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:** March 18, 2021

**Posted:** March 23, 2021

[Name and address redacted]

**Re: OIG Advisory Opinion No. 21-01**

Dear [Name redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [name redacted] ("Requestor") regarding a free drug provided by Requestor to certain patients to whom Requestor's drug has been prescribed (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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.

Requestor has 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 Arrangement, and we have relied solely on the facts and information you provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG

will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

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

Requestor is a pharmaceutical manufacturer that manufactures [drug redacted] (the "Drug"), a [therapy redacted] approved by the U.S. Food and Drug Administration ("FDA") for two indications: (i) patients up to 25 years of age with [disease redacted] that is refractory or in second or later relapse; and (ii) adult patients with relapsed or refractory [disease redacted] after two or more lines of systemic therapy.[2] The Drug is a personalized medicine made from the patient's own cells and is intended to be a one-time, potentially curative treatment. Because of the patient safety risks associated with the Drug, the FDA required Requestor to implement a Risk Evaluation and Mitigation Strategy ("REMS"), which includes elements to assure safe use ("ETASU"). In accordance with the REMS with ETASU, the Drug may be administered only at a health care facility certified by Requestor to meet certain Drug safety requirements (a "Center") and prescribed only by a physician trained to meet the requirements of the Drug's REMS with ETASU (a "Center Physician").[3]

Requestor currently offers the Drug at no charge to patients who satisfy specified criteria ("Eligible Patients"). Requestor certified that the free Drug it provides under the Arrangement is designed to

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

[2] Requestor certified that the Drug is indicated only for patients who have undergone two or more lines of systemic therapy (i.e., the Drug is a treatment of last resort) and for patients who did not respond to their initial treatment(s).

[3] Requestor does not own or operate, directly or indirectly, any providers or suppliers that administer the Drug.

benefit patients who do not have insurance coverage for and cannot afford the Drug.[4] Eligible Patients are individuals who:

- Are U.S. residents;
- Have been prescribed the Drug by a Center Physician, in accordance with the Drug label for an FDA-approved indication;
- Have (i) no health insurance, (ii) no insurance coverage for the Drug, (iii) received a denial of prior authorization and first-level appeal from their insurer, as determined by a Center, or (iv) a first-level appeal for coverage for the Drug that has been pending for at least 10 days, as determined by a Center; and
- Have an annual household income equal to or less than $75,000 for a single-person household and no more than an additional $25,000 per each additional household member.

Typically, the Drug is administered only once; therefore, the vast majority of Eligible Patients receive only one dose of the Drug under the Arrangement.[5] Requestor provides the free Drug to all Eligible Patients for all FDA-approved indications, irrespective of: (i) whether the Drug is administered to an Eligible Patient as a Center inpatient or outpatient; and (ii) the Eligible Patient's type of health insurance, if any (including Federal health care programs). In other words, Requestor offers all similarly situated patients, regardless of payor, access to the free Drug through the Arrangement.

[4] Requestor certified that the wholesale price in the United States of the Drug for [disease redacted] is [amount redacted] and for [disease redacted] is [amount redacted]. Requestor also certified that it does not provide cost-sharing assistance—either directly or indirectly—to any Federal health care program beneficiary who has been prescribed the Drug.

[5] Requestor is sometimes able to manufacture more than a single dose of the Drug out of the cells collected from the patient. Requestor certified that only one patient in 2020 received a second free dose of the Drug. Requestor certified that an Eligible Patient could receive a second dose of the Drug under the Arrangement only in the infrequent circumstances where Requestor manufactures more than a single dose of the Drug out of the patient's original cells and his or her physician determines administration of the second dose is medically necessary.

To Requestor's knowledge, no Medicare beneficiary has qualified as an Eligible Patient or received the free Drug under the Arrangement,[6] nor does Requestor anticipate that a Medicare beneficiary would apply to become an Eligible Patient.[7] However, other Federal health care program beneficiaries, including Medicaid and TRICARE beneficiaries, may qualify as Eligible Patients under the Arrangement.

Requestor certified that an Eligible Patient may receive the free Drug under the Arrangement regardless of which Center or Center Physician the Eligible Patient selects. Requestor also certified that the provision of the free Drug is not contingent on any future orders of the Drug by a Center Physician. When a Center Physician orders (or intends to order) the Drug for a patient, the Center Physician may contact Requestor to determine the patient's eligibility for the Arrangement. In addition, the Center Physician must indicate to Requestor that he or she prescribed the Drug on-label for each Eligible Patient by selecting one of two available indications in the Arrangement's product request form.

Under the Arrangement, the Center and the Center Physician prescribing the Drug must agree to follow certain guidelines established by Requestor, including attesting that neither the Center Physician nor the Center will submit any claim for payment to any Federal health care program for the cost of the Drug.[8] Requestor anticipates Centers and Center Physicians may bill third-party payors, including Federal health care programs, for professional services, facility fees, or other fees for health care items and services provided to Eligible Patients related to administering the free Drug to Eligible Patients, if appropriate. No Center or Center Physician incurs any acquisition cost for the Drug when used for an Eligible Patient under the 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, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable

[6] The Drug may be covered by Medicare. See section 310.1 of the Medicare National Coverage Determinations Manual. According to Requestor, Medicare has not denied coverage for the Drug for any Medicare beneficiary to date.

[7] As of February 2021, 15 Eligible Patients received the Drug under the Arrangement. None of these patients were Medicare beneficiaries.

[8] The physician who completes the product request form also attests to the accuracy of all information on the form.

under a Federal health care program.[9] The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.[10] 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.[11] 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 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. The OIG also may initiate 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

Under the Arrangement, Requestor's provision of the free Drug to Eligible Patients, Centers, and Center Physicians constitutes remuneration and implicates the Federal anti-kickback statute. The Arrangement provides Centers and Center Physicians remuneration in the form of an opportunity

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

[10] Id.

[11] 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).

to earn income or facility fees while administering the free Drug to Eligible Patients, without incurring any acquisition cost for the Drug. Such remuneration may induce Centers and Center Physicians to prescribe the Drug or arrange for or recommend future purchases of the Drug when payable by a Federal health care program. Similarly, the free Drug constitutes remuneration to Eligible Patients, some of whom may be Federal health care program beneficiaries, and may induce them to select the Drug and Federally reimbursed items and services related to Drug treatment. Despite implicating the Federal anti-kickback statute in both instances, for the following reasons we conclude that the Arrangement presents a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute.

First, the Arrangement is distinguishable from other potentially problematic arrangements in which a manufacturer provides drugs for free. The Drug is a potentially curative treatment, generally administered only once, and individually manufactured for the Eligible Patient using the patient's own cells. In addition, the free Drug is only available to patients who have been prescribed the Drug in accordance with the Drug label for an FDA-approved indication. Requestor also certified that provision of the free Drug is not contingent on any future orders of the Drug by a Center Physician.

The risk of seeding (i.e., inducements for future referrals of a drug when it would be payable by a Federal health care program) is unlikely under the Arrangement because a patient only receives one dose (or infrequently, may receive two doses developed from a single patient-cell-removal procedure). Therefore, the Arrangement is distinguishable from problematic arrangements where, for example, a manufacturer offers a free initial dose of a drug for a chronic condition to induce the patient to continue to purchase the drug in the future when it would be billed to Federal health care programs.[12]

Second, the Arrangement is available to patients for both FDA-approved Drug indications. Therefore, the Arrangement is distinct from a suspect arrangement where a manufacturer offers a free drug for one clinical indication to maintain a high price for all of the drug's indications when paid for by Federal health care programs.

Third, Requestor provides the free Drug to all Eligible Patients regardless of whether the Drug is administered to a Center inpatient or outpatient. Access to the free Drug in every care setting

[12] The Arrangement's structure is also distinguishable from problematic arrangements where a manufacturer excludes covered Federal health care program beneficiaries from a manufacturer's free drug program and shifts them to a drug cost-sharing assistance program, subsidized by the manufacturer, to generate revenue from Federal health care programs and to induce purchases of its drug. Although patients with insurance coverage for the Drug are excluded from participating in the Arrangement, Requestor certified that it does not provide cost-sharing assistance—either directly or indirectly—for patients who have been prescribed the Drug. This certification minimizes the risk that Requestor will shift a beneficiary to a cost-sharing assistance program where Requestor directly or indirectly subsidizes the beneficiary's cost sharing for its Drug.

mitigates the risk that the availability of the free Drug will inappropriately steer a patient to one care setting over another. In addition, Requestor offers all similarly situated patients, regardless of payor, access to the free Drug through the Arrangement. This safeguard ensures that the Arrangement will not lead to discrimination against a beneficiary due to payor status.

Finally, we recognize that Centers and Center Physicians may receive a financial benefit under the Arrangement when they earn income, including professional service fees and facility fees in connection with administration of the free Drug. However, the risk that a Center or Center Physician would overutilize the Drug to earn a fee is reduced here because: (i) the Drug is a potentially curative treatment that is generally administered only one time; and (ii) the free Drug is available only when prescribed on-label for patients who have undergone two or more lines of systemic therapy (i.e., the Drug is a treatment of last resort) and for patients who did not respond to initial treatment with other therapies.

For these reasons, we conclude that we will not subject Requestor to sanctions under the Federal anti-kickback statute in connection with the Arrangement.

2. Beneficiary Inducements CMP

In evaluating the Arrangement under the Beneficiary Inducements CMP, we consider whether Requestor would know or should know that the remuneration it offers 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. Under the Arrangement, after a Center Physician prescribes the Drug to an Eligible Patient, Requestor provides the free Drug to the Center Physician to administer to an Eligible Patient at a Center. The provision of the free Drug could constitute remuneration under the Beneficiary Inducements CMP if the free Drug were likely to influence the beneficiary to select Drug treatment by a particular Center or Center Physician where the free Drug is available. However, for the reasons described below, we conclude that the Arrangement does not implicate the Beneficiary Inducements CMP.

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. Here, Requestor is a pharmaceutical manufacturer, and it does not own or operate, directly or indirectly, any providers or suppliers of the Drug. Therefore, Requestor is not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP.

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 implicates 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. However, based on the combination of facts presented in the Arrangement, we conclude that the remuneration offered by Requestor under the Arrangement is not likely to influence a beneficiary to select a particular provider, practitioner, or supplier (i.e., Center or Center Physician) to administer the Drug, and therefore the Beneficiary Inducements CMP is not implicated.[13]

Under the Arrangement, Requestor does not make eligibility for the free Drug dependent on the beneficiary's use of a particular provider, practitioner, or supplier (e.g., a particular Center or Center Physician). Requestor certified that a beneficiary is eligible to obtain the free Drug regardless of which Center Physician prescribes the Drug. Although Eligible Patients are limited to receiving the Drug from Requestor-certified Centers, this requirement is based on the Drug's REMS with ETASU imposed by the FDA to ensure patient safety, not the remuneration offered by Requestor under the Arrangement. In other words, although the free Drug may only be used at a Center or administered by Center Physicians, it is not the Arrangement that dictates that limitation; rather, any patient who receives the Drug can receive it only at a Center whether the patient receives the Drug for free as an Eligible Patient or whether the patient's insurance plan covers the Drug. Thus, based on the facts available to us, we conclude that the remuneration provided to Eligible Patients under the Arrangement is not likely to influence beneficiaries' selection of one Center or Center Physician over another. Accordingly, the Arrangement does not implicate the Beneficiary Inducements CMP, and we will not subject Requestor to administrative sanctions under the Beneficiary Inducements CMP in connection with the Arrangement.

## III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

## IV. LIMITATIONS

The limitations applicable to this opinion include the following:

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

[13] No pharmacies or other similar suppliers participate in the Arrangement.

- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person 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 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 Arrangement and has no applicability to other arrangements, even those that appear similar in nature or scope.

- 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 will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. 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. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs