DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

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

Issued: February 23, 2023

Posted: February 28, 2023

[Address block redacted]

Re: OIG Advisory Opinion No. 23-02

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor"), regarding a program to provide a drug for free, for a limited time, to patients who experience a delay in their insurance approval process for the drug (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 Requestor 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 generate prohibited remuneration under 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

A. The Drug

Requestor, a pharmaceutical company, acquired [redacted] (the "Drug"), an enzyme replacement therapy ("ERT"), in November 2020. The U.S. Food and Drug Administration ("FDA") approved the Drug in October 2018 with a sole indication for the treatment of [redacted] (the "Condition"). The Condition is an inherited genetic disorder that results in a severely compromised immune system, typically diagnosed within a few months of birth.[2] The Condition is fatal if left untreated. Requestor certified that only about 6 to 15 new patients per year are diagnosed with the Condition in the United States.

The only FDA-approved treatments in the United States for the Condition are ERT and bone marrow transplantation ("BMT").[3] Requestor certified that the Drug is the only currently available[4] ERT approved in the United States for treatment of the Condition. The Drug is administered by intramuscular injection, typically by the patient or the patient's caregiver.[5] It does not cure the Condition but treats it on an ongoing basis. Therefore, in the absence of successful BMT or another treatment that may be developed and approved in the future, patients could continue taking the Drug for the rest of their lives. Requestor certified that, as of July 2021, 49 patients in the United States were receiving the Drug to treat the Condition, 6 of whom were Medicare beneficiaries and 32 of whom were Medicaid beneficiaries.

B. The Arrangement

Under the Arrangement, Requestor provides a free 14-day supply of the Drug to patients who meet certain conditions. Specifically, to be eligible to receive a free supply of the Drug, a patient

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

[2] Requestor certified that all 50 states include [redacted] as part of the standard newborn screening panel; the Condition is one type of [redacted].

[3] Requestor certified that: (i) patients can undergo BMT only if a suitable donor is available; (ii) BMT is not successful in all patients who attempt it; and (iii) patients often will be stabilized with ERT before receiving BMT.

[4] Requestor certified that, although another FDA-approved ERT was available in the past, such ERT is no longer being produced and the supply has been fully exhausted.

[5] Requestor certified that the Drug is shipped to the patient. If the patient is new to the Drug, the patient's health care provider may administer the initial dose(s) while the patient is in the hospital, and the provider typically trains the patient or patient's caregiver to administer subsequent doses.

must: (i) be diagnosed with the Condition by a licensed health care professional; (ii) have received a prescription for the Drug but not previously been treated with the Drug; (iii) be insured, regardless of the source of insurance (e.g., commercial payor or a Federal health care program); and (iv) have experienced a delay in a coverage determination for the Drug of at least 48 hours once the patient's insurer has received all required information. In addition, if a patient is still awaiting a coverage determination or has received a denial and is diligently pursuing appeal rights, the patient is eligible for one additional 14-day supply of the Drug.[6] Requestor certified that the 48-hour time period was established based on: (i) the severe nature of the Condition; (ii) existing payor policies; and (iii) Federal and state laws and regulations, some of which Requestor certified already require payors to make coverage determinations within 48 hours or less in like circumstances. If a patient's insurer makes a favorable coverage decision within 48 hours of receiving all required information, then the patient would not be eligible for a free supply of the Drug under the Arrangement, and the Drug would be billed per the patient's plan's requirements, including any applicable cost-sharing requirements.

Requestor certified that eligibility for and participation in the Arrangement are not contingent on any requirement to purchase the Drug. Specifically, both providers and patients or their caregivers are explicitly advised that a patient's participation in the Arrangement does not result in any future purchase obligation. In addition, providers and patients or their caregivers are informed through program materials that neither patients nor providers are permitted to seek reimbursement for the free Drug or administration of the free Drug, even if a provider administers the first dose. Patients or their caregivers are also informed that any free Drug provided under the Arrangement is provided outside the Medicare benefit, if applicable, and that it should not be counted toward the patient's true out-of-pocket ("TrOOP") cost for any Part D enrollee.

Requestor expects that the number of supplies of the Drug dispensed under the Arrangement will continue to be a very small percentage of all prescribed vials of the Drug. Specifically, Requestor expects that only 0.0078 percent or fewer of all prescribed vials of the Drug will be provided under the Arrangement.

Because of the use, storage, and handling requirements associated with the Drug, and the small number of patients nationwide who use the Drug, Requestor works with only one specialty pharmacy, [redacted] (the "Specialty Pharmacy"),[7] to manage prescriptions for the Drug. The Specialty Pharmacy ships the Drug directly to the patient, not to the patient's provider or practitioner. Requestor requires the Specialty Pharmacy to implement certain safeguards for any free Drug distributed under the Arrangement. For example, Requestor requires the Specialty Pharmacy to sign a specific certification stating that the free Drug may not be sold, traded, or distributed for sale, nor may it be billed to a third-party payor for separate reimbursement or payment. In addition, the Specialty Pharmacy notifies the patient's health plan that the free

[6] Requestor certified that the last effort to assess the coverage determination would be made on the 10th day after receiving the first supply so that the patient would receive the second supply, if necessary, by the end of the initial 14 days to avoid a gap in treatment.

[7] Requestor does not own or operate, directly or indirectly, the Specialty Pharmacy, or any other pharmacies, pharmacy benefit management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.

supply of the Drug is provided outside of the plan benefits and that no claim should be filed with a payor by a patient or a provider for the free Drug.

Requestor certified that it does not, nor would it in the future, permit or arrange for any advertisements of the Arrangement, including direct-to-consumer advertisements, on third-party websites or in magazines commonly read by potential patients or prescribing physicians. Requestor also notifies, and will continue to notify, physicians that they are prohibited from marketing their participation in the Arrangement. Requestor's own website may include information (approved by the relevant legal, regulatory, and medical divisions of Requestor) for patients, patient caregivers, and providers about the Arrangement and its terms and conditions, which will emphasize the requirements and limitations discussed above. Requestor's representatives also may distribute Requestor-approved, non-promotional communications to health care providers regarding the Arrangement. Finally, Requestor may include information regarding the Arrangement in certain non-promotional materials (e.g., educational materials about disease states) that are intended to inform the public of the programs and initiatives that Requestor has established and undertaken in efforts to help facilitate the well-being of patients with rare diseases.

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 under a Federal health care program.[8] 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.[9] 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.[10] 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

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

[9] Id.

[10] 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).

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

Requestor, via the Specialty Pharmacy, provides patients with a free 14-day supply of the Drug if they experience a delay in receiving a coverage determination for the Drug from their insurer of at least 48 hours once the insurer receives all required information. Patients may receive one free 14-day refill if the delay continues beyond the initial 14-day period. The Arrangement implicates the Federal anti-kickback statute because patients, some of whom are Federal health care program beneficiaries, receive remuneration (the free 14-day supply of the Drug, with one possible 14-day refill) that could induce future purchases of the Drug, which is an item for which payment may be made by a Federal health care program. Nevertheless, for the following reasons, we find the Arrangement to be sufficiently low risk under the Federal anti-kickback statute.

First, it is unlikely that the Arrangement will lead to overutilization of the Drug. The Drug's sole FDA-approved indication is for treatment of the Condition, and the Arrangement is limited to patients who: (i) have been diagnosed with the Condition by a licensed health care professional; (ii) have been prescribed the Drug; (iii) have not previously been treated with the Drug; and (iv) experience a delay in receiving a favorable coverage decision. If the patient's insurer makes a favorable coverage decision before 48 hours have elapsed, which Requestor certified is required by some Federal and state laws and regulations, then the patient would not be eligible for the Arrangement, and the Drug would be covered by their insurance plan, subject to any applicable cost-sharing amounts. A patient who received the Drug under the Arrangement also would be subject to any applicable cost-sharing amounts for the Drug after the free doses have been administered if insurance coverage is eventually approved. Regardless of whether insurance coverage ultimately is approved or denied, the patient is eligible for no more than a 14-day free supply and possibly a 14-day refill of the Drug under the Arrangement.

Second, the Arrangement is distinguishable from problematic "seeding" programs in which a manufacturer might offer a drug for free or at a greatly reduced cost to induce a patient onto that drug so that the patient will obtain subsequent supplies that would be billed to Federal health care programs. Because the Arrangement is available only in the event of a delay in the

insurance coverage determination process, patients and prescribers likely assume at the time the Drug is prescribed that the patient's insurance will cover the Drug and that the patient will be subject to applicable cost-sharing amounts. Thus, having the Arrangement in place for those cases in which insurance approval decisions extend beyond 48 hours is unlikely to influence patients or prescribers to choose the Drug over alternative therapies, particularly where, as here, the only current treatment alternative is BMT.

Third, the prescriber receives no financial benefit under the Arrangement. The self-administered Drug is dispensed directly to the patient from the Specialty Pharmacy. Therefore, prescribers have no opportunity to bill for the Drug. Even if the prescriber administers the first dose, which could be the dose included in the Arrangement, the prescriber is prohibited from billing an administration fee.

Fourth, the Arrangement entails no cost to Federal health care programs. No patient, pharmacy, payor, or other third party is billed for the free supplies of the Drug or for administration of the Drug. Requestor also certified that, if a Federal health care program beneficiary receives a free supply of the Drug, the Specialty Pharmacy notifies the patient's health plan that the free supply of the Drug is provided outside of the plan benefits and that no claim should be filed by a patient or a provider for such supply. Patients or their caregivers also are informed that any free Drug provided under the Arrangement is provided outside the Medicare benefit, if applicable, and that it should not be counted toward the patient's TrOOP for any Part D enrollee.

Finally, while giving remuneration to a Federal health care program beneficiary to purchase an item or service from a particular pharmacy could implicate the Federal anti-kickback statute, we consider the circumstances present in the Arrangement to be sufficiently low risk. The remuneration is the free Drug, and the Specialty Pharmacy is the only pharmacy that dispenses the Drug. Accepting the free Drug under the terms of the Arrangement does not obligate a patient to continue obtaining the Drug, or any other item or service, from the Specialty Pharmacy in the future.

Our conclusion with respect to the Federal anti-kickback statute is based on the particular facts of this Arrangement. We might reach a different conclusion on different facts, such as if the Arrangement were used as a marketing tool or if Requestor were providing free Drug outside of the context of a legitimate delay in a coverage determination or appeal.

2. Beneficiary Inducements CMP

We also must determine whether the Arrangement is likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. A pharmaceutical manufacturer such as Requestor is not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP unless it also owns or operates, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. Because Requestor does not own or operate, directly or indirectly, the Specialty Pharmacy that dispenses the Drug or other pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs, Requestor is not a provider, practitioner, or supplier for purposes of the Beneficiary Inducements CMP.

Notwithstanding this fact, remuneration offered by a pharmaceutical manufacturer 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 pharmacy) implicates the Beneficiary Inducements CMP. The Specialty Pharmacy is a "supplier," so the Arrangement potentially implicates the statute. However, because the Specialty Pharmacy is the only pharmacy that dispenses the Drug, all patients prescribed the Drug must obtain it from this source, regardless of the Arrangement. Therefore, we conclude that the remuneration offered by the Requestor under the Arrangement is not likely to influence a beneficiary to purchase the Drug from the Specialty Pharmacy. In addition, we believe it is unlikely that the possibility of receiving an initial free supply of the Drug following an insurance delay (with one possible refill) is likely to influence a patient to purchase other federally reimbursable products from the Specialty Pharmacy in the future.

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 generate prohibited remuneration under the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

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

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

- This advisory opinion may not be introduced into evidence by a person 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.

- 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,

/E. Reynolds Wilson/

E. Reynolds Wilson
Acting Assistant Inspector General for Legal Affairs