



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 associated with the individual or entity, unless otherwise approved by the requestor.]*

**Issued:** September 18, 2020

**Posted:** September 23, 2020

[Name and address redacted]

**Re:   OIG Advisory Opinion No. 20-05**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical manufacturer's proposal to provide cost-sharing assistance directly to Medicare beneficiaries who are prescribed either of two formulations of its drug (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied on the facts and information presented to us and, in accordance with 42 C.F.R. § 1008.39(d), other publicly available information. We have not undertaken an independent investigation of the certified facts and information presented to us by [company redacted], the requestor of this opinion. This opinion is limited to the facts presented to us by [company redacted] and other publicly available information found in the course of our independent inquiry in connection with our assessment of the Proposed Arrangement.

Based on the facts certified in your request for an advisory opinion, supplemental submissions, and other publicly available information, we conclude that: (i) the Proposed Arrangement, as structured, would not generate prohibited remuneration under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act; and (ii) the Proposed Arrangement would generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present and that the Office of Inspector General (“OIG”) could potentially impose administrative sanctions on [company redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback statute violation requires consideration of all of the facts and circumstances of the arrangement as implemented, including a party’s intent.<sup>1</sup> Where, as is the case here, the arrangement is proposed but has not yet been implemented, we cannot reach a definitive conclusion regarding the existence of an anti-kickback statute violation.

This opinion may not be relied on by any persons other than [company redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## **I. FACTUAL BACKGROUND**

### **A. The Disease and Available Treatment Options**

[Disease redacted] ([disease redacted] or the “Disease”) is a progressive, rare disease caused by [description redacted] that can lead to heart failure and death.<sup>2</sup> The Disease can be an inherited condition, known as the hereditary form, or it can occur spontaneously, known as the [description redacted] form. [Company redacted]

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<sup>1</sup> See accord OIG, Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 62 Fed. Reg. 7,351–52 (Feb. 19, 1997), available at <https://oig.hhs.gov/authorities/docs/interim.pdf>.

<sup>2</sup> National Institutes of Health, [source redacted]; see also [Name redacted], [Title redacted], JACC: Heart Failure, [number redacted] [date redacted], available at [website redacted].

(“Requestor”), a pharmaceutical manufacturer, estimated that approximately 100,000 to 150,000 Americans are affected by the Disease.<sup>3</sup>

Requestor manufactures and markets two forms of [drug redacted] (each, a “Medication” and collectively, the “Medications”). In 2019, the U.S. Food and Drug Administration (“FDA”) approved the Medications for the treatment of both [description redacted] forms of the Disease in adults to reduce [description redacted] mortality and [description redacted] hospitalization.<sup>4</sup> Requestor certified that the majority of patients with the Disease are Medicare beneficiaries, and the majority of patients who may be prescribed the Medications will be Medicare beneficiaries. According to Requestor, the Medications are not curative. However, a multicenter, international, double-blind, placebo-controlled phase 3 trial found that one form of the Medications reduced all-cause mortality and the frequency of [description redacted] hospitalizations and also reduced decline in functional capacity and quality of life.<sup>5</sup>

With respect to alternative treatments for the Disease, Requestor certified that there may be non-pharmacological treatments (e.g., a [description redacted] transplant or dual [description redacted] and [description redacted] transplant); while such transplants have had some success, Requestor certified that they have limited application because most patients with the Disease are too sick and have too many comorbidities to meet transplant

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<sup>3</sup> Requestor certified that its prevalence estimate of the Disease is based on information available to Requestor and that such estimate may change over time as knowledge of the Disease improves.

<sup>4</sup> Prior to its approval of the Medications, the FDA had not approved a pharmacological therapy to treat the Disease. According to Requestor, it does not expect FDA approval for a competitor therapy until 2021 or later. Requestor further certified that some patients who could not afford their cost-sharing obligations for the Medications elected to enroll in a phase 3, placebo-controlled, clinical trial for a drug of another manufacturer that is being studied for the treatment of the Disease. Requestor asserted that, even if the FDA were to approve another therapy for the treatment of the Disease, “if the Medications demonstrate superior efficacy and safety” then that superior efficacy and safety would be relevant to the fraud and abuse analysis of the Proposed Arrangement in the same way that the lack of FDA-approved alternatives is now.

<sup>5</sup> [Name redacted], [Title redacted], N Engl J. Med. [number redacted] [date redacted], available at [website redacted].

criteria. In addition, according to Requestor, some physicians prescribe [drug redacted] and [drug redacted] off-label for treatment of the Disease.<sup>6</sup>

Requestor set the list price at \$225,000 for each one-year course of treatment with the Medications. According to Requestor, at this price and based on cost-sharing requirements in the phases of the standard Medicare Part D benefit (i.e., deductible, initial coverage, coverage gap, catastrophic), a Medicare beneficiary enrolled in the standard benefit must pay annually approximately \$13,000 in out-of-pocket expenditures for the Medications. According to Requestor, a significant portion of Medicare beneficiaries cannot afford to purchase the Medications because of these annual out-of-pocket expenses; stated another way by Requestor, these out-of-pocket costs operate as a financial impediment for a substantial portion of the Medicare population, preventing them from purchasing the Medications. Requestor certified that, in 2019, many Medicare beneficiaries filling their first order for the Medications would face \$5,100 in true out-of-pocket (“TrOOP”) spending, and therefore would reach the catastrophic phase (which had a threshold of \$5,100 in 2019) with their first prescription.<sup>7</sup> Requestor also certified that, once beneficiaries are in the catastrophic coverage phase, the coinsurance requirement in that phase would be prohibitive for many beneficiaries.<sup>8</sup>

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<sup>6</sup> According to Requestor, “some physicians have prescribed off-label a drug that is not approved to treat [the Disease] . . . because that other drug is covered under Medicare Part B, for which Medigap insurance is available to reduce the patient’s out-of-pocket expenses.” Requestor further certified that, “[t]here is no question that some physicians may consider drug costs and a patient’s out-of-pocket burden when making prescribing judgments.”

<sup>7</sup> In the catastrophic phase of the Part D benefit, the Medicare program pays 80 percent of the costs for pharmacological therapies through reinsurance; the plan pays 15 percent of these costs; and the beneficiary is responsible for coinsurance equal to the greater of (i) 5 percent of the costs of therapies such as the Medications or (ii) \$3.60 for generic drugs and \$8.95 for brand-name drugs in 2020. See Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System (June 2020), available at [http://www.medpac.gov/docs/default-source/reports/jun20\\_reporttocongress\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/jun20_reporttocongress_sec.pdf?sfvrsn=0); see also Kaiser Family Foundation, An Overview of the Medicare Part D Prescription Drug Benefit (Nov. 2019), available at <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>.

<sup>8</sup> Underscoring the significance of ability-to-pay as an impediment to purchasing the Medications, Requestor stated, “offering co-payment assistance to help eligible patients afford a clinically-appropriate medication, when such medication is the only approved medication for the disease and the principal reason that patients would not fill their

## **B. The Proposed Arrangement**

### 1. The Subsidy Program

Requestor certified that it has designed an assistance program to address the financial impediment of the out-of-pocket costs for the Medications. Specifically, under the Proposed Arrangement, Requestor would institute a cost-sharing assistance program specific to Medicare beneficiaries who are prescribed the Medications (the “Subsidy Program”). To be eligible for financial assistance under the Subsidy Program, the applicant must: (i) be a Medicare beneficiary enrolled in either a Part D plan or a Medicare Advantage – Part D (“MA-PD”) plan that covers the Medications; (ii) be a United States resident; (iii) meet the Subsidy Program’s criteria for financial need, which Requestor would set as a household income between 500 percent and 800 percent of the Federal Poverty Level (“FPL”); and (iv) have been prescribed one of the Medications on-label for the treatment of the Disease. Requestor certified that Medicare beneficiaries with household incomes up to 500 percent of the FPL would continue to be eligible for Requestor’s existing free drug program for the Medications, except that Requestor has required, and would continue to require, that patients not be able to receive assistance from other funding sources, including the Medicare Low-Income Subsidy,<sup>9</sup> in order to be eligible for Requestor’s free drug program.

Requestor certified that it would not offer assistance under the Subsidy Program as part of any advertisement or solicitation for the Medications. According to Requestor, if a beneficiary qualifies for the Subsidy Program, Requestor, through a third-party Subsidy Program administration vendor,<sup>10</sup> would complete enrollment by activating a physical

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prescriptions is the inability to pay their out-of-pocket costs, does not improperly induce the underlying prescribing decisions” (emphasis added).

<sup>9</sup> The Medicare Low-Income Subsidy provides premium and cost-sharing assistance for beneficiaries with household incomes up to 150 percent of the FPL. According to publicly available data, as of March 2020, approximately 27.2 percent of Medicare beneficiaries enrolled in Medicare Part D receive a full or partial subsidy from the Federal government as part of the Medicare Low-Income Subsidy. See Centers for Medicare and Medicaid Services, LIS Enrollment by Plan (Mar. 2020), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/LIS-Enrollment-by-Plan>. Counts and percentages are calculated based on plan enrollments greater than 10.

<sup>10</sup> We have not been asked to opine on, and express no opinion regarding, the arrangement between Requestor and the third-party vendor.

card, issuing a personal identification number to the beneficiary, or both (collectively, the “Subsidy Card”) that the beneficiary would use at the point of sale to receive cost-sharing assistance when purchasing the Medications. Under the Subsidy Program, a beneficiary would be responsible for a monthly copayment of up to \$35 at the point of sale each time he or she fills a prescription for one of the Medications. Requestor, through its vendor, would pay 100 percent of the beneficiary’s remaining cost-sharing obligations for the Medications, including any deductible and required cost sharing owed during the initial coverage phase, the coverage gap phase, and the catastrophic coverage phase.<sup>11</sup> Requestor certified that a beneficiary would be eligible to obtain a Subsidy Card regardless of which provider or practitioner prescribes the Medications.

Requestor certified that the Subsidy Program would provide assistance only for the Medications and would not provide financial support for other FDA-approved pharmacological therapies to treat the Disease or other medical needs of beneficiaries diagnosed with the Disease (*e.g.*, prescription drugs used by the patient in connection with managing the Disease, treating symptoms of the Disease, or treating pain and other side effects of the Disease). Requestor also certified that certain foundations operating patient assistance programs presently have funds covering [disease redacted] (of which the Disease is a type).

Based on publicly available data maintained by the Centers for Medicare and Medicaid Services, approximately 91 percent of Medicare beneficiaries have a household income below 800 percent of the FPL.<sup>12</sup> Of the beneficiaries comprising that 91 percent, based on facts certified by Requestor, those with incomes at or below 500 percent of the FPL would be eligible to receive assistance through either the Medicare Low-Income Subsidy or Requestor’s free drug program, and the balance (with household incomes between 500 percent and 800 percent of the FPL) would be eligible to receive cost-sharing assistance through the Subsidy Program. The remaining 9 percent of Medicare beneficiaries would not be eligible for assistance through the Subsidy Program, Requestor’s free drug program, or the Medicare Low-Income Subsidy.

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<sup>11</sup> Requestor certified that the purpose of the Subsidy Program is “to provide copay assistance directly to eligible Medicare Part D beneficiaries to help them pay the TrOOP costs required to matriculate through the Part D deductible, initial coverage phase and coverage gap and then to assist patients with affording the 5% coinsurance required during the catastrophic phase.”

<sup>12</sup> Centers for Medicare and Medicaid Services, Medicare Current Beneficiary Survey, Survey File data. Baltimore, MD: U.S. Department of Health and Human Services, 2018, available at <https://www.cms.gov/research-statistics-data-and-systemsresearchmcbcodebooks/2018-mcbs-survey-file>.

## 2. The Hub

Requestor has developed a patient support hub, [hub name redacted] (the “Hub”), that is operated by a third-party vendor pursuant to a written services agreement.<sup>13</sup> The Hub would administer the Subsidy Program. Requestor certified that prescribing physicians would be able to contact the Hub to learn about the Subsidy Program.

Requestor certified that the Hub, which is already in place, currently uses the following enrollment process and would employ the process in the same manner for purposes of enrolling patients in the Subsidy Program. First, Requestor certified that, to enroll a patient in the Hub, both the prescriber and the patient must complete and sign a patient enrollment form. According to Requestor, the prescriber must provide prescription information and must confirm that he or she has prescribed the Medication for the treatment of the Disease. The prescriber also must certify that he or she has made an independent judgment that the Medication is medically necessary for the patient and that all information provided on the form is accurate. If the patient seeks financial assistance, the patient also must provide certain financial information and documentation of annual household income.

For purposes of the Subsidy Program, Requestor certified that, once a beneficiary is enrolled in the Hub, the Hub would conduct a benefits investigation to determine coverage for the Medication under the applicant’s Part D or MA-PD plan, including out-of-pocket costs and payor coverage requirements. If the beneficiary seeks financial assistance, the Hub first would conduct alternative funding research to determine if other options (e.g., the Medicare Low-Income Subsidy) are available to provide financial assistance to the beneficiary.

Requestor certified that the Hub would conduct an individualized, case-by-case income determination based on a uniform measure of financial need and would determine a beneficiary’s eligibility for the Subsidy Program in a verifiable, uniform, and consistent manner. Once the Hub verifies that a beneficiary is eligible for the Subsidy Program, it would enroll the beneficiary and would communicate such enrollment to the beneficiary, the prescriber (upon the prescriber’s request), and the applicable specialty pharmacy, as described in more detail below.

## 3. Dispensing Pharmacies

Requestor certified that eligible beneficiaries would be able to use the Subsidy Card at any specialty pharmacy that Requestor authorizes to dispense the Medications (a

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<sup>13</sup> We have not been asked to opine on, and express no opinion regarding, the services arrangement between Requestor and the Hub.

“Dispensing Pharmacy”), and the Subsidy Card would not be conditioned on a beneficiary using a particular Dispensing Pharmacy.<sup>14</sup> Likewise, according to Requestor, the Subsidy Program would not give preference to any particular Dispensing Pharmacy and is structured such that the beneficiary would have the same limited cost-sharing obligation (\$35 per monthly fill) regardless of the Dispensing Pharmacy he or she selects to fill the prescription for the Medications.

According to Requestor, Dispensing Pharmacies are the only pharmacies authorized by Requestor to dispense the Medications to any patient who wishes to purchase the Medications, regardless of whether the patient is eligible for the Subsidy Program. Prior to the commercial launch of the Medications, Requestor conducted a request for proposal (“RFP”) process inviting specialty pharmacies to submit information describing their qualifications to be a Dispensing Pharmacy. To be eligible to serve as a Dispensing Pharmacy, the specialty pharmacy must have met several criteria set forth by Requestor.

At the conclusion of the RFP process, Requestor selected a number of pharmacies that met its criteria. Requestor certified that no other specialty pharmacies have since requested to be a Dispensing Pharmacy. According to Requestor, if other specialty pharmacies were to ask Requestor to participate as a Dispensing Pharmacy, Requestor would evaluate their qualifications under the same criteria referenced above and would base its decision on whether to include the specialty pharmacy on: (i) the ability of the specialty pharmacy to meet the criteria and (ii) whether it is in the best interests of patients to include the additional specialty pharmacy.

Requestor further certified that regional specialty pharmacies that are owned or affiliated with institutions (i.e., hospitals and integrated delivery networks) that: (i) have experience with the Disease, including diagnosing and managing patients diagnosed with the Disease, (ii) agree to contract with Requestor or Requestor’s agent and comply with all contract terms, and (iii) are able to meet certain basic data reporting requirements, are eligible to be a Dispensing Pharmacy. Requestor identified specialty pharmacies owned by or affiliated with institutions that met these requirements, and some of these specialty pharmacies chose to participate as a Dispensing Pharmacy.

Requestor certified that, to its knowledge, there has not been any instance where there were no Dispensing Pharmacies included among the preferred pharmacies in a beneficiary’s Medicare Part D or MA-PD plan. Requestor certified that if a beneficiary’s plan were to require the beneficiary to use a particular specialty pharmacy (“Plan Pharmacy”) and that Plan Pharmacy is a Dispensing Pharmacy, then the beneficiary would be able to use the Subsidy Card at that Plan Pharmacy. If a beneficiary’s plan were to allow the beneficiary to obtain the Medications at more than one Dispensing

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<sup>14</sup> Requestor certified that it does not own or operate, directly or indirectly, any pharmacies that dispense the Medications.



Pharmacy, the Hub would ask the beneficiary and the prescribing physician whether they have a preference. If neither the beneficiary nor the prescribing physician has a preference, the Hub would transfer the prescription to a Plan Pharmacy that is a Dispensing Pharmacy using an objective “round robin” process.

Notwithstanding the foregoing, Requestor certified that, if a Part D or MA-PD plan would otherwise require a beneficiary to use a Plan Pharmacy that is not a Dispensing Pharmacy, the Hub would send the prescription to the beneficiary’s or the prescribing physician’s preferred Dispensing Pharmacy. If neither the patient nor the prescribing physician expresses a preference, the Hub would send the prescription to the Dispensing Pharmacy with the lowest patient out-of-pocket costs (as determined by the Part D or MA-PD plan). If more than one Dispensing Pharmacy offers the patient lowest out-of-pocket costs or if the out-of-pocket costs are the same across all or many Dispensing Pharmacies, the Hub would send the prescription to one of the Dispensing Pharmacies offering the lowest out-of-pocket costs using an objective, “round robin” process. The recipient pharmacy would then address coverage and reimbursement issues with the beneficiary’s plan.

## **II. LEGAL ANALYSIS**

### **A. Law**

#### **1. Federal Anti-Kickback Statute**

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward, among other things, referrals for, or purchases of, items or services reimbursable by a Federal health care program.<sup>15</sup> Where remuneration is paid purposefully to induce or reward referrals or purchases of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.<sup>16</sup>

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<sup>15</sup> See section 1128B(b) of the Act.

<sup>16</sup> 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

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

Congress has developed several statutory exceptions to the Federal anti-kickback statute.<sup>18</sup> In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to sanctions under the anti-kickback statute, even though they potentially may be capable of inducing referrals of federally reimbursable business.<sup>19</sup> The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

## 2. Beneficiary Inducements CMP

A separate section of the Act, section 1128A(a)(5) (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 benefactor 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

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and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991), available at <https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm>.

<sup>17</sup> See, 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), cert. denied, 474 U.S. 988 (1985).

<sup>18</sup> Section 1128B(b)(3) of the Act.

<sup>19</sup> See 42 C.F.R. § 1001.952.

Medicare or a State health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. The Beneficiary Inducements CMP “is a separate and distinct authority, completely independent of the [Federal] anti-kickback statute.”<sup>20</sup>

A distinct definition of “remuneration” applies exclusively to section 1128A of the Act, which includes the Beneficiary Inducements CMP. Specifically, section 1128A(i)(6) of the Act defines “remuneration” to include “the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value.”<sup>21</sup> Section 1128A(i)(6) of the Act also sets forth a number of exceptions to the definition of “remuneration” that apply for purposes of section 1128A of the Act. These exceptions protect certain remuneration from violating the Beneficiary Inducements CMP. These exceptions<sup>22</sup> apply only for the purposes of the definition of “remuneration” applicable to section 1128A of the Act (the CMP statute); they do not apply for purposes of section 1128B(b) of the Act (the Federal anti-kickback statute).

## **B. Analysis**

Under the Proposed Arrangement, Requestor seeks to provide cost-sharing subsidies directly to Medicare beneficiaries who purchase its Medications. As an initial matter, the OIG has been and continues to be extremely mindful of the importance of ensuring that beneficiaries who enroll in Medicare Part D have access to medically necessary drugs. We also recognize that, presently, there are no other FDA-approved pharmacological therapies for treatment of the Disease. Our prior guidance has contemplated this scenario; specifically, we have stated that we believe lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs, including in those instances where there may be only

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<sup>20</sup> OIG, Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From the Health Insurance Portability and Accountability Act of 1996, 63 Fed. Reg. 14,393, 14,395 (Mar. 25, 1998), available at <https://www.govinfo.gov/content/pkg/FR-1998-03-25/pdf/FR-1998-03-25.pdf>.

<sup>21</sup> See also 42 C.F.R. § 1003.110 (defining “remuneration,” for purposes of the regulations implementing the Beneficiary Inducements CMP, to be consistent with the definition of “remuneration” set forth at section 1128A(i)(6) of the Act).

<sup>22</sup> See, e.g., section 1128A(i)(6)(E) of the Act (setting forth the exception for waivers of coinsurance and deductible amounts); section 1128A(i)(6)(F) of the Act (setting forth the exception for remuneration that promotes access to care and poses a low risk of harm to patients and Federal health care programs).

one drug to treat a disease.<sup>23</sup> However, the Subsidy Program proposed by Requestor differs materially from the lawful avenues described in our prior guidance.

In the course of reviewing this request, we found certain publicly available information that relates to the subject of this request for an advisory opinion that was not provided by Requestor but informs our conclusion about the fraud and abuse risks posed by the Proposed Arrangement.<sup>24</sup> Therefore, we first provide additional context—otherwise available to the public—in this analysis.

1. Additional Publicly Available Background Information

According to a study published in 2020, Requestor’s Medications constitute the most expensive [description redacted] drug ever launched in the United States.<sup>25</sup> The study concluded that treating all eligible patients with the Disease with the Medications (n=120,000) would increase health care spending in the United States by \$32.3 billion a year, with nearly all of the budget impact resulting from the cost of the Medications.<sup>26</sup> With respect to the annual increase in spending of \$32.3 billion, the study explained that:

[t]his includes a \$31.9 billion increase in annual prescription drug expenditures, which would increase the total US spending for all prescription drugs by 9.3% (from \$344 billion in 2018 to \$375.9 billion).[] As diagnosis rates increase, as a result of greater awareness about [Disease redacted], increased use of nuclear scintigraphy for accurate diagnosis, and more widespread uptake of genetic tests to screen family members of

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<sup>23</sup> OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSspecialAdvisoryBulletin.pdf> (hereinafter the “2005 Bulletin”); see also OIG, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120 (May 30, 2014), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf> (hereinafter the “2014 Bulletin”).

<sup>24</sup> We conducted an appropriate independent inquiry to better inform our understanding of the Medications and the Disease as it relates to our assessment of the Proposed Arrangement. See 42 C.F.R. § 1008.39(d).

<sup>25</sup> [Name redacted] et al., [Title redacted], Circulation. [number redacted]:[page redacted] (originally published [date redacted]), available at [website redacted].

<sup>26</sup> Id. at [page redacted].

individuals with variant [Disease redacted], the budget impact of [drug redacted] is expected to increase as well.<sup>27</sup>

A recent commentary in *JAMA Cardiology* co-authored by an investigator on the Medications’ pivotal phase 3 clinical trial also raised concerns regarding pricing of the Medications.<sup>28</sup> Further, according to these authors, current estimates that the prevalence of the Disease is approximately 100,000 people in the United States “may be a substantial underestimate of the number of patients eligible for” the Medications.<sup>29</sup>

We likewise take into consideration our recent enforcement history involving conduct by pharmaceutical manufacturers–vis-à-vis foundations that operate assistance programs–that the United States alleged was illegal. To date, the United States has settled enforcement actions totaling more than \$900 million against ten pharmaceutical manufacturers, [information redacted],<sup>30</sup> and four foundations, for conduct solely involving the allegedly illegal use of foundations that operate patient assistance programs as conduits for improper payments to patients.<sup>31</sup> Central to these allegations is a concern that pharmaceutical manufacturers blunt the impact of patient cost sharing to induce

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<sup>27</sup> Id. (internal citations omitted).

<sup>28</sup> [Name redacted]. [Title redacted]. *JAMA Cardiol.* [number redacted]:[page redacted] [citation redacted], available at [website redacted]. (“[T]he very high prices for [the Medications] are not justified and appear to be a particularly egregious example of price gouging.”).

<sup>29</sup> Id. at [page redacted].

<sup>30</sup> See DOJ, Press Release, [Title redacted][date redacted], available at [website redacted]; OIG, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and [Requestor] [date redacted], available at [website redacted].

<sup>31</sup> See, e.g., DOJ, Press Release, Novartis Agrees to Pay Over \$51 Million to Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations (July 1, 2020), available at <https://www.justice.gov/usao-ma/pr/novartis-agrees-pay-over-51-million-resolve-allegations-it-paid-kickbacks-through-co-pay> (noting that the United States has collected over \$900 million from ten pharmaceutical companies relating to similar conduct); DOJ, Press Release, Fourth Foundation Resolves Allegations that it Conspired with Pharmaceutical Companies to Pay Kickbacks to Medicare Patients (Jan. 21, 2020), available at <https://www.justice.gov/usao-ma/pr/fourth-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay> (explaining that four foundations have paid a total of \$13 million to settle similar allegations).

patients to fill prescriptions for costly medications. This, in turn, removes a potential downward pressure on the price of the drugs. Most of these settlements involved concurrent execution of integrity agreements with the OIG.<sup>32</sup>

## 2. Federal Anti-Kickback Statute

In evaluating the Proposed Arrangement under the Federal anti-kickback statute, we look to whether it would involve remuneration to an individual to induce that individual to purchase an item or service for which payment may be made under a Federal health care program. The Proposed Arrangement plainly would. Specifically, under the Subsidy Program, Requestor would provide remuneration in the form of a valuable Subsidy Card to eligible Medicare beneficiaries. To be eligible, a Medicare beneficiary must, among other criteria, be prescribed one of the Medications for treatment of the Disease, meet certain financial need criteria, and be enrolled in a Part D or MA-PD plan that provides coverage for the Medications. These beneficiaries would, in turn, use the Subsidy Card at the point of sale to pay virtually all of the cost-sharing obligations that would otherwise apply for the Medications. In this respect, the Subsidy Program would operate as a quid pro quo—Requestor would offer remuneration (the Subsidy Card) to the beneficiary in return for the beneficiary purchasing one of the Medications.<sup>33</sup> We note also that the Subsidy Card can only be used to pay for Medicare cost-sharing obligations specific to the Medications; it has no value outside of these cost-sharing obligations, and it cannot be used to assist with expenses related to the other medical needs of beneficiaries diagnosed with the Disease (e.g., prescription drugs used by the patient in connection with managing the Disease, treating symptoms of the Disease, or treating pain and other side effects of the Disease).<sup>34</sup>

Requestor certified that beneficiary cost-sharing obligations for the Medications are approximately \$13,000 per year, and Requestor identified inability to pay these cost-sharing obligations as an impediment to a significant portion of Medicare beneficiaries purchasing the Medications. Requestor designed the Subsidy Program to address this

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<sup>32</sup> None of these settlement agreements with the Department of Justice or associated integrity agreements with the OIG involve any admission of wrongdoing by any pharmaceutical manufacturer or foundation.

<sup>33</sup> Any definitive conclusion regarding a prohibited quid pro quo would require consideration of a party's intent when implementing the Proposed Arrangement, which has not yet occurred.

<sup>34</sup> We also note that Requestor has identified foundations that operate patient assistance programs that presently have funds covering [disease redacted]. The Disease is a type of [disease redacted].

impediment. Thus, the Subsidy Card would be offered to beneficiaries to induce them to purchase a covered item by removing what would otherwise be an impediment that would deter such purchase.<sup>35</sup> Based on Requestor’s certifications, a beneficiary would know about the availability of the Subsidy Program at the time he or she purchases the Medications. Accordingly, where a Medicare beneficiary otherwise may be unwilling or unable to purchase the Medications due to his or her cost-sharing obligations, which are driven by the list price of the Medications, the Subsidy Program would induce that beneficiary to purchase the Medications by removing the financial impediment, and the Medicare program would bear the costs for the Medications.<sup>36</sup> Using the language of the Federal anti-kickback statute, Requestor proposes to provide remuneration (the Subsidy Card) to a person (the Medicare beneficiary) to induce that person to purchase an item (the Medications) reimbursable under a Federal health care program (Medicare).<sup>37</sup>

There is no statutory exception or regulatory safe harbor to the Federal anti-kickback statute that would apply to protect the remuneration offered under the Proposed Arrangement.<sup>38</sup> Absent any protection under a statutory exception or regulatory safe

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<sup>35</sup> As we have stated previously, “[t]he meaning of the term ‘to induce,’ which describes the intent of those who offer or pay remuneration in paragraph (2) of the [anti-kickback] statute, is found in the ordinary dictionary definition: ‘to lead or move by influence or persuasion,’” which reflects the “congressional intent to create a very broadly worded prohibition.” 56 Fed. Reg. 35,952 (July 29, 1991), [available at https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm](https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm).

<sup>36</sup> Among the arguments advanced by Requestor in its request for this advisory opinion is that “offering co-pay assistance to help eligible patients afford a clinically-appropriate medication, when such medication is the only approved medication for the disease and the principal reason that patients would not fill their prescriptions is their inability to pay their out-of-pocket costs, does not improperly induce the underlying prescribing decisions.” We disagree with Requestor’s formulation of the legal standard. The central inquiry here is whether one purpose of the remuneration offered and provided by Requestor is to induce the beneficiary to purchase the Medications. If, as Requestor’s formulation indicates, the principal reason a beneficiary would not fill a prescription is inability to pay the out-of-pocket expenses, then remuneration that would address that inability to pay would, without question, influence the patient’s purchasing decision.

<sup>37</sup> Any definitive conclusion regarding a violation of the anti-kickback statute would require consideration of a party’s intent when implementing the Proposed Arrangement, which has not yet occurred.

<sup>38</sup> There is a statutory exception to the Federal anti-kickback statute that protects certain non-routine waivers by pharmacies of cost-sharing obligations. Section 1128B(b)(3)(G)

harbor, we examine whether the Proposed Arrangement would pose more than a minimal risk of fraud and abuse under the anti-kickback statute. While the Proposed Arrangement could help individual beneficiaries access the Medications, this potential benefit neither: (i) changes the fact that the Proposed Arrangement plainly would involve remuneration to an individual to induce that individual to purchase an item for which payment may be made under a Federal health care program; nor (ii) sufficiently mitigates the risks of fraud and abuse present in the Proposed Arrangement. In particular, where, as here, a manufacturer offers remuneration (the Subsidy Card) contingent on the purchase of its products, the remuneration presents many of the traditional risks of fraud and abuse that the anti-kickback statute is designed to prevent, including increased costs to Federal health care programs (e.g., through elimination of beneficiary sensitivity towards the price of the Medications); beneficiary steering and anti-competitive effects; and interference with or skewing of clinical decision making.

In light of these risks, and for the combination of the following reasons, we conclude that the Proposed Arrangement would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute; indeed, we find the Proposed Arrangement highly suspect under the Federal anti-kickback statute because one purpose of the Subsidy Program—perhaps the primary purpose—would be to induce Medicare beneficiaries to purchase Requestor’s federally reimbursable Medications.

a. Risk of Improper Increased Costs to the Medicare Program

The Proposed Arrangement could improperly increase overall costs to the Medicare program by insulating Medicare beneficiaries from the economic effects of the cost of the Medications, thereby abrogating a market safeguard that Congress included to protect against inflated drug prices.

i. Requestor’s List Price

In evaluating the risk of increased costs, we cannot ignore that the initial list price for the Medications—which Requestor set—has been characterized as the most expensive cardiovascular drug ever launched in history, and the facts and circumstances here suggest that the implementation of the Proposed Arrangement, in conjunction with other

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of the Act (42 U.S.C. § 1320a-7b(b)(3)(G)); see also 42 C.F.R. § 1001.952(k)(3) (implementing the statutory exception for a pharmacy’s waiver of beneficiary copayment, coinsurance, and deductible amounts). This statutory exception and regulatory safe harbor do not apply to the Subsidy Program because Requestor is not a pharmacy. Moreover, insofar as Requestor would reimburse the pharmacy on behalf of the Medicare beneficiary, the Proposed Arrangement would operate as a subsidy, rather than a waiver, of the beneficiary’s cost-sharing obligations.



assistance available to patients, is critical to Requestor’s ability to maintain the price at this level.<sup>39</sup> The fact that a new treatment will generate costs to the Federal health care programs in absolute terms is not relevant to our analysis. All treatments generate costs to the Federal health care programs. However, where the projected costs are derived from pricing terms that necessitate the subsidization of cost-sharing obligations for beneficiaries, information about the projected costs is directly relevant to our analysis.

While we do not express any opinion as to the appropriateness of the Medications’ list price, we cannot ignore how the Proposed Arrangement would operate to drive up costs to the Medicare program by providing remuneration to beneficiaries to shield them from the economic impacts of the list price and, in so doing, influence their decision to purchase the Medications.<sup>40</sup> We cautioned against this specific concern in our 2005 Bulletin, where we observed:

[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.<sup>41</sup>

Moreover, we believe there is a significant risk that the Proposed Arrangement could be used to support future increases in the list price, further driving up costs to Federal health care programs and resulting in additional harm to the Medicare fisc.

ii. Abrogation of Part D Program Safeguard

There is a significant risk that the Proposed Arrangement would effectively abrogate statutory cost-sharing requirements under the Medicare Part D program. Specifically, the design of the Proposed Arrangement appears to be calibrated to circumvent one of the

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<sup>39</sup> As noted above, Requestor’s Medications alone could “increase the total US spending for all prescription drugs by 9.3%” if all patients with the Disease were prescribed—and purchased—the Medications. [Name redacted] et al., [Title redacted], Circulation. [number redacted]:[page redacted], (originally published [date redacted]), available at [website redacted].

<sup>40</sup> Id.

<sup>41</sup> 2005 Bulletin, 70 Fed. Reg. at 70,626.

key pricing controls (exposing beneficiaries to the economic effects of drug pricing)<sup>42</sup> that Congress instituted in its design of the standard Medicare Part D prescription drug benefit and would lay bare the dangers of removing this market safeguard.<sup>43</sup>

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<sup>42</sup> 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), available at <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/07-21-medicare.pdf>. 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.

<sup>43</sup> 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).

Simply put, the Proposed Arrangement would leave Requestor's price for the Medications unbridled by a key market constraint inherent to the Medicare Part D drug benefit design, while the Medicare program and taxpayers bear the financial brunt of an unchecked drug price. It is not appropriate for pharmaceutical manufacturers to use remuneration that would be prohibited by the Federal anti-kickback statute as a backdoor way to sidestep the cost-sharing requirements that Congress included in the standard Part D benefit.

iii. Elimination of Cost-Sharing Obligations for Almost All Medicare Beneficiaries

We view the Subsidy Program holistically with other assistance that would be available to Medicare beneficiaries who are prescribed the Medications to demonstrate the potentially improper impact on costs to the Federal health care programs. Requestor certified that the majority of patients who may be prescribed the Medications will be Medicare beneficiaries. Requestor further certified that the cost-sharing obligations present a prohibitive financial barrier for a significant proportion of these Medicare patients. The Subsidy Program would eliminate any meaningful cost-sharing obligations and, operating in conjunction with Requestor's free drug program and the Medicare Low-Income Subsidy, would mean all but approximately 9 percent of Medicare beneficiaries who are prescribed one of the Medications would be able to purchase it without incurring any significant out-of-pocket costs.<sup>44</sup> Nonetheless, under the Proposed Arrangement, Requestor would continue to be paid for, and the Medicare program would continue to bear the cost of, the Medications purchased by all beneficiaries who do not qualify for Requestor's free drug program (including beneficiaries who qualify for the Subsidy Program and beneficiaries who qualify for the Medicare Low-Income Subsidy).

We also note that, in our guidance related to patient assistance programs operated by foundations, we explained that funds that have generous financial need criteria, particularly when a fund is limited to a subset of available drugs or the drugs of a major donor, could be evidence of intent to fund a substantial part of the cost sharing for a

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<sup>44</sup> As discussed in section I(B)(1), *supra*, approximately 91 percent of Medicare beneficiaries have a household income below 800 percent of the FPL, which is the upper income threshold of the Subsidy Program. Those beneficiaries falling between 500 percent and 800 percent of the FPL would be eligible for the Subsidy Program. Those with household incomes below 500 percent of the FPL, which is the lower income threshold of the Subsidy Program, would be eligible for either the Medicare Low-Income Subsidy or Requestor's free drug program. This leaves only approximately nine percent of Medicare beneficiaries (*i.e.*, those with incomes above 800 percent of the FPL) responsible for paying the full cost-sharing amounts when purchasing these Medications.

particular drug for the purpose of inducing the use of that drug.<sup>45</sup> The same concern holds true for purposes of the Subsidy Program, which establishes financial need thresholds that, operating in conjunction with Requestor’s free drug program and the Medicare Low-Income Subsidy, ensure that approximately 91 percent of Medicare beneficiaries would not have any significant out-of-pocket costs associated with the Medications.

Requestor also certified that, based on 2019 thresholds, many Medicare beneficiaries would reach the catastrophic phase with their first purchase of the Medications and that the Subsidy Program is designed to move these beneficiaries into the catastrophic phase of the Part D benefit. Our concern regarding increased costs to the Medicare program is magnified where, as here, the Proposed Arrangement would hasten Medicare beneficiaries’ progression to the catastrophic phase, where the Medicare program pays 80 percent of the costs for pharmacological therapies through reinsurance, in addition to the money the Medicare program has already paid plans to deliver the Part D drug benefit.<sup>46</sup>

b. Risk of Patient Steering and Anti-Competitive Effects

We have longstanding concerns that cost-sharing subsidies provided by a pharmaceutical manufacturer can: (i) have the practical effect of steering beneficiaries to, and locking them into, the manufacturer’s product; and (ii) lead to anti-competitive effects.<sup>47</sup> We believe it would be ill-advised to draw a conclusion with respect to the Proposed Arrangement without considering the facts certified by Requestor surrounding existing treatments for, and potential future advances in treating, the Disease. In addition, the patient’s decision to purchase the Medications does not occur in a vacuum; a critical prerequisite to such decision is the treating physician’s decision to order (or not to order) a prescription for the Medications. In this respect, Requestor acknowledged that “[t]here is no question that some physicians may consider drug costs and a patient’s out-of-pocket burden when making prescribing judgments.” We agree, and we anticipate that the treating physician will consider the costs and the availability of the Subsidy Program when determining the preferred treatment option for a patient. Likewise, because Requestor has set the list price at \$225,000 for each annual course of treatment, we fully expect patients to consider the cost of the Medications—as well as the availability of the Subsidy Program—in evaluating the Medications over an alternative option. In light of these circumstances, we conclude that Requestor’s Subsidy Program would present more than a minimal risk of steering beneficiaries to, and locking them into, the Medications.

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<sup>45</sup> 2014 Bulletin, 79 Fed. Reg. at 31,122.

<sup>46</sup> See 2005 Bulletin, 70 Fed. Reg. at 70,625–26.

<sup>47</sup> Id. at 70,626.

The fact that the Medications are the only FDA-approved pharmacological therapy for the Disease as of today does not alleviate our concerns regarding patient steering and anti-competitive effects. By Requestor's own certifications, patients and their health care providers presently have a choice when selecting a treatment for the Disease and may have additional treatment options in the future. More specifically, Requestor described two medications that physicians have prescribed off-label to treat patients with the Disease and indicated that they are aware of physicians opting to prescribe one of these medications because it is covered under Medicare Part B, for which a beneficiary may have Medigap coverage to defray cost-sharing obligations.<sup>48</sup> We understand that physicians may also consider non-pharmacological treatments (e.g., organ transplants) as an option for at least some patients with the Disease, but we recognize the complexity and severity of these treatments means they may not be a feasible option for many beneficiaries. We take no position on the effectiveness of one treatment over another; we only highlight that where a patient may have a choice in treatment, and the Subsidy Program is designed to influence that choice, there is more than a minimal risk that the remuneration (the Subsidy Card) would steer patients to the Medications.

In addition, the fact that there is no other FDA-approved pharmacological therapy for the Disease available today does not foreclose the possibility that new treatments will emerge, nor that new treatments could be less expensive or equally (or more) effective. Indeed, Requestor's certifications indicate that FDA approval of a competitor therapy in 2021 is a possibility. Even so, Requestor asserted its view that, even if the FDA were to approve another therapy for the treatment of the Disease, "if the Medications demonstrate superior efficacy and safety" then that superior efficacy and safety would be relevant to the fraud and abuse analysis of the Proposed Arrangement in the same way the lack of FDA-approved alternatives is now. We disagree. The Subsidy Program would virtually

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<sup>48</sup> Requestor certified that the list price for these alternative pharmacological treatments is higher than the list price for the Medications. We note, however, that our concerns regarding patient steering derive from the relative costs of treatment options to the beneficiary, rather than the relative costs to the Medicare program. In addition, even if the alternative treatments are more expensive to the Medicare program, that fact does not alleviate our concern that the Subsidy Program would inappropriately increase overall costs to the Medicare program by insulating Medicare beneficiaries from the economic effects of the price of the Medications. In other words, the increased costs to the Medicare program would be a direct result of the improper remuneration in the Subsidy Program. Finally, we note that, standing alone, the fact that the list price of an alternative pharmacological treatment may be higher than the list price of the Medications is not determinative of overall costs to Federal health care programs for the various pharmacological treatment alternatives; any comparison of total costs would likely require a complex economic analysis, the results of which would not address our concerns about the patient-steering risks of the Subsidy Program.

eliminate cost-sharing obligations for the Medications, which could inappropriately divert many beneficiaries with the Disease from any other treatment option—now or in the future—to the Medications because of the minimal out-of-pocket expenses when compared to those for other treatment options. In fact, we believe the Subsidy Program shares many of the risky features of problematic seeding programs insofar as it would steer patients to the Medications now so that these beneficiaries would continue to purchase the Medications in the future, even if other FDA-approved therapies emerge. Further, we believe that the Subsidy Program could negatively affect competition for as long as it remains in existence because it would give a financial advantage to the Medications over competing treatments, regardless of whether such other treatments are equally as effective.<sup>49</sup>

c. Potential Effects on Clinical Decision-Making

While remuneration that would induce a beneficiary to purchase the Medications, standing alone, would implicate the Federal anti-kickback statute, we also believe the remuneration offered under the Subsidy Program could affect a physician’s clinical decision-making, which is relevant to our assessment of the overall risk of the Proposed Arrangement. We recognize that the Proposed Arrangement would not involve remuneration to prescribers; rather, Requestor would offer remuneration to a Medicare beneficiary to induce the beneficiary to purchase the Medications. As discussed above, a critical prerequisite to such decision is the treating physician’s decision to order (or not to order) a prescription for the Medications, and Requestor acknowledged that “[t]here is no question that some physicians may consider drug costs and a patient’s out-of-pocket burden when making prescribing judgments.” In addition, as described above, Requestor certified that some physicians presently prescribe another pharmacological therapy instead of the Medications because the other treatment is a Part B drug, and some beneficiaries have purchased Medigap insurance policies that cover some or all of their Part B cost-sharing obligations.<sup>50</sup> Much like our conclusion that patients would consider the costs of the Medications in deciding their preferred treatment option with their

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<sup>49</sup> “Ensuring fair competition in the health care marketplace is one of the goals of the anti-kickback statute.” OIG, Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63533 (Nov. 19, 1999), available at <https://oig.hhs.gov/fraud/docs/safeharborregulations/getdoc1.pdf>.

<sup>50</sup> Unlike Medigap insurance policies, which beneficiaries may choose to purchase to cover a variety of health care costs and which are a long-standing feature in the Medicare program that must follow requirements and standards set forth by Congress, the Subsidy Program is designed by Requestor in a way that would support the list price for its Medications while undermining the Part D benefit constructed by Congress.

physician, we likewise anticipate that some—if not most—physicians would consider a patient’s out-of-pocket costs for the Medications when deciding whether to prescribe them.

Requestor further certified that a physician must work with a beneficiary to enroll him or her in the Hub and may contact the Hub to find out about the Subsidy Program. The Hub also would communicate patient enrollment in the Subsidy Program to the patient’s prescribing physician (upon the prescriber’s request). Based on these facts, it is reasonable to anticipate that physicians would learn of the Subsidy Program soon after its implementation (e.g., through their first communication with the Hub) and, once a physician is aware of the program, every subsequent prescribing decision would be made with the knowledge that the Subsidy Program is available to minimize out-of-pocket costs for Medicare beneficiaries.

With this knowledge, we believe the Subsidy Program could affect the prescriber’s decision as to whether to order the Medications. To be clear, we are not suggesting that it is inappropriate for a physician to consider costs to patients; however, in these circumstances where Requestor has certified that cost-sharing obligations are the impediment to a significant portion of Medicare beneficiaries purchasing the Medications, we believe that the availability of the Subsidy Card may impact the treating physician’s clinical decision-making, i.e., whether to prescribe the Medications for those beneficiaries. Moreover, both presently and if any new treatments emerge in the future—which Requestor certified could be as early as 2021—we believe there is a risk that the availability of the Subsidy Program could sway a physician to prescribe the Medications over any other treatment, even if such treatments are equally (or more) effective or have a lower overall cost.

### 3. 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 would offer to beneficiaries is 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. Here, we conclude that, although the Subsidy Card is clearly remuneration to a beneficiary, the Proposed Arrangement would not implicate the Beneficiary Inducements CMP.

#### a. Scope of Beneficiary Inducements CMP

As a threshold matter, we note that the Beneficiary Inducements CMP (section 1128A(a)(5) of the Act) contains a different, narrower prohibition than the Federal anti-kickback statute (section 1128B(b) of the Act) and uses a definition of “remuneration” that does not apply for purposes of the Federal anti-kickback statute. The Federal anti-

kickback statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward, among other things, referrals for, or purchases of, any item or service payable by a Federal health care program. In contrast, the Beneficiary Inducements CMP is focused on remuneration that the offeror knows or should know is likely to influence a beneficiary’s selection of a particular provider, practitioner, or supplier for items or services reimbursable by Medicare or a State health care program.

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.<sup>51</sup> Here, Requestor is a pharmaceutical manufacturer, and it does not own or operate, directly or indirectly, any pharmacies that dispense the Medications. Therefore, Requestor is not a “provider, practitioner, or supplier” for purposes of the Beneficiary Inducements CMP. Because Requestor is not a “provider, practitioner, or supplier,” the fact that the Subsidy Card would influence a beneficiary to purchase Requestor’s product (the Medications) would not implicate the Beneficiary Inducements CMP with respect to Requestor, notwithstanding the fact that this same remuneration stream would implicate the Federal anti-kickback statute.

#### b. Analysis of Proposed Arrangement

Where a pharmaceutical manufacturer offers remuneration to a beneficiary that the manufacturer knows or should know is likely to influence the beneficiary to select a particular provider, practitioner, or supplier (e.g., a physician or a pharmacy), that remuneration would implicate the Beneficiary Inducements CMP. In other words, a pharmaceutical manufacturer, such as Requestor, can be the offeror or transferor of remuneration that implicates (and violates) the Beneficiary Inducements CMP.<sup>52</sup> However, based on the unique combination of facts presented in the Proposed

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<sup>51</sup> OIG, Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries (Aug. 2002), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

<sup>52</sup> See 2014 Bulletin, 79 Fed. Reg. at 31,121 (noting that a subsidy for cost-sharing obligations provided by a pharmaceutical manufacturer through an independent foundation’s patient assistance program may implicate the Beneficiary Inducements CMP, if the subsidy is likely to influence a Medicare or State health care program beneficiary’s selection of a particular provider, practitioner, or supplier, such as by making eligibility for the subsidy dependent on, for example, the patient’s use of certain prescribing physicians).



Arrangement, we conclude that the remuneration offered by the Requestor under the Proposed Arrangement is not likely to influence a beneficiary to order the Medications from a particular provider, practitioner, or supplier.

First, under the Proposed Arrangement, Requestor would not make eligibility for the Subsidy Card dependent on the beneficiary's use of certain prescribing providers or practitioners. Requestor certified that a beneficiary would be eligible to obtain a Subsidy Card regardless of which provider or practitioner prescribes the Medications, and Requestor has not provided any facts to indicate that a beneficiary's ability to obtain a Subsidy Card would otherwise be impacted in any way by his or her selection of a particular provider or practitioner. Thus, based on the facts available to us, the remuneration that would be provided to beneficiaries under the Proposed Arrangement would not influence their selection of a particular prescribing provider or practitioner.

Second, Requestor would not make eligibility for the Subsidy Card dependent on the beneficiary's use of a particular pharmacy. Specifically, the remuneration would not be conditioned on the beneficiary using a particular Dispensing Pharmacy, and the Subsidy Program would not give preference to any particular Dispensing Pharmacy. An eligible beneficiary would be able to use the Subsidy Card at any Dispensing Pharmacy, and the amount of assistance that would be offered to a beneficiary under the Subsidy Program would not vary based on which Dispensing Pharmacy furnishes the Medications. That is, the Subsidy Program is structured such that the beneficiary would have the same limited cost-sharing obligation (\$35 per monthly fill) regardless of the Dispensing Pharmacy he or she selects to fill the prescription for the Medications. Thus, the remuneration would not influence the beneficiary's selection of one Dispensing Pharmacy over another Dispensing Pharmacy.<sup>53</sup>

Requestor also certified that beneficiaries would have the opportunity to express a preference with respect to which Dispensing Pharmacy they use to obtain the Medications. Absent a preference, the Hub would select a Dispensing Pharmacy to fill a particular beneficiary's prescription based on the Dispensing Pharmacy with the lowest patient out-of-pocket costs or using a "round robin" process. While we recognize that some beneficiaries may face a more limited set of Dispensing Pharmacies to select from due to their Part D or MA-PD plans having a narrower list of Plan Pharmacies, that

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<sup>53</sup> We contrast this with an arrangement where the nature or structure of the arrangement is such that the offeror knows or should know that the beneficiary would select a particular provider, practitioner, or supplier following the offer or transfer of the remuneration, *e.g.*, an arrangement that requires a beneficiary to use the provider, practitioner, or supplier that is geographically closest to the beneficiary's location. If the Requestor structured the Subsidy Program in such a manner, then the Beneficiary Inducements CMP would be implicated, and no exception would apply.

limitation is due to plan benefit design, not the remuneration offered by Requestor under the Proposed Arrangement. Any remuneration streams associated with such plan benefit designs are outside the scope of this advisory opinion.

Requester further certified that, to its knowledge, there has not been any instance where there were no Dispensing Pharmacies included among the preferred pharmacies in a beneficiary's Part D or MA-PD plan. Requester certified that, if such a circumstance were to arise, the Hub would send the prescription to the beneficiary's or the prescribing physician's preferred Dispensing Pharmacy. Absent a preference, the Hub would select a Dispensing Pharmacy to fill a particular beneficiary's prescription based on the Dispensing Pharmacy with the lowest patient out-of-pocket costs (that would otherwise be charged to the beneficiary but would instead, under the terms of the Subsidy Program, be paid for using the Subsidy Card) or using a "round robin" process.

In addition, Dispensing Pharmacies are the only pharmacies authorized by Requestor to dispense the Medications to any patient who wishes to purchase the Medications, regardless of whether the patient is eligible for the Subsidy Program. Thus, while we recognize that the Subsidy Card may only be used at a Dispensing Pharmacy, it is not the Subsidy Program that dictates that limitation.<sup>54</sup>

### III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement, as structured, would not generate prohibited remuneration under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act; and (ii) the Proposed Arrangement would generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present and that the OIG could potentially impose administrative sanctions on [company redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires consideration of all of the facts and circumstances of the arrangement as implemented, including a party's intent. Where, as is the case here, the arrangement is proposed but

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<sup>54</sup> We distinguish the facts here, where the Medications are available only through a limited number of Dispensing Pharmacies, from circumstances where remuneration influences beneficiaries to select a provider, practitioner, or supplier from a network over non-network providers, practitioners, or suppliers or where the value of remuneration to a beneficiary varies based on which provider, practitioner, or supplier the beneficiary selects. In such circumstances, the Beneficiary Inducements CMP would be implicated.

has not yet been implemented, we cannot reach a definitive conclusion regarding the existence of an anti-kickback violation.

#### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [company redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entity other than [company redacted] 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 is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party 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,

/Robert K. DeConti/

Robert K. DeConti  
Assistant Inspector General for Legal Affairs