the OIG's guidance regarding the operation of Co-Pay Programs, including applicable CPAP Advisory Opinions.

In short, we believe that both criteria would be viewed unfavorably by the OIG as they potentially raise compliance concerns as neither is consistent with OIG guidance regarding the operation of Co-Pay Programs. Thus, CPAPs utilizing these additional eligibility criteria (as well as manufacturers donating to any CPAP that does) are at risk of scrutiny by the OIG and, potentially, the Department of Justice ("DOJ").

A more detailed analysis follows.

I. OVERVIEW OF REGULATORY LANDSCAPE

[1] While the CPAPs may not refer to the requirements as "eligibility criteria," the requirements described in further detail in this memo are *de facto* eligibility requirements.

As you know, CPAPs and the Co-Pay Programs they operate have long been considered high-risk and are an ongoing target of government scrutiny.[2] Improperly structured Co-Pay Programs implicate the Federal Anti-Kickback Statute ("AKS")[3] (and thus the False Claims Act[4]), as well as the Beneficiary Inducement Civil Monetary Penalties law ("CMPL").[5] The OIG has identified two elements of Co-Pay Programs that implicate these laws: (1) indirect remuneration to patients in the form of donor contributions to the Co-Pay Program and (2) direct remuneration in the form of financial assistance provided to patients.

As described in more detail below, the OIG has issued guidance regarding the operation of Co-Pay Programs and how such programs may be structured and operated to mitigate the risk of violating the AKS and CMPL. Relevant guidance includes guidance that is generally applicable to all CPAPs operating Co-Pay Programs (*e.g.*, Special Advisory Bulletins), as well as guidance that is binding with respect to one CPAP, but may nevertheless provide general insight into how the OIG views certain practices (*e.g.*, Advisory Opinions and Corporate Integrity Agreements). Failure to operate a Co-Pay Program within the parameters accepted by the OIG increases the risk of an enforcement action by the OIG or the DOJ.

a. Special Advisory Bulletins

The OIG first issued a special Advisory Bulletin[6] in 2005 addressing the Medicare Part D prescription drug benefit and the potential AKS implications raised by donations to CPAP Co-Pay Programs from pharmaceutical manufacturers. To safeguard against manufacturer influence of these programs and to mitigate the AKS risks identified by the OIG, the agency outlined a list of factors it considered "fundamental" to the operation of a properly structured and low risk Co-Pay Program. Specifically, independent Co-Pay Programs and the CPAPs that operate them should (1) not be influenced or controlled, either directly or indirectly, by pharmaceutical manufacturers that donate, or potentially could donate, to the CPAP; (2) award assistance in an independent manner that severs the link between the pharmaceutical manufacturer's funding and the beneficiary; (3) award assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan; and (4)

[2] To date, the DOJ has recovered in excess of $1.5 billion from manufacturers and CPAPs as part of the Massachusetts' U.S. Attorneys' Office's investigation into the relationship between manufactures and CPAPs. operating outside of the compliance framework established by OIG. Cases against two manufacturers related to these issues are still pending. *See United States v. Regeneron Pharmaceuticals*, No. 1:20-cv-11217-FDS, 2023 WL 6296393, (D. Mass. Sept. 27, 2023); *see also United States v. Teva Pharmaceuticals USA et al.*, No. 1:20-cv-11548-NMG, 2023 WL 4565105, (D. Mass. July 14, 2023).
[3] 42 U.S.C. § 1320a-7b(b).
[4] 31 U.S.C. §§ 3729-3733.
[5] 42 U.S.C. § 1320a-7a(a)(5).
[6] *See* OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005).

provide assistance based upon a reasonable, verifiable, and uniform measure of financial need applied in a consistent manner.

In its 2014 Supplemental Special Advisory Bulletin the OIG reiterated the need to use "a reasonable, verifiable, and uniform measure of an individual's financial need" to determine whether a patient meets the Co-Pay Program's financial eligibility criteria. According to the 2014 guidance, CPAPs have flexibility when determining what factors to consider when evaluating a patient's financial eligibility for the program.[7] Programs can inquire about a patient's cost of living, income, and anticipated medical expenses as part of the application process but CPAPs must apply any financial factors consistently across applicants.[8]

AKS and CMPL risks are mitigated where a Co-Pay Program follows the guidelines established by the OIG in the Special Advisory Bulletins.

b. Other Guidance: Advisory Opinions and Corporate Integrity Agreements

The OIG has also addressed the operation of Co-Pay Programs in Advisory Opinions and Corporate Integrity Agreements ("CIAs"). While Advisory Opinions and CIAs are only binding as to the parties to the documents, they nevertheless provide insight into how the OIG may view certain operational activities and arrangements and thus provide additional guidance for CPAPs to consider when developing and implementing Co-Pay Programs.

i. Advisory Opinions

The OIG has issued a number of Advisory Opinions evaluating the risks associated with the operation of specific Co-Pay Programs and the safeguards CPAPs implement to mitigate those risks.[9]

CPAPs that have received favorable Advisory Opinions regarding operation of Co-Pay Programs share certain characteristics. Specifically, these CPAPs have certified that they will operate their Co-Pay Programs in a manner that (1) makes eligibility decisions based solely on financial need, according to uniform standards applied consistently; (2) offers assistance on a first-come, first-serve basis; (3) offers assistance without interfering with a patient's freedom of choice with respect to providers, suppliers, or treatment options; and (4) limits donor influence over the development and operation of Co-Pay Program funds. In favorable Advisory Opinions, OIG has acknowledged

[7] *See* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014).
[8] *Id.*
[9] *See, e.g.,* Adv. Op. 06-13 (Sept. 18, 2006) (Modified Dec. 15, 2015); Adv. Op. 02-01 (Mar. 3, 2017).

that adherence to these safeguards sufficiently mitigates the risk that the Co-Pay Programs will violate the AKS and CMPL.

ii. Corporate Integrity Agreements

Where there have been enforcement actions against CPAPs that fail to adhere to the parameters of their respective Advisory Opinions in operating their Co-Pay Programs and thus potentially have violated the AKS and CMPL, the OIG has entered into CIAs with the CPAPs as part of a broader resolution.[10] Existing CIAs with CPAPs reiterate the same compliance safeguards the OIG has addressed in other applicable guidance. A reoccurring element of these CIAs is to stress that the financial need screening process cannot require applicants to demonstrate an inability to receive financial assistance from other sources before first applying to a Co-Pay Program.[11] This is referred to as acting as a "payer of last resort," and is described by the OIG as a factor that is inconsistent with awarding assistance based on a reasonable, uniform, and verifiable measure of financial need.

The CIAs also reiterate the importance of a patient's freedom of choice.[12]

Based on the OIG's admonition of the payer of last resort requirement and emphasis of patient freedom of choice in CIAs, it is likely the OIG would view Co-Pay Programs using a payer of last resort requirement and limiting patient freedom of choice in an unfavorable light, thus increasing the risk of OIG scrutiny.

II. RELIANCE ON IMPERMISSIBLE CRITERIA

Implementing "payer of last resort" or "double dipping" criteria as part of a Co-Pay Program's application process in an unverifiable manner[13] that impact's a potential applicant's qualifications for eligibility or delays an applicant's ability to apply (regardless of when or how the criteria is

[10] The OIG typically enters into corporate integrity agreements as part of a civil resolution with a company that has been the subject of an enforcement action by the OIG and/or the DOJ. It is a tool used by OIG to prescribe the manner in which a company (*e.g.*, a CPAP) is permitted to operate. *See Corporate Integrity Agreements Snapshot*, Centers for Medicare & Medicaid Services, E-bulletin (Aug. 2016).

[11] *See* HHS OIG, Corporate Integrity Agreement Between the Office of the Inspector General of the Department of Health and Human Service and Patient Access Network Foundation (effective Oct. 24, 2019); *see also* Corporate Integrity Agreement Between the Office of the Inspector General of the Department of Health and Human Service and Chronic Disease Fund, Inc., d/b/a Good Days (effective Oct. 24, 2019); *see also* Corporate Integrity Agreement Between the Office of the Inspector General of the Department of Health and Human Service and The Assistance Fund, Inc. (effective Nov. 19, 2019).

[12] *See Id.*

[13] A patient attestation is not a "verifiable" measure of financial need sufficient to determine a patient's ability to meet a defined eligibility requirement.

presented as part of the application process[14]) appears to go beyond what is contemplated by the OIG in terms of permitted financial eligibility requirements. Reasonable financial need criteria are permitted as part of a CPAP's application process only if they are administered consistently and in a uniform and verifiable manner. Because a patient's eligibility with the "payer of last resort" and "double dipping" criteria are confirmed via patient attestation, it is nearly impossible for the criteria to be verified or uniformly applied. These criteria also potentially violate the first-come, first-serve safeguard and may limit a patient's freedom of choice. Thus, use of these criteria potentially violates OIG guidance, including, the operative Advisory Opinion(s), thereby increasing the risk that the CPAPs using these criteria for their Co-Pay Programs have violated the AKS and CMPL. We analyze each criterion in turn below.

a. Payer of Last Resort

A CPAP positions itself as a "payer of last resort" if it requires patients to demonstrate or attest to an inability to receive assistance from other sources before applying for assistance through the CPAP's Co-Pay Program. For example, a CPAP that requires patients to seek assistance from the pharmaceutical manufacturer that provides his or her treatment and makes denial of such a request a factor considered in its application process. Because payer of last resort requirements are not a "verifiable and uniform measure of financial need" and because the OIG has expressed its concern about such provisions in CIAs,[15] CPAPs implementing payer of last resort requirements risk potentially violating their Advisory Opinions and applicable laws and thus risk enforcement action by the OIG or the DOJ.

The OIG has repeatedly reiterated in its guidance that Co-Pay Program eligibility must be based on a reasonable, verifiable, and uniform measure of financial need applied in a consistent manner. Co-Pay Programs can consider a range of factors as part of the financial screening process, such as household income, number of dependents in the household, and cost of living implications (*e.g.*, through a cost of living adjustment based on high-cost geographic areas).

However, requiring a patient to demonstrate an inability to secure assistance from a manufacturer or other source is not criteria established by the CPAP and based on a "reasonable, verifiable, and uniform measure of financial need applied in a consistent manner." Rather, it is based on whether the manufacturer of the patient's treatment offers co-payment assistance and whether the patient ***qualifies for that program based on financial eligibility criteria that the manufacturer has established***, which can vary by program. Even if manufacturers evaluate a patient's financial circumstances for their assistance programs, manufacturers' application criteria may vary (*e.g.*, different manufacturers have different financial eligibility thresholds) and, as a result, ***a CPAP***

[14] While a CPAP may not explicitly refer to the requirements as "eligibility criteria," any information gathered from the applicant that impacts their ability to apply is a *de facto* eligibility requirement.
[15] *See,* FN 12, supra.

operating as payer of last resort accepts or denies patients based on the existence of a manufacturer program for a specific product and, if so, the non-uniform criteria of manufacturer programs, rather than uniform criteria established by the CPAP itself.

Moreover, for an eligibility requirement to be consistent with OIG guidance, the applicant to the Co-Pay Program would need to provide documentation or proof of a lack of manufacturer assistance, or the denial of assistance if the applicant is ineligible. Asking a patient to attest to an inability to receive financial support from a pharmaceutical manufacturer is not a sufficient verification process (i.e., it would be no different than a CPAP asking a patient to provide their income data without any process to verify the accuracy or validity of the provided data).

Additionally, patients who need to pause a Co-Pay Program application to first confirm that they are ineligible for other forms of assistance may then miss the window for financial assistance from the CPAP's Co-Pay Program altogether. If the patient has not already attempted to apply for support from a manufacturer's program, doing so will require the patient to pause the application process with the Co-Pay Program. By the time an otherwise eligible patient is able to obtain a denial from a manufacturer program (as is required under a fund with a payer of last resort requirement), the Co-Pay Program fund may have closed, resulting in the patient losing the opportunity to received needed financial assistance. In this way, CPAPs implementing the payer of last resort requirement are not providing the "safety net assistance" OIG has indicated is characteristic of a compliant Co-Pay Program awarding assistance on a first-come, first-serve basis.[16]

CPAPs also are required to maintain their independence from manufacturer donors and potential donors. Explicitly linking Co-Pay Program eligibility to drug specific co-payment programs administered by pharmaceutical manufacturers that are or could be donors to the CPAP potentially allows the manufacturer to directly or indirectly influence the Co-Pay Program or, at a minimum, gives the impression that the CPAP is associated with the manufacturer. This is a clear violation of the independence required by CPAPs. While it is in the manufacturer's best interest for a patient on the manufacturer's product(s) to receive assistance directly from the manufacture's program (because such assistance is limited to patients on the manufacturer's product(s))[17], the requirement that a patient obtain a denial from the manufacturer's program before being eligible for the CPAP's program creates the impression that the two programs are associated or linked. As a result, the CPAPs are awarding assistance in a manner that benefits the interest of certain pharmaceutical manufacturers, something the CPAPs are prohibited from doing.

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[16] *See e.g.,* Adv. Op. 14-11 (Jan. 5, 2015).

[17] In contrast, a patient receiving assistance from a CPAP can use their award funds for any product covered by the CPAP, which includes, at a minimum, all FDA approved drugs to treat the patient's diagnosed illness (i.e., not solely the manufacture's product(s)). This ensures patient's maintain their "freedom of choice" as to their treatment drugs.

A CPAP acting as a payer of last resort also risks awarding assistance based on the patient's choice of product or prioritizing certain categories of patients by potentially favoring patients on certain drugs in violation of the "first-come, first-serve" requirement in OIG guidance and Advisory Opinions. For example, patients on drugs manufactured by a manufacturer that does ***not*** offer co-payment assistance will be favored under a fund with a "payer of last resort" criteria as such patients will not have to go through the process of applying and receiving a denial from the manufacturer's program. Ironically, this will likely benefit patients who are on generic, rather than branded, drugs, though there are some branded drugs without co-payment assistance programs. Regardless, the criteria could favor patients on certain drugs.

Lastly, you could envision a scenario where a manufacturer does not operate a co-payment assistance program for a specific treatment (manufacturer product), but instead donates to a CPAP's Co-Pay Program for a disease fund that covers the manufacturer's product, coordinating the timing of its donations with its HUB so that the HUB can flood the CPAP with applications for patients on the donor's product. If patients on other drugs are required to seek assistance from the manufacturer of their drug before completing their application with the CPAP, then patients on the donor's drug are effectively moved ahead in the application queue. The manufacturer could then offer donations to ensure funding is available for patients primarily on the donor's drug, to the detriment of other patients who otherwise may be eligible for assistance, but for the payer of last resort requirement.

For these reasons, we believe requiring patients to first seek assistance from a manufacturer's program before completing a Co-Pay Program application (*i.e.*, effectively making the CPAP Co-Pay Program the "payer of last resort") violates OIG guidance.

b. "Double Dipping"

A CPAP incorporates "double dipping" as an exclusion criteria for eligibility when it requires patients to attest or demonstrate that they do not have, and will not seek, a grant from another Co-Pay Program for the same disease or treatment, or as a condition of eligibility, while the patient still has funding through their grant with the CPAP.

While it would be illegal for patients (or providers or specialty pharmacies) to seek double reimbursement for a specific claim (*i.e.*, to seek payment for the same co-payment amount from multiple Co-Pay Programs), nothing in the OIG guidance suggests that patients should not have the freedom to enroll in multiple CPAPs, some of which provide additional financial assistance beyond what might be available from a single CPAP.

A financially needy patient is likely to have a wide range of medical costs for which they might need assistance during their course of treatment for a specific disease. CPAPs have adopted

different models for the range of products and services covered by their Co-Pay Programs.[18] For example, one CPAP may choose to cover drugs approved by the Food and Drug Administration ("FDA") for treatment of the disease covered by a particular fund, along with those products listed in a nationally-recognized drug compendia, while another CPAP may, in addition to treatment drugs, cover those used to manage the disease. Other CPAPs may cover insurance premiums, or labs, scans, and other tests. CPAPs also differ in the amount of funding awarded under their grants. Regardless, a patient receiving assistance from one CPAP could reasonably need assistance offered by another CPAP for expenses that are covered under only one of the CPAP's Co-Pay Programs.

Thus, the prohibition against double dipping has the potential to harm patients by limiting their ability to cover high medical costs, which can include not only the co-payments associated with the cost of the patient's treatment drug, but also co-payments for associated treatment visits, labs, scans, and other tests, as well as health insurance premiums, all of which may be covered by other Co-Pay Programs. The reality is that different CPAPs cover different medical costs, all to the benefit of the patient and without raising concerns that the patient, provider, or specialty pharmacy is seeking reimbursement from multiple CPAPs for the same co-payment. In this way, CPAPs collectively contribute to positive patient health outcomes by helping to ensure patients can continue affording the costs of their medical treatment with the help of a wide-range of financial assistance.

If a CPAP broadly prohibits patients from receiving assistance from other sources (*e.g.*, from another CPAP) while they have a grant with the CPAP, patients may need to make tough decisions prioritizing which of their medical costs will be covered by charitable assistance. For example, the patient may have to choose between a grant from a CPAP with a double dipping prohibition that covers only the cost of the patient's treatment drug ***or*** a grant from a CPAP without such prohibition that covers insurance premiums and associated medical costs (like labs and scans). Many patients could legitimately need financial assistance for both types of expenses and CPAPs with double dipping prohibitions are effectively limiting the assistance patients can receive. Ultimately, if a CPAP requires patients to certify that they are not double dipping, the patients' freedom of choice regarding their provider and treatment could potentially be influenced as the patient may not be able to afford some types of treatment or tests without financial assistance for which they would otherwise be eligible, but for the double dipping prohibition.

To the extent CPAPs have implemented a prohibition against double dipping as an eligibility criteria to ensure the CPAP is providing grants to the most needy, i.e., those who do not receive other forms of financial assistance and thus arguably have a greater "need," the prohibition likely

[18] The OIG has approved Advisory Opinions for Co-Pay Programs covering a variety of ranges of products and services. The OIG's only requirements regarding what must be covered under a specific Co-Pay Program is with respect to "single drug, singled donor" funds as described in the 2015 Advisory Opinion modifications. *See, e.g.,* OIG Adv. Op. 04-15, modification issued Dec. 30, 2015.

is having the opposite effect. A CPAP with an eligibility criteria that excludes patients receiving assistance from another CPAP is likely to penalize lower income patients who are more likely to need assistance from multiple charities. Most CPAPs have financial eligibility requirements tied to the federal poverty level ("FPL") and award grants to patients with income up to, in some cases, 600% of FPL. It is more likely that a patient with income at 200% or 300% of FPL is going to have greater financial need that cannot be met by a single CPAP grant, while a patient at 600% of FPL may only need one CPAP grant to meet all or most of their financial needs.

Additionally, regardless of the reasoning behind a CPAP's adoption of a prohibition against double dipping, the design limits patients' ability to address their needs and appears to benefit donating manufacturers. A CPAP's adoption of this prohibition limiting patients' ability to receive financial assistance may attract manufacturers to donate to the CPAP's Co-Pay Programs, rather than the Co-Pay Programs of CPAPs allowing patient support without the prohibition. Due to the appearance of the design benefitting manufacturers over patients, designs excluding double dipping could invite questions of donors attempting to influence or control, either directly or indirectly, a CPAP and its Co-Pay Program. As made clear in prior OIG guidance, including the SABs, CPAPs must award assistance without regard to the interest of an existing or potential donor. However, a CPAP design that prohibits double dipping can serve the interest, implicitly or explicitly, of manufacturers donating to a disease fund at the CPAP over a disease fund at a CPAP without these limits because the manufacturer's donations may more likely support patients on the donor's drug, rather than providing financial assistance for other types of health care items or services (*e.g.*, labs, scans, treatment visits, etc.) that would be available to patients with the same disease from other CPAPs. Thus, manufacturers have more control over how their donations are being used, beyond just making a donation to a specific disease category. In short, double dipping prohibitions give the appearance that the CPAP could be tailoring its eligibility criteria, at least in part, to benefit its donors, inviting scrutiny.

Lastly, to the extent the CPAP uses a patient attestation to confirm the patient is not "double dipping," the same concerns exist as described in more detail above, regarding whether this is a verifiable measure of financial need. A patient attestation is not a "verifiable" measure of financial need.

For these reasons, we believe that the prohibition against double dipping is inconsistent with OIG guidance prohibiting donor influence and requiring Co-Pay Programs to preserve a patient's freedom of choice.

III. CONCLUSION

As outlined above, including in a Co-Pay Program application process the payer of last resort requirement and/or a prohibition against double dipping contradicts OIG guidance for the operation of Co-Pay Programs by bona fide CPAPs. Thus, we believe that a CPAP that implements

these policies would not be operating its Co-Pay Program in accordance with OIG Guidance and, therefore, is at increased risk of potential enforcement by the OIG or the DOJ for violations of the AKS and CMPL.[19]

[19] Manufacturers donating to such programs would likely also be at an increased risk of enforcement.