DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).*]

Issued: September 30, 2022

Posted: October 5, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-19

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor") regarding a proposal whereby certain pharmaceutical manufacturers would: (i) fund, through Requestor, cost-sharing subsidies for the manufacturers' Part D oncology drugs; (ii) fund, through Requestor, specified programs and eligible beneficiaries' health insurance premiums; and (iii) finance Requestor's operating costs (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

You have certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement. In issuing this opinion, we have relied on the facts and information you presented to us and, in accordance with 42 C.F.R. § 1008.39(d), other publicly available information. This opinion is limited to the relevant facts and information you presented to us, which we have not independently investigated, and the other publicly available information we reviewed in connection with our assessment of the Proposed Arrangement.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, as well as certain publicly available information, we conclude that: (i) the Proposed Arrangement, if undertaken, would generate prohibited remuneration if the requisite intent were

present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act; and (ii) the Proposed Arrangement, if undertaken, would not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP. Any definitive conclusion regarding the existence of a Federal anti-kickback statute violation requires consideration of all of the facts and circumstances of the arrangement as implemented, including a party's intent. The determination of a party's intent is a necessary element to prove that the Federal anti-kickback statute has been violated. Because such a determination is beyond the scope of the advisory opinion process, we cannot reach a definitive conclusion regarding the existence of a Federal anti-kickback statute violation in this opinion.

This opinion may not be relied on by any person[1] other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Requestor

Requestor is a C-corporation that has applied for 501(c)(3) status under the Internal Revenue Code. Under the Proposed Arrangement, Requestor's operations would be funded entirely by pharmaceutical manufacturers that manufacture oncology drugs reimbursed by Medicare Part D (each, a "Funding Manufacturer"). Requestor is directed by a Board of Directors (the "Board") that is comprised of individuals with health care backgrounds and with expertise in pharmacy operations, public health, patient advocacy, legal services, accounting, and other relevant areas. Requestor certified that no Board member is, nor would any Board member be, an employee, director, or officer of a Funding Manufacturer. Board members also do not, and would not, have any financial relationships with the Funding Manufacturers.

B. The Proposed Arrangement

1. Background

Many patients with cancer have significant financial burdens associated with their care, potentially including a range of costs related to, for example: (i) services furnished by health care facilities, physicians, and other providers and suppliers; (ii) travel; and (iii) prescription drugs and medical devices. With respect to the impact of such financial burdens, Requestor cited to a series of studies that have found that high out-of-pocket costs for prescription drugs are associated with higher rates of delaying treatment initiation following a new diagnosis or disease progression, delays in product refills, and earlier discontinuation of product use.[2] Consistent

[1] We use "person" herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

[2] See, e.g., Stacie B. Dusetzina et al., Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients With Chronic Myeloid Leukemia, J. Clinical Oncology (Feb. 1, 2014), https://ascopubs.org/doi/pdf/10.1200/JCO.2013.52.9123; Alfred I. Neugut et al., Association

with these studies, Requestor certified that patient access to prescription drug treatment is often hindered by prescription drug benefit designs and, specifically, the out-of-pocket costs incurred by patients under these benefit designs.

Requestor certified that it perceives existing patient assistance models involving cost-sharing subsidies and OIG guidance regarding these models[3] to be inadequate to facilitate access to prescription drugs. Requestor, through the Proposed Arrangement, would establish a new model based, in part, on OIG's initial guidance in the 2005 Bulletin regarding certain "nascent efforts by some in the industry to develop arrangements through which multiple pharmaceutical manufacturers would join together to offer financially needy Part D enrollees a card or similar vehicle that would entitle the enrollees to subsidies of their cost-sharing obligations for the manufacturers' products."[4]

2. Types of Subsidies and Eligibility

Under the Proposed Arrangement, each Funding Manufacturer would subsidize three different categories of costs: (i) cost sharing incurred by eligible Part D enrollees when filling prescriptions for that Funding Manufacturer's Part D oncology drugs; (ii) specified programs (e.g., programs designed to increase health equity in clinical trial participation) and certain beneficiaries' health insurance premiums; and (iii) Requestor's operating costs.

a) Cost-Sharing Subsidies

Under the Proposed Arrangement, Funding Manufacturers, through Requestor, would subsidize cost-sharing amounts for their own products for eligible Medicare Part D enrollees. In other words, the Proposed Arrangement would establish a pathway for each Funding Manufacturer to subsidize the cost-sharing amounts owed only for their own drugs, not for the drugs of any other Funding Manufacturer. All manufacturers of branded and generic oncology products reimbursed by Medicare Part D would be eligible to participate in the Proposed Arrangement. Requestor expects manufacturers whose products constitute approximately 90 percent of existing Medicare Part D oncology utilization to participate, which would mean Requestor would make cost-sharing subsidies available for approximately 50 oncology products reimbursed by Medicare Part

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between prescription co-payment amount and compliance with adjuvant hormonal therapy in women with early-stage breast cancer, J. Clinical Oncology (June 20, 2011), https://pubmed.ncbi.nlm.nih.gov/21606426/.

[3] See OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf (hereinafter the "2005 Bulletin"); OIG, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120 (May 30, 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf (hereinafter the "2014 Bulletin").

[4] 2005 Bulletin, 70 Fed. Reg. at 70,627.

D. A Part D enrollee would be eligible for cost-sharing subsidies under the Proposed Arrangement if: (i) the enrollee has a cancer diagnosis; (ii) the enrollee has a household income between 150 percent and 350 percent of the Federal Poverty Level;[5] (iii) the enrollee has been prescribed a Part D oncology drug manufactured by a Funding Manufacturer; and (iv) the enrollee's Part D plan has made the initial decision to cover that particular product for that particular enrollee.

In lieu of the current Part D enrollee cost-sharing obligations enacted by Congress as part of the Medicare Part D program's defined standard benefit[6] (or an alternative benefit structure developed by a Medicare Part D plan or Medicare Advantage plan that provides qualified prescription drug coverage), the Proposed Arrangement would, in practice, establish a different cost-sharing structure for qualifying Part D enrollees unique to Part D oncology drugs manufactured by Funding Manufacturers. A Part D enrollee receiving subsidies from Requestor would pay cost sharing in the amount of: (i) $35 per month for branded drugs and $10 per month for generic drugs; and (ii) either 10 percent or 25 percent of the total coinsurance that would otherwise be owed for branded drugs during the catastrophic phase of coverage.[7] The applicable Funding Manufacturer, through Requestor, would pay all remaining cost-sharing obligations a qualifying Part D enrollee otherwise would have to pay for that Funding Manufacturer's Part D oncology drug. Requestor would not subsidize a Part D enrollee's cost sharing for a branded drug if a biosimilar or an AB-rated generic equivalent were available.

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[5] According to the 2020 Medicare Current Beneficiary Survey, 28.9 percent of the Medicare population has a household income below 150 percent of the Federal Poverty Level, 33.4 percent of the Medicare population falls within the range included in the Proposed Arrangement, and 37.7 percent of the Medicare population has a household income at or above 350 percent of the Federal Poverty Level. See Centers for Medicare and Medicaid Services ("CMS"), Medicare Current Beneficiary Survey File Limited Data Set (2020), https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/MCBS.

[6] See 42 U.S.C. § 1395w–102(b). During the course of our review of the Proposed Arrangement, Congress enacted the Inflation Reduction Act of 2022, Public Law 117-169, which restructures the cost sharing imposed on beneficiaries under Medicare Part D. In particular, the new law eliminates Medicare Part D enrollees' 5 percent cost sharing in the catastrophic phase beginning in 2024 and also caps enrollees' annual out-of-pocket costs for Part D drugs at $2,000 beginning in 2025 (with the cap updated annually thereafter). We are opining on the state of the law as it currently stands, which will continue until the Inflation Reduction Act of 2022's provisions take effect. However, nothing in our review of the Inflation Reduction Act of 2022 suggests that our assessment of the Proposed Arrangement would change once the new provisions are implemented, and it could be that the Proposed Arrangement would present new or different risks of fraud and abuse under the Federal anti-kickback statute.

[7] Part D enrollees with a household income between 150 percent and 250 percent of the Federal Poverty Level would pay 10 percent of the coinsurance otherwise owed, while enrollees with a household income between 250 percent and 350 percent of the Federal Poverty Level would pay 25 percent of the coinsurance otherwise owed.

Requestor certified that some Part D oncology products have a retail cost of $10,000 or more for a monthly supply. Under the current standard Medicare Part D prescription drug benefit, for a branded drug with a retail cost of $10,000 per month, an enrollee[8] would nearly reach the catastrophic phase of coverage in the first month alone (or sooner, if the enrollee filled other Part D prescriptions). A Part D enrollee in the 2022 standard Medicare Part D benefit filling a prescription for this $10,000 per month drug would be responsible for a $480 deductible, 25 percent coinsurance during the initial coverage phase, and 25 percent coinsurance during the coverage gap[9] (all of which would total approximately $2,800 in the first month). Under the Proposed Arrangement, the same enrollee filling the same prescription would pay $35 in the first month (assuming the beneficiary filled no other Part D prescriptions), which Requestor certified would be the maximum monthly contribution before the beneficiary reaches the catastrophic phase. For most of the remainder of the year, a Part D enrollee in the 2022 standard Medicare Part D benefit would be in the catastrophic phase, when the enrollee is responsible for 5 percent coinsurance on spending (which totals $500 of monthly out-of-pocket spending for the drug in this example). However, under the cost-sharing structure designed by Requestor, an enrollee receiving subsidies for a branded drug through the Proposed Arrangement would pay either $50 or $125 per month (i.e., either 10 percent or 25 percent of the $500 that would be owed under the standard Medicare Part D benefit), plus the $35 monthly obligation.

b) Additional Funding

Requestor also would require Funding Manufacturers to contribute specified amounts to finance the following categories of costs: (i) health insurance premiums, including Medicare Part D premiums for certain Medicare beneficiaries; and (ii) select programs, which Requestor identifies as promoting oncology screening and health equity (e.g., encouraging access to clinical trial participation). Medicare Part D enrollees who have a cancer diagnosis and have a household income between 150 percent and 350 percent of the Federal Poverty Level would be eligible for health insurance premium subsidies (including, but not limited to, subsidies for Part D premiums) under the Proposed Arrangement; unlike the cost-sharing subsidies, these premium subsidies would be available to beneficiaries regardless of whether they use any Part D oncology drug manufactured by a Funding Manufacturer.

Requestor certified that Funding Manufacturers, collectively, would be required to contribute a total of $15 million in additional funding in the first year of the Proposed Arrangement's operation and a total of $20 million in the second year of the Proposed Arrangement's operation; in subsequent years, the Board would determine the total contribution amount. The responsibility for financing the first 50 percent of the costs associated with this additional funding would be divided among all Funding Manufacturers, with Funding Manufacturers that

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[8] This example would apply to enrollees who do not qualify for Medicare Part D's Low-Income Subsidy. By law, individuals who qualify for and enroll in the Low-Income Subsidy program pay zero or nominal cost sharing. See 42 C.F.R. § 423.782.

[9] See Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, Table V-2 (Jan. 15, 2021), https://www.cms.gov/files/document/2022-announcement.pdf.

sell branded oncology drugs paying a greater share of such costs than Funding Manufacturers that sell generic oncology drugs. The remaining 50 percent of the costs associated with this additional funding would be determined by separating Funding Manufacturers into tiers based on their Part D oncology market share. All Funding Manufacturers on the same tier would be responsible for the same percentage of these additional funding costs.

c) Operating Costs

Funding Manufacturers also would be required to finance all of Requestor's operating costs, as described in more detail below. Requestor anticipates its operating costs could total approximately $20 million per year. Requestor would allocate the operating costs by the same method described above for allocating the additional funding costs.

3. Operationalizing the Proposed Arrangement

Requestor would utilize a Request for Proposal process to select a third party (the "Administrator") to administer the logistical components of the Proposed Arrangement. The Administrator would not be owned, in whole or in part, by any pharmaceutical manufacturer. Requestor certified that the agreement with the Administrator would comply with the personal services and management contracts and outcomes-based payment arrangements safe harbor to the Federal anti-kickback statute.[10]

One duty of the Administrator would be to collect sufficient documentation from each Medicare Part D enrollee applying to Requestor to determine whether the applicant satisfies Requestor's eligibility criteria both initially and as part of an annual reenrollment process (if applicable). The Administrator would administer the assistance via a subsidy card issued to each eligible Part D enrollee that would indicate that the enrollee is eligible for subsidies under the Proposed Arrangement.[11] In the case of cost-sharing subsidies, the Part D enrollee would present the subsidy card at the pharmacy, which would indicate that the pharmacy can initiate an electronic payment transaction administered by the Administrator to subsidize the enrollee's cost-sharing obligations if the enrollee purchases a Part D oncology product manufactured by a Funding Manufacturer. The Administrator would ensure that Requestor's subsidy card would be accepted at a wide range of pharmacies[12] and that the eligibility criteria would be applied without regard to: (i) providers, practitioners, or suppliers selected by the Part D enrollee; or (ii) the Part D enrollee's Medicare Advantage plan or Part D plan. Because Requestor would make eligibility for cost-sharing subsidies contingent on the applicant using a Part D oncology drug

[10] 42 C.F.R. § 1001.952(d).

[11] Beneficiaries eligible for health insurance premium subsidies or other programs would receive a subsidy card to present to the applicable entity to access the funding.

[12] Requestor certified that any pharmacy willing to accept the subsidies from Requestor on behalf of eligible Part D enrollees would be able to accept the subsidy card.

manufactured by a Funding Manufacturer, the oncology drug selected for therapy would dictate eligibility.[13]

The Administrator would invoice Requestor on a periodic basis for the subsidies provided to eligible Part D enrollees for drugs manufactured by Funding Manufacturers. Next, Requestor would invoice each Funding Manufacturer for its required contribution, which would include the sum of the amounts owed by the Funding Manufacturer for the three separate categories of costs associated with the Proposed Arrangement: (i) the total amount of cost-sharing subsidies provided to eligible Part D enrollees who filled prescriptions for that Funding Manufacturer's Part D oncology drugs; (ii) the Funding Manufacturer's share of the financing to subsidize premiums and other specified programs; and (iii) the Funding Manufacturer's share of Requestor's operating costs.

Requestor certified that it would implement certain safeguards to promote compliance with applicable law, such as: (i) implementing a compliance program that aligns with OIG's Compliance Program Guidance for Pharmaceutical Manufacturers;[14] (ii) conducting regular compliance audits, both internally and in connection with the Administrator; and (iii) refraining from, and prohibiting the Administrator, Funding Manufacturers, and others from, what Requestor refers to as "unauthorized communications," including marketing or advertising the Proposed Arrangement to prescribers, beneficiaries, or other third parties as a reason to prescribe or use any product. Requestor would provide educational information to patients, providers, and advocacy groups about the availability of subsidies through media advertisements (e.g., print media, television, radio, social media) and other means. Requestor certified that individual products would not be advertised or promoted by Requestor or in connection with the Proposed Arrangement, but Requestor would make available a list of all covered products in a neutral fashion on a public website and in a practitioner brochure. The Administrator would be prohibited from communicating to any Funding Manufacturer any data that identifies the product selected or used by specific health care practitioners or beneficiaries; however, under certain circumstances, a Funding Manufacturer could request product-specific information.[15] In addition, Requestor certified that Requestor would not favor or otherwise give preference to any

[13] The Administrator, however, would apply Requestor's eligibility criteria without regard to which Part D oncology product manufactured by a Funding Manufacturer has been prescribed to an applicant.

[14] See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).

[15] In particular, if a Funding Manufacturer certifies that it has a financial or securities reporting obligation requiring product-specific information, then the Funding Manufacturer may receive such information (but such information would not include the identity of any patient or practitioner). Requestor stated the product-specific information would be provided only to a small set of reporting personnel upon the Funding Manufacturer requesting such information. In addition, Requestor stated that it would require that: (i) the Funding Manufacturer not share such information with brand, marketing, or sales personnel; and (ii) any use of such information must be as required by the underlying financial or securities reporting obligation.

pharmacy, provider, practitioner, or plan selected by any Part D enrollee eligible for cost-sharing subsidies, nor would any individual pharmacy, provider, practitioner, or plan be listed in any educational or promotional material.

Requestor also certified that it would notify CMS, applicable Medicare Advantage plans and Medicare Part D plans, and state Medicaid agencies of Part D enrollees who receive cost-sharing subsidies under the Proposed Arrangement.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer or pay any remuneration to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any item or service reimbursable under a Federal health care program.[16] In addition, the Federal anti-kickback statute prohibits any person from soliciting or receiving any remuneration in return for arranging for the purchasing of any item for which payment may be made in whole or in part under a Federal health care program. For purposes of the Federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.[17] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The OIG also may initiate

[16] Section 1128B(b) of the Act.

[17] E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

1. Federal Anti-Kickback Statute

a) Background[18]

We preface this analysis by underscoring that beneficiary access to potentially life-saving medications, including Funding Manufacturers' Part D oncology products, is of paramount concern to OIG. However, as with every advisory opinion request, OIG must evaluate the Proposed Arrangement in light of the statutory obligation under section 1128D(b) of the Act, which requires the Secretary to issue advisory opinions on, as relevant here: (i) what constitutes prohibited remuneration within the meaning of the Federal anti-kickback statute (i.e., whether remuneration would violate the Federal anti-kickback statute if the requisite intent were present);[19] and (ii) whether a proposed activity would constitute grounds for the imposition of sanctions by OIG. As we have stated since the inception of OIG's advisory opinion process, "[o]ur goal is to render meaningful and informed opinions . . . protecting in the process only

[18] We conducted an appropriate independent inquiry to better inform our understanding of the Part D design and cost sharing for Part D oncology drugs in order to evaluate the Proposed Arrangement. See 42 C.F.R. § 1008.39(d). In the course of this inquiry, we found and considered certain publicly available information that relates to the subject of this request for an advisory opinion and informs our conclusion about the fraud and abuse risks posed by the Proposed Arrangement.

[19] When OIG established the advisory opinion process, it made clear that it does not opine on intent in advisory opinions. See OIG, Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 62 Fed. Reg. 7,350, 7,351–52 (Feb. 19, 1997), https://oig.hhs.gov/authorities/docs/interim.pdf. This approach is consistent with the legislative history relating to the statutory provision establishing advisory opinions, which shows that Congress did not intend for OIG to issue advisory opinions opining on the intent of the parties. In particular, see accord Sen. Cohen, "Health Insurance Portability and Accountability Act of 1996," Congressional Record 142;117 (Aug. 2, 1996) S.9511–12 ("Finally, as the author of the original enhanced guidance to providers section, I would like to make some affirmative and declarative statements on the actual advisory opinion language. Although advisory opinions are an appropriate means of giving guidance to the industry on some issues, it is clearly unwise to have the agencies in the position of opining on the intent of the person requesting the opinion.").

those arrangements that pose little or no risk of fraud or abuse to the Federal health care programs."[20]

Consistent with this statutory obligation, OIG considers two central questions in this advisory opinion in connection with the Proposed Arrangement: (i) whether the Proposed Arrangement would involve prohibited remuneration that would violate the Federal anti-kickback statute if the requisite intent were present; and (ii) whether, in consideration of the facts and circumstances, including any potential benefits and consequences to beneficiaries and Federal health care programs, the Proposed Arrangement would pose a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute such that OIG—in an exercise of its enforcement discretion—would not seek to impose sanctions in connection with the Proposed Arrangement.

Like Requestor, OIG recognizes that some patients, including some Federal health care program beneficiaries, are unable or unwilling to access medically necessary oncology drugs due to the significant out-of-pocket costs incurred under the current Medicare Part D cost-sharing structure for these products. OIG also recognizes that Medicare Part D enrollees' cost sharing is driven in large part by the list prices pharmaceutical manufacturers set for these drugs. As an example of rising list prices—which, in turn, may result in out-of-pocket costs that patients are unwilling or unable to pay—a recent JAMA Network research letter examining launch prices for new drugs explained that "[f]rom 2008 to 2021, launch prices for new drugs increased exponentially by 20% per year."[21] This same article stated that "[i]n 2020-2021, 47% of new drugs were initially priced above $150000 per year" and also that "[t]he highest prices were among . . . oncology drugs (median, $155091 [IQR, $109832-$233916] per year)."[22]

High drug list prices often translate into prohibitively high out-of-pocket costs for Medicare Part D enrollees and other patients that render them unwilling or unable to fill their prescription.[23] For example, a study of 78 Part D oncology drugs found that the mean annual out-of-pocket cost

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[20] OIG, Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38,311, 38,312 (July 16, 1998), https://oig.hhs.gov/authorities/docs/frfinal.pdf.

[21] Benjamin N. Rome et al., Trends in Prescription Drug Launch Prices, 2008-2021, JAMA Network (June 7, 2022), https://jamanetwork.com/journals/jama/fullarticle/2792986; see also Deena Beasley, Newly launched U.S. drugs head toward record-high prices in 2022, Reuters (Aug. 16, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/newly-launched-us-drugs-head-toward-record-high-prices-2022-2022-08-15/.

[22] Benjamin N. Rome et al., Trends in Prescription Drug Launch Prices, 2008-2021, JAMA Network (June 7, 2022), https://jamanetwork.com/journals/jama/fullarticle/2792986.

[23] See, e.g., id. ("Spending is driven by high-cost brand-name drugs, for which manufacturers freely set prices after approval. Rising brand-name drug prices often translate to payers . . . imposing unaffordable out-of-pocket costs for patients.") (internal citations omitted); see also Stacie B. Dusetzina et al., Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions, Health Affairs (Apr. 2022).

was $5,285 in 2019.[24] Studies further demonstrate that patients undergoing potentially life-saving treatment may forgo taking certain prescription drugs due to these significant out-of-pocket costs. For example, in one study examining the impact of out-of-pocket costs on cancer patients, participant surveys showed that, "[t]o save money, 20% took less than the prescribed amount of medication, 19% partially filled prescriptions, and 24% avoided filling prescriptions altogether."[25] Another study regarding the use of a particular type of drug to treat chronic myeloid leukemia found that "high copayment requirements for drugs are associated with substantially reduced use. Patients with relatively higher cost-sharing requirements were 70% more likely to discontinue therapy and were 42% more likely to have inadequate adherence."[26]

b) OIG Guidance Regarding "Coalitions"

In the 2005 Bulletin, we stated that we were "mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs" and that we "support[] efforts . . . to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws." In this guidance, as stated above, OIG noted that there were "nascent efforts" in the industry to develop a new model to facilitate cost-sharing subsidies, pursuant to which multiple pharmaceutical manufacturers would join together to form a "coalition" to subsidize Part D enrollees' cost sharing for those manufacturers' drugs. At the outset of this single-paragraph discussion of "coalitions," OIG cautioned that it was "premature to offer definitive guidance on these evolving programs." However, the same paragraph went on to offer examples of certain safeguards that could reduce the risk of this type of model, such as:

> (i) The program contains features that adequately safeguard against incentives for card holders to favor one drug product (or any one supplier, provider, practitioner, or Part D plan) over another; (ii) the program includes a large number of manufacturers, including competing manufacturers and manufacturers of both branded and generic products, sufficient to sever any nexus between the subsidy

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[24] Thomas J. Hwang et al., Assessment of Out-of-Pocket Costs With Rebate Pass-through for Brand-name Cancer Drugs Under Medicare Part D, JAMA Oncology (Jan. 2022), https://jamanetwork.com/journals/jamaoncology/fullarticle/2786074; see also Juliette Cubanski et al., The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019 (Feb. 2019), https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019 (finding that 14 of the 15 specialty tier cancer drugs studied had a median annual out-of-pocket cost that exceeded $8,000).

[25] S. Yousuf Zafar et al., The Financial Toxicity of Cancer Treatment: A Pilot Study Assessing Out-of-Pocket Expenses and the Insured Cancer Patient's Experience, Oncologist (Feb. 26, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3639525. Seventy-five percent of the participants in this study applied for financial assistance.

[26] Stacie B. Dusetzina et al., Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients With Chronic Myeloid Leukemia, J. Clinical Oncology (Feb. 1, 2014), https://ascopubs.org/doi/pdf/10.1200/JCO.2013.52.9123.

> and a beneficiary's choice of drug; and (iii) each participating pharmaceutical manufacturer offers subsidies for all of its products that are covered by any Part D plan formulary . . . . [A] program under which Part D enrollees pay a portion of their drug costs out-of-pocket would tend to reduce the risk of abuse by preserving the beneficiary's incentive to locate and purchase equally effective, lower cost drugs.[27]

The OIG emphasized that "[o]ther safeguards may also be needed to reduce the risk of an improper inducement."[28]

c) Evaluation of the Proposed Arrangement

There are three categories of costs, as described in section B.1 of the Factual Background (namely, cost-sharing subsidies, additional funding, and operating costs), that would create several distinct streams of remuneration within the Proposed Arrangement and that would, or in certain instances could, implicate the Federal anti-kickback statute. We considered each category of cost and its associated remuneration stream(s) in our assessment of the Proposed Arrangement and describe each in varying levels of detail below. Ultimately, this advisory opinion addresses the Proposed Arrangement as a whole and inclusive of the three categories of costs and the associated remuneration streams, concluding that the Proposed Arrangement, if undertaken, would generate remuneration that would violate the Federal anti-kickback statute if the requisite intent were present.

First, Funding Manufacturers would provide cost-sharing subsidies—through Requestor and for only their products—to eligible Part D enrollees who purchase the oncology drugs that they manufacture and that are reimbursed under Medicare Part D. This "cost-sharing subsidy" category creates three streams of remuneration for purposes of an analysis under the Federal anti-kickback statute: (i) the indirect remuneration from Funding Manufacturers to qualifying Part D enrollees purchasing the Funding Manufacturers' drugs; (ii) the remuneration from Requestor (via the Administrator[29]) to the Part D enrollees purchasing the Funding Manufacturers' drugs; and (iii) the direct remuneration from Funding Manufacturers to Requestor to cover the cost-sharing subsidies for their drugs. Second, Funding Manufacturers would provide financing to Requestor that Requestor would: (i) allocate to patients, including Federal health care program beneficiaries, in the form of premium subsidies; and (ii) use to fund certain other programs (e.g., programs designed to increase health equity in clinical trial participation). This "additional funding" category also would create several distinct streams of remuneration. Third, the "operating costs" category would result in remuneration from Funding Manufacturers to Requestor in the form of payment for their allocated shares of Requestor's operating costs.

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[27] 2005 Bulletin, 70 Fed. Reg. at 70,627 (emphasis in original).

[28] Id.

[29] Recognizing that the Administrator would act as Requestor's agent for certain aspects of the Proposed Arrangement, our discussion of remuneration streams below involving Requestor includes actions taken by the Administrator when acting as Requestor's agent.

Below, we assess each of these categories of costs in greater detail.

(i) Cost-Sharing Subsidies

In evaluating the Proposed Arrangement under the Federal anti-kickback statute, we first look to whether it would involve remuneration to an individual to induce that individual to purchase, or arrange for the purchase of, an item or service for which payment may be made under a Federal health care program. For purposes of the Federal anti-kickback statute, "any remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.[30] In addition, we have explained that the meaning of the term "to induce" is "found in the ordinary dictionary definition: 'to lead or move by influence or persuasion . . . '"[31] The cost-sharing subsidies in the Proposed Arrangement would fit squarely within the Federal anti-kickback statute's plain language prohibiting the offer of remuneration to induce the purchase, or arrange for the purchase, of an item for which payment may be made under a Federal health care program, if the requisite intent were present.

First, the cost-sharing subsidies provided indirectly by a Funding Manufacturer to eligible Part D enrollees filling prescriptions for the drugs it manufactures, and directly by Requestor to eligible Part D enrollees, plainly would constitute remuneration.[32] Specifically, Requestor and a Funding Manufacturer would provide remuneration directly and indirectly, respectively, in the form of valuable cost-sharing subsidies (through a subsidy card) to eligible Medicare Part D enrollees who are prescribed the Funding Manufacturer's drugs. These Medicare Part D enrollees would use the subsidy card at the point of sale to subsidize the majority of the cost-sharing obligations that they otherwise would owe under the current Medicare Part D benefit for the Funding Manufacturer's drugs. While the full amount of cost sharing a Medicare Part D enrollee otherwise would owe (absent the Proposed Arrangement) would vary based on, among other factors, the list price set by the Funding Manufacturer for the drug prescribed, the subsidies under the Proposed Arrangement would be significant. For example, in 2019, the mean annual

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[30] As we have stated previously, "Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever. The statute's language makes clear that illegal payments are prohibited beyond merely 'bribes,' 'kickbacks,' and 'rebates,' which were the three terms used in the original 1972 statute." OIG, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,958 (July 29, 1991), https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm.

[31] See id. In addition, the Second Circuit recently explained that "[t]he plain meaning of 'induce' is to 'entic[e] or persuad[e] another person to take a course of action," which is consistent with OIG's longstanding interpretation of such term. Pfizer, Inc. v. HHS, No. 21-2764-cv, slip op. at 17 (2d Cir., July 25, 2022).

[32] As explained below, inherent in the structure of this portion of the Proposed Arrangement is remuneration that flows from each Funding Manufacturer to Requestor to reimburse Requestor for the cost-sharing subsidies provided to Part D enrollees who purchase that Funding Manufacturer's—and only that Funding Manufacturer's—Part D oncology drugs.

out-of-pocket costs for Part D enrollees for drugs constituting 93.3 percent of total Part D cancer drug spending was $5,285.[33] Using this 2019 average and under the current standard Part D benefit, it is reasonable to extrapolate that the average per-beneficiary cost-sharing subsidy that an eligible enrollee would receive under the Proposed Arrangement would be over $4,000 annually.[34] Using Requestor's example of a $10,000 per month drug, the subsidies would be close to $8,000 annually under the current standard Part D benefit.

Studies show that many patients, including Medicare Part D enrollees, do not fill prescriptions for oncology drugs because of the high out-of-pocket costs associated with such drugs. By allowing a Funding Manufacturer to subsidize a Part D enrollee's out-of-pocket costs for only its own drugs—for a category of patients for whom medication non-adherence is common because of high cost-sharing obligations—the Proposed Arrangement would create an avenue for these manufacturers, via Requestor, to direct remuneration to Part D enrollees that would remove a financial barrier (i.e., cost) for those Part D enrollees purchasing that Funding Manufacturer's drug. If the reason a Part D enrollee would not fill a prescription is the enrollee's inability (or unwillingness) to pay the out-of-pocket costs associated with the drug, then remuneration that would address that inability (or unwillingness) to pay very likely would influence the patient's purchasing decision.[35]

Therefore, each stream of remuneration related to cost-sharing subsidies appears to be designed to remove that barrier so that eligible Part D enrollees will purchase Funding Manufacturers' drugs. First, Requestor's cost-sharing subsidies would directly relieve qualifying Part D enrollees of a significant portion of their cost-sharing obligations for any Part D oncology product manufactured by a Funding Manufacturer, which appears to be designed to induce the purchase of oncology drugs that are manufactured by a Funding Manufacturer and reimbursed under Medicare Part D. Next, Funding Manufacturers would provide remuneration indirectly,

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[33] Thomas J. Hwang et al., Assessment of Out-of-Pocket Costs With Rebate Pass-through for Brand-name Cancer Drugs Under Medicare Part D, JAMA Oncology (Jan. 2022), https://jamanetwork.com/journals/jamaoncology/fullarticle/2786074.

[34] If a Part D enrollee had a Part D drug that cost $4,600 per month at retail in 2022, the annual out-of-pocket cost under the standard Part D benefit would be approximately $5,257, with the enrollee reaching catastrophic coverage in March (assuming that the enrollee initiated treatment with the drug in January). Under the Proposed Arrangement, that enrollee's annual out-of-pocket cost would be less than $1,000: $35 for 12 months, 25 percent of the approximately $156 owed under catastrophic coverage in March, and 25 percent of the $230 standard Part D benefit's catastrophic amount of $230 for April through December. Therefore, the enrollee would receive over $4,000 in subsidies under the Proposed Arrangement.

[35] See, e.g., Leemore Dafny et al., Giving A Buck Or Making A Buck? Donations By Pharmaceutical Manufacturers To Independent Patient Assistance Charities, Health Affairs (Sept. 2022), https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00177 (noting, in the context of contributions made to foundations operating patient assistance programs, that, "[t]o some degree, that donations induce utilization is not surprising: Cost sharing is known to reduce utilization, so defraying it should logically induce some portion.").

via Requestor, to eligible Part D enrollees filling prescriptions for drugs they manufacture, which similarly appears calculated to induce Part D enrollees to purchase their Part D oncology drugs. And finally, through the design of the Proposed Arrangement, each Funding Manufacturer would pay remuneration (i.e., the cost-sharing subsidies for qualifying Part D enrollees who purchase its products) to Requestor that Requestor then would use to subsidize the cost-sharing obligations for Medicare Part D enrollees who purchase that Funding Manufacturer's products. While Requestor would be agnostic as to which Funding Manufacturer's Part D oncology drug a qualified enrollee would purchase, that does not change the fact that the Proposed Arrangement would involve paying remuneration (i.e., cost-sharing subsidies) to Medicare Part D enrollees so that such enrollees would "purchase . . . any item for which payment may be made in whole or in part under a Federal health care program . . . ,"[36] so long as the item is a Part D oncology drug manufactured by a Funding Manufacturer.

These cost-sharing subsidies would not meet the requirements of any statutory exception or regulatory safe harbor to the Federal anti-kickback statute. Therefore, we next must identify whether the cost-sharing subsidies would constitute grounds for the imposition of sanctions. In doing so, we must evaluate whether the Proposed Arrangement would pose little-to-no risk of fraud and abuse under the Federal anti-kickback statute. Congress set forth a number of factors to consider when developing safe harbors; while not binding with respect to the assessment of arrangements presented in requests for an advisory opinion, they are instructive for assessing risk under the Federal anti-kickback statute.[37] For example, our advisory opinions frequently consider factors such as overutilization, increased costs to Federal health care programs, corruption of medical decision-making, patient steering, and unfair competition. Several of these

[36] See, e.g., Pfizer, Inc. v. HHS, No. 1:20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021) ("[T]here is no language in the [Federal anti-kickback statute] proximate to or modifying 'induce' that premises liability on a corrupt quid pro quo transaction where a benefit must flow to the requestor. The plain meaning of the word 'inducement' implies a 'one-way' transaction, where the requestor simply gets someone to take an action. See Inducement, BLACK'S LAW DICTIONARY (11th ed. 2019) ('The act or process of enticing or persuading another person to take a certain course of action.') . . . In other words, the [Federal anti-kickback statute] requires only that payments are made with an intent to influence a decision about medical care or purchases, and does not require any further proof of intent or purpose.").

[37] See section 1128D(a)(2) of the Act, citing to: (i) an increase or decrease in: access to health care services, the quality of health care services, patient freedom of choice among health care providers, competition among health care providers, the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations, the cost to Federal health care programs, or the potential overutilization of health care services; (ii) the existence or nonexistence of any potential financial benefit to a health care professional or provider which may vary based on their decisions of whether to order a health care item or service or whether to arrange for a referral of health care items or services to a particular practitioner or provider; and (iii) any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs.

concerns are reiterated in the Compliance Program Guidance for Pharmaceutical Manufacturers.[38]

We recognize that Requestor based the structure of the Proposed Arrangement on our brief discussion in the 2005 Bulletin about a potential "coalition model" program, and the Proposed Arrangement would include many of the provisional safeguards that, in 2005, we posited might reduce the risk of fraud and abuse under the Federal anti-kickback statute. At the time of publication of the 2005 Bulletin, we noted that it was premature to offer any definitive guidance on this model. Among other considerations, the Part D program had not yet launched in 2005; it went into effect in 2006. This advisory opinion reflects our first opportunity to evaluate an arrangement involving a coalition of manufacturers subsidizing cost sharing for their own drugs and to do so in the context of an implemented Part D program. Our assessment of the coalition model presented in the Proposed Arrangement, unlike our preliminary commentary from 2005, is further informed by almost two decades of enforcement experience, various appraisals of the administration of the Medicare Part D program, and increasing drug prices.[39]

While OIG previously acknowledged the possibility of a "coalition model," OIG also has consistently expressed concerns about manufacturers subsidizing beneficiaries' cost sharing for the manufacturers' own drugs. Requestor's design of the Proposed Arrangement would ensure that each Funding Manufacturer can funnel its financial contributions for cost sharing through Requestor to only those eligible Part D enrollees who are taking that Funding Manufacturer's drugs—thereby creating a fact pattern that collides with OIG's prior warnings. For example, the 2005 Bulletin stated, in the context of concerns regarding pharmaceutical manufacturer-sponsored patient assistance programs:

> [C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions.[40]

More recently, the 2014 Bulletin indicated our concern that "the ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support."[41]

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[38] See 68 Fed. Reg. at 23,734.

[39] See, e.g., Juliette Cubanski & Tricia Neuman, Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020 (Feb. 25, 2022), https://www.kff.org/medicare/issue-brief/prices-increased-faster-than-inflation-for-half-of-all-drugs-covered-by-medicare-in-2020/.

[40] 2005 Bulletin, 70 Fed. Reg. at 70,626.

[41] 2014 Bulletin, 79 Fed. Reg. at 31,122.

Through the cost-sharing subsidies that would be furnished under the Proposed Arrangement, each Funding Manufacturer—via Requestor—would offer remuneration (the cost-sharing subsidies) to a qualifying Part D enrollee that would be contingent on the purchase of that particular Funding Manufacturer's oncology products (i.e., no Funding Manufacturer would subsidize any other manufacturer's products). This remuneration presents many of the hallmark risks of fraud and abuse that the Federal anti-kickback statute is designed to prevent, including the potential for inappropriately increased costs to Federal health care programs (e.g., through the ability of manufacturers to increase drug prices or set high launch prices as a result of the reduction of beneficiary sensitivity towards the price of the product); potential for beneficiary steering and anti-competitive effects; and possible interference with or skewing of clinical decision-making. Consequently, and for the combination of the following reasons, we conclude that the cost-sharing subsidies under the Proposed Arrangement would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute.

(A) Circumvention of the Part D Design and Risk of Inappropriately Increased Costs to Federal Health Care Programs

The Proposed Arrangement effectively would permit Requestor and Funding Manufacturers to redesign the current Part D cost-sharing structure for qualifying Medicare Part D enrollees for approximately 90 percent of Part D oncology products by implementing a self-designed cost-sharing structure. The proposal raises multiple concerns stemming from this significant abrogation of the cost-sharing requirements instituted by Congress and the potential for inappropriately increased costs to Federal health care programs.

Under the Part D statutory framework, Part D plan sponsors and pharmacy benefit managers ("PBMs") negotiate prices with pharmaceutical manufacturers for Part D drugs.[42] One category of drugs, oncology (antineoplastic), is a protected class under Medicare Part D, which means that formularies for Part D plans must include all drugs in that class, with limited exceptions.[43] According to a recent Congressional Research Service report, "[s]ponsors and PBMs have the most leverage to negotiate rebates when there are competing drugs on the market; they have less ability to secure rebates for sole-source drugs or those in the protected classes." Consequently, the Proposed Arrangement would target a class of drugs over which Part D plan sponsors already have more limited ability to negotiate favorable pricing terms and for which the majority have seen price increases (in both the list price and the price after accounting for estimated rebates and discounts) that exceed inflation.[44] In addition to the more limited ability to negotiate favorable

[42] See Congressional Research Service, Negotiation of Drug Prices in Medicare Part D (updated May 23, 2022), https://crsreports.congress.gov/product/pdf/IF/IF11318.

[43] See section 1860D-4(b)(3)(G) of the Act; 42 C.F.R § 423.120(b)(2)(vi).

[44] See Congressional Research Service, Negotiation of Drug Prices in Medicare Part D (updated May 23, 2022), https://crsreports.congress.gov/product/pdf/IF/IF11318; see also Thomas J. Hwang et al., Price Increases of Protected-Class Drugs in Medicare Part D, Relative to Inflation, 2012-2017, JAMA (July 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6635901/.

pricing terms that already exists, the Proposed Arrangement could further hinder Part D plan sponsors' ability to control costs for this protected class of drugs because, for example, it would largely insulate beneficiaries from price increases or high launch prices.

Specifically, the design of the Proposed Arrangement would circumvent one of the key pricing controls (exposing beneficiaries to the economic effects of drug prices set by manufacturers)[45] that Congress instituted in the current standard Medicare Part D prescription drug benefit and would lay bare the dangers of allowing manufacturers to dictate the terms of this market safeguard.[46] While the Proposed Arrangement would maintain some beneficiary sensitivity to branded drug pricing after eligible Part D enrollees enter the catastrophic phase of the Part D

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[45] See Congress of the United States, Congressional Budget Office, A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit (July 2004), https://www.cbo.gov/publication/15841. Specifically, with respect to its estimate for the Medicare prescription drug benefit, the Congressional Budget Office stated:

> CBO assumed that even the most aggressive use of cost-management tools by drug plans would be unlikely to keep prices for some drugs from rising as a result of a Medicare drug benefit. By reducing the cost to consumers of obtaining covered drugs, the new Medicare drug benefit would correspondingly make Medicare enrollees . . . less sensitive to drug prices. For instance, if a drug's target population consisted mainly of Medicare beneficiaries and close substitutes for that drug did not exist, the manufacturer could raise the drug's price—or, in the case of a new drug, could enter the market with a higher launch price. The loss in sales resulting from that price hike would not be large enough to reduce the manufacturer's profit, however, because beneficiaries would pay only a portion of that higher price. Preventing such price hikes would be difficult without imposing direct price controls or threatening to deny or delay coverage of the drug. Most drugs, however, face competition from close substitutes, and the most likely effect of a Medicare drug benefit would be modest price increases for the subset of drugs that had patent protection or exclusive marketing rights. CBO modeled that 'price effect' as a function of drug spending by enrollees who previously did not have prescription drug coverage . . . . CBO estimated that the cost-sharing requirements of the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003] would limit the extent of that price effect. Beneficiaries . . . would still face the full negotiated price of the drugs they purchased before they reached their deductible and when their spending fell between their initial coverage limit and the catastrophic threshold. Even after they reached the catastrophic threshold, beneficiaries would generally face some coinsurance and thus would not be completely insulated from price increases.

Id.

[46] See generally section 1860D-2(b) of the Act; see also 2005 Bulletin, 70 Fed. Reg. at 70,626 ("Inflated prices could have a 'spillover' effect on the size of direct subsidies, reinsurance payments, and risk corridor payments paid by Medicare to Part D plans in future years, potentially resulting in higher costs to the Medicare program.") (internal citations omitted).

benefit, that sensitivity would be greatly reduced as compared to the current statutory cost-sharing structure enacted by Congress for the catastrophic phase. Simply put, the cost-sharing subsidies offered under the Proposed Arrangement would leave Funding Manufacturers' prices for their products largely unconstrained by a key market control inherent to the current Medicare Part D drug benefit design, while the Medicare program and taxpayers would bear the financial brunt of those unchecked drug prices.

In sum, the Proposed Arrangement would, in effect, create a new cost-sharing design (designed by Requestor and supported by pharmaceutical manufacturers, the latter of whom stand to have a potentially significant financial benefit from any such redesign) for Part D oncology drugs. Requestor's different cost-sharing structure for a class of Part D drugs could result in increased drug prices; improperly increased costs to Federal health care programs, taxpayers, and beneficiaries, including both beneficiaries who do not qualify for the Proposed Arrangement and Part D enrollees who receive subsidies under the Proposed Arrangement; and a potential windfall for manufacturers.[47] While we cannot conclude that the cost-sharing structure proposed by Requestor would, in fact, result in increased drug prices and improperly increased costs to Federal health care programs, the Proposed Arrangement presents significant risk of such outcomes, thus making it inappropriate for OIG to offer prospective immunity in connection with the Proposed Arrangement. It is also not appropriate for pharmaceutical manufacturers, either directly or through Requestor, to use remuneration that is highly suspect under the Federal anti-kickback statute as a way to sidestep the cost-sharing structure that Congress included in the standard Part D benefit. Congress instituted specified cost-sharing requirements in the standard Medicare Part D benefit when it enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; Congress has considered, and recently enacted, changes to these requirements in the Inflation Reduction Act of 2022. OIG defers to Congress in any redesign of cost-sharing requirements under Medicare Part D and declines to exercise its enforcement discretion to permit private parties to rewrite the cost-sharing rules for an entire class of drugs.

(B) Risk of Patient Steering, Anti-Competitive Effects, and Skewed Clinical Decision-Making

Requestor anticipates that manufacturers of drugs constituting approximately 90 percent of Part D oncology utilization would participate as Funding Manufacturers. While the large number of products included might reduce the risk of steering beneficiaries to one product over another, it would not eliminate the risk, and it also could unduly pressure manufacturers to participate as a Funding Manufacturer. More specifically, the Proposed Arrangement carries the risk of penalizing a manufacturer that does not participate because a nonparticipating manufacturer

[47] See, e.g., Dafny supra note 35, at 1270 (noting, in the context of manufacturer-supported patient assistance programs, that the assistance "is likely to worsen the affordability of prescription drugs for the health care system overall. These programs are likely not only to induce the use of assisted drugs (some of which may be cost-ineffective or inappropriate) but also to weaken manufacturers' incentives to accept lower prices from insurers. By undermining patient cost sharing, assistance programs leave insurers with a less effective tool kit for steering utilization and containing spending. As a result, patient assistance programs likely harm a range of stakeholders, including the patients these charities are ostensibly designed to help.").

could be at risk of having beneficiaries steered away from their products if they do not subsidize cost sharing for their products. Insofar as Requestor expects approximately 10 percent of Part D oncology drugs not to be subsidized through the Proposed Arrangement, some of which would be excluded due to a manufacturer being unable or unwilling to become a Funding Manufacturer, we believe the risk to competition for these products is material.

Similarly, because the Proposed Arrangement would include cost-sharing subsidies only for drugs manufactured by Funding Manufacturers, prescribers could be dissuaded from prescribing a product for which a beneficiary would pay the full cost-sharing amount if a different, clinically appropriate drug were covered by the Proposed Arrangement. We recognize that Requestor has certified that individual products would not be advertised or promoted by Requestor or in connection with the Proposed Arrangement, and Requestor would prohibit Funding Manufacturers from advertising the Proposed Arrangement as a reason to prescribe a particular product. However, Requestor also certified that it would make available a list of all covered products in a neutral fashion on a public website and in a practitioner brochure. Therefore, we believe it is reasonable to assume prescribers would learn over time—or immediately, if the prescriber reviews the practitioner brochure, refers to the public website, or if the prescriber works with the patient to apply for subsidies from Requestor—which products are or are not subsidized through the Proposed Arrangement. Consequently, in the event that a prescriber has two clinically appropriate options for treatment, the prescriber could choose the product covered by the Proposed Arrangement, rather than the alternative.

(ii) Contributions for Additional Funding and Operating Costs

In addition to billing Funding Manufacturers for the cost-sharing subsidies distributed for their drugs, Requestor proposes to charge each Funding Manufacturer for its share of a predetermined amount of funding every year for health insurance premium support and programs to increase health equity in clinical trial participation and oncology screening. Requestor also would require Funding Manufacturers to finance Requestor's operating costs. Funding Manufacturers' contributions related to this additional funding and operating costs would depend, in part, on their Part D oncology market share. Some of the remuneration streams that would be created by these contributions implicate the Federal anti-kickback statute because, for example: (i) paying a beneficiary's Medicare premiums enables that beneficiary to purchase items and services payable by a Federal health care program; and (ii) Requestor would require Funding Manufacturers to finance Requestor's operating costs in return for Requestor arranging for eligible Part D enrollees' purchase of federally reimbursable items (i.e., Funding Manufacturers' products) through the distribution of cost-sharing subsidies for such items. While these remuneration streams implicate the Federal anti-kickback statute, we do not include a detailed analysis of the risks of fraud and abuse under the statute associated with the remuneration streams related to the "additional funding" and "operating costs." Instead, this opinion addresses the Proposed Arrangement as a whole, inclusive of these remuneration streams, because, based on the information submitted by Requestor, these contributions would be requirements for Funding Manufacturers to participate in the Proposed Arrangement. We have no facts to suggest that either of these categories of costs and their attendant remuneration streams would exist in the absence of the cost-sharing subsidies, and we cannot analyze them in a vacuum. In other words, these contributions would be intrinsically tied to the Funding Manufacturers' contributions to subsidize cost-sharing amounts for their own drugs and Requestor's use of those

funds to subsidize Part D enrollees' cost sharing, and therefore the Proposed Arrangement, as a whole, would carry the unacceptable risks outlined above with respect to cost-sharing subsidies.

Notably, requiring Funding Manufacturers to contribute to Requestor's operating costs and to contribute additional funding that would support, among other things, certain beneficiaries' health insurance premiums, does not change the fact that each Funding Manufacturer would be individually responsible for funding the cost-sharing subsidies for only its own products. All Funding Manufacturers would be aware that the total amount reflected on the invoice would include three separately calculated categories of costs for three very different purposes, one of which would reflect only cost-sharing subsidies paid for that manufacturer's products. Adding three separate charges together on one invoice does not dilute the risks of fraud and abuse under the Federal anti-kickback statute that we identified above in connection with the cost-sharing subsidies.

We conclude that the Proposed Arrangement, as a whole, would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute.

2. Beneficiary Inducements CMP

In evaluating the Proposed Arrangement under the Beneficiary Inducements CMP, we consider whether Requestor would know or have reason to know that the remuneration it directly would offer (and Funding Manufacturers indirectly would offer) to eligible Part D enrollees would be likely to influence their selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. Requestor is not a provider, practitioner, or supplier, nor does Requestor furnish any items or services reimbursable by Federal health care programs. For purposes of the Beneficiary Inducements CMP, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.

With respect to the Proposed Arrangement, Requestor certified that cost-sharing subsidies would be available without regard to a Part D enrollee's choice of provider, practitioner, Part D plan, or supplier (including pharmacies). Requestor certified that any pharmacy willing to accept the subsidies would be able to do so and that the Administrator would work to ensure that a wide range of pharmacies would accept the subsidies. Therefore, we conclude that the remuneration that would be offered directly by Requestor (and indirectly by Funding Manufacturers) under the Proposed Arrangement would not be likely to influence a beneficiary to select a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, as well as certain publicly available information, we conclude that: (i) the Proposed Arrangement, if undertaken, would generate prohibited remuneration if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections

1128A(a)(7) and 1128(b)(7) of the Act; and (ii) the Proposed Arrangement, if undertaken, would not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP. Any definitive conclusion regarding the existence of a Federal anti-kickback statute violation requires consideration of all of the facts and circumstances of the arrangement as implemented, including a party's intent. The determination of a party's intent is a necessary element to prove that the Federal anti-kickback statute has been violated. Because such a determination is beyond the scope of the advisory opinion process, we cannot reach a definitive conclusion regarding the existence of a Federal anti-kickback statute violation in this opinion.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.

- This advisory opinion may not be introduced into evidence by a person or entity other than Requestor to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Acting Assistant Inspector General for Legal Affairs