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: June 17, 2024

Posted: June 20, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-04 (Favorable)

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: (i) a limited-time program to refund, waive, or delay requiring receipt of payment for a drug in the event of an insurance reimbursement denial or delay (the "Refund Program"); and (ii) certain discounts to the cost of the drug (the "Discount Program," and, collectively with the Refund Program, the "Arrangement"). Specifically, with respect to the Refund Program, you have inquired whether this program 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. With respect to the Discount Program, you have inquired whether this program constitutes grounds for the imposition of sanctions under the civil monetary penalty provision at section 1128A(a)(7) of the Act or the exclusion authority at section 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

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, with respect to the Refund Program, we conclude that: (i) although this program would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, OIG will not impose administrative sanctions on Requestor in connection with the Refund Program 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) this program does not generate prohibited remuneration under the Beneficiary Inducements CMP, so OIG will not impose administrative sanctions on Requestor in connection with the Refund Program 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. In addition, based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, with respect to the Discount Program, we conclude that Requestor's offer of remuneration under this program does not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG will not impose administrative sanctions on Requestor in connection with the Discount Program 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.

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 is a U.S. corporate affiliate of the pharmaceutical manufacturer (the "Manufacturer") that developed [redacted] (the "Drug"). Requestor provides support services for the supply chain for the Drug—including all services related to implementation and operation of the Arrangement—on behalf of the Manufacturer.[2] The Drug is a regenerative tissue-based therapy that is indicated for immune reconstitution in pediatric patients with [redacted] (the "Condition"). The Condition is an ultra-rare primary immunodeficiency disorder that affects approximately 17 to 24 out of the approximately 4 million children born each year in the United States. The Condition is characterized by the absence of a thymus at birth, which is an organ that plays an essential role in the development of T cells, a type of infection-fighting white blood cell. Newborn screening for severe combined immunodeficiency, a screening that is required nationwide, can identify possible cases of the Condition, which can then be confirmed by further laboratory testing and diagnosed by the patient's treating physician. Requestor certified that patients with the Condition have high health care utilization because their supportive care involves strict isolation measures, prolonged inpatient hospitalizations, frequent outpatient visits,

[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] We have not been asked to opine on, and we express no opinion regarding, any arrangements between Requestor and the Manufacturer.

home health care, significant diagnostic and monitoring testing, treatment and prophylactic medications, and diagnostic and surgical procedures.[3] Requestor further certified that children with the Condition who receive only supportive care typically die within the first 2 years of life.

Requestor certified that the Drug is a one-time, potentially curative treatment for the Condition.[4] It is the only treatment option available to rebuild the immune system of a patient diagnosed with the Condition; there are no competing treatment options. To make the Drug, donor thymus tissue must be obtained from donors who are 9 months of age or younger and undergoing cardiac surgery. Then, the thymus tissue is aseptically processed and cultured for 12 to 21 days. The Drug is administered via surgical implantation in the thigh muscle of patients with the Condition.

The Drug can be administered only at [redacted] (the "Treatment Center")[5] by a qualified surgeon. The Drug has been investigated at the Treatment Center since 1993, and the Biologics License Application approval letter from the U.S. Food and Drug Administration ("FDA") approved only a single manufacturing facility, which is located on the campus of the Treatment Center. Because the shelf life of the Drug after manufacturing is only 3 hours, it must be implanted in close proximity to the site of manufacturing.[6] If the Treatment Center does not purchase the Drug, it cannot be administered to patients with the Condition. Any Drug that is produced but is not quickly purchased and administered to patients must be destroyed or used for research purposes.

The patient's treating physician, who practices in the patient's local area, is typically the physician who makes the initial diagnosis of the Condition and refers the patient to the Treatment Center for treatment with the Drug (the "Referring Physician"). Requestor certified that it would be exceedingly rare that the Referring Physician would be a doctor who practices at, or is otherwise affiliated with, the Treatment Center because: (i) the Condition affects so few

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[3] Requestor certified that, in the first 3 years of life, the average total economic burden associated with supportive care for patients with the Condition is over $5.5 million but can be as high as $11.7 million.

[4] According to sources provided by Requestor, treatment with the Drug led to estimated survival rates of 77 percent 1 year post-implantation. Further, children who survive the first year post-implantation generally will survive long-term. See [redacted].

[5] Requestor does not own or operate, directly or indirectly, the Treatment Center, any pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. Requestor certified that the Treatment Center is an entity that reports its costs on a cost report required by the U.S. Department of Health and Human Services ("HHS") or a State health care program.

[6] Specifically, Requestor certified that the FDA recognized that the limited distribution system involves manufacturing a single lot of the Drug and transporting it to the Treatment Center on foot to be implanted within 3 hours of manufacture. Requestor does not have—and would need—FDA approval to transport the Drug to other treatment facilities. Requestor has not asked us to opine on, and we express no opinion regarding, this manufacturing arrangement.

children each year; and (ii) the Drug is manufactured and administered only in one location. Even if the Referring Physician were affiliated with the Treatment Center, it would be unlikely that the Referring Physician would be the physician who administers the Drug since the Drug is implanted by a surgeon.[7]

Currently, the wholesale acquisition cost ("WAC") of the Drug is approximately $[redacted]. Requestor certified that, of the patients seeking treatment with the Drug, approximately 50 percent have commercial insurance coverage, approximately 50 percent have Federal health care program coverage (typically through Medicaid, rarely through TRICARE, and not through any other Federal health care programs), and likely none are uninsured. Requestor further certified that no Medicaid program has declined to cover the Drug in any of the cases to date where the Drug was administered to a patient enrolled in Medicaid, and Requestor expects broad Medicaid coverage of the Drug through the inpatient hospital services benefit going forward.[8]

B. The Arrangement

1. Refund Program

Under the Refund Program, subject to certain conditions described in more detail below, Requestor has agreed to: (i) waive or refund the Treatment Center 100 percent of the WAC of the Drug if an insurer refuses to reimburse the Treatment Center despite initially approving the Drug for a particular patient; or (ii) allow the Treatment Center to delay payment for the Drug in the event of reimbursement delays for a particular patient. Although Requestor certified that it is likely that all patients seeking treatment with the Drug have insurance coverage, it also certified that the Treatment Center was hesitant to purchase the Drug (and subsequently make it available to patients) absent the Refund Program. The Treatment Center informed Requestor that its hesitancy was due to concerns about the financial liability it might incur in the event of an insurance reimbursement denial or delay, as many patients would not be able to pay the Treatment Center for the Drug given its significant cost.[9] Requestor certified that it entered into the Refund Program with the Treatment Center to address this hesitancy.

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[7] Requestor certified that, except in the exceedingly rare and unlikely situation that the Referring Physician is affiliated with the Treatment Center and is also the surgeon who administers the Drug, the Referring Physician would receive no financial benefit related to the Refund Program or the procedure to implant the Drug.

[8] The Treatment Center enters into reimbursement agreements for the Drug with State Medicaid programs on a case-by-case basis, and Requestor is not aware of how these agreements are structured with respect to patient cost-sharing obligations. The Drug has not yet been administered to any patient with insurance coverage through TRICARE.

[9] Requestor reported that few Medicaid beneficiaries would be able to discharge an approximately $[redacted] obligation (i.e., the WAC of the Drug), so in most cases the financial risk of non-coverage of the Drug by an insurer would likely be borne by the Treatment Center in the absence of the Refund Program. We have not been asked to opine on, and we express no opinion regarding, any arrangements involving allocation of financial risk between and among

The Refund Program began approximately 7 months after the Drug received FDA approval and continues for a 3-year period (the "Purchase Term"), with the possibility of a waiver or refund under the Refund Program extending for 18 months beyond the Purchase Term (the "Reconciliation Term" and, collectively with the Purchase Term, the "Refund Program Term"). Any Drug delivered to the Treatment Center during the Purchase Term is eligible for the Refund Program, subject to meeting all conditions of the Refund Program. These conditions include, among others:

- Before a patient is administered the Drug, the Treatment Center must have given the patient "Clinical and Financial Clearance," which means that the Treatment Center has: (i) clinically cleared the patient to receive the Drug; (ii) received written approval from the patient's insurer indicating that treatment with the Drug is covered for the patient; and (iii) signed an agreement with the insurer specifying the terms and conditions on which the insurer will reimburse the Treatment Center for the Drug and related inpatient and outpatient hospital and provider services (the "Special Pricing Agreement").

- The Treatment Center must comply with all known prior authorization and claims processing requirements of the patient's insurer related to the administration of the Drug.

- If reimbursement is initially denied because of the Treatment Center's administrative or procedural error, the Treatment Center must submit a corrected claim to the insurer. In addition, the Treatment Center must appeal a final reimbursement denial through the first level of appeal.

- Requestor does not advertise the Refund Program to patients or Referring Physicians.

- Requestor reports the existence of the Refund Program on invoices for the Drug delivered to the Treatment Center, and the Treatment Center reports to the insurer, and reflects in its cost reports, any waiver of payment or refund issued by Requestor.

- The Treatment Center and Requestor provide to Federal and State health care officials upon request all information related to waivers of payment and refunds for the Drug.

Provided all conditions of the Refund Program are met, the Treatment Center generally is required to pay Requestor for the WAC of the Drug by the earlier of the following two dates (each subject to an extension of 15 business days): (i) 18 months after the date that the Drug was delivered to the Treatment Center; or (ii) within 60 days after the date on which the Treatment Center receives reimbursement for the Drug from the insurer.[10] However, if the Treatment

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the Treatment Center, the patient, or any other persons for the WAC of the Drug in the case of non-coverage by insurance in the absence of the Refund Program.

[10] These payment timeframes are longer than the timeframes for payment of the Drug outside of the Refund Program Term (under the procurement agreement that governs the terms of the Treatment Center's purchase of the Drug from Requestor) to permit delayed payment under the Refund Program in the event of insurance delays.

Center pays Requestor for the full WAC of the Drug before it receives payment from the insurer and coverage of the Drug is later denied by the insurer (and the Treatment Center is unsuccessful in its appeal of that denial through the first level of appeal), then Requestor will refund the Treatment Center for the full WAC of the Drug. If the Treatment Center receives a coverage denial from the insurer for the Drug before payment is due to Requestor (and the Treatment Center is unsuccessful in its appeal of that denial through the first level of appeal), then Requestor will issue a waiver to the Treatment Center for the full WAC of the Drug.[11]

In the event Requestor provides a refund or waiver for the WAC of the Drug to the Treatment Center under the Refund Program, the Treatment Center returns to the patient any collected cost-sharing amounts that apply to the Drug. In this way, Requestor assumes the financial risk that otherwise would be held by the patient if the insurer denies coverage of the Drug, because the patient normally would incur a financial obligation to the Treatment Center for the WAC of the Drug in this instance.[12] Ultimately, this results in the patient receiving the Drug for free.[13]

In Requestor's experience with the Refund Program, no insurer has denied coverage of the Drug after providing written approval indicating that treatment with the Drug is covered for the patient, and Requestor believes the risk of an insurer doing so in the future is very low.[14] In

[11] Requestor does not provide a refund or waiver for the WAC of the Drug to the Treatment Center based on only partial reimbursement denials (i.e., underpayment of the Drug) by the insurer; it provides a refund or waiver for the WAC of the Drug only if the full WAC is denied by the insurer. We have not been asked to opine on, and we express no opinion regarding, any arrangements involving allocation of financial risk between and among the Treatment Center, the patient, or any other persons in the event of partial reimbursement denials (as opposed to full reimbursement denials) for the Drug by insurance.

[12] Because Requestor does not advertise the Refund Program to patients or Referring Physicians, Requestor believes it is unlikely that patients or their caregivers would learn of the existence of the Refund Program until after the insurer denies coverage of the Drug and all conditions of the Refund Program have been met, at which point the patient already would be a patient of the Treatment Center and already would have received the Drug.

[13] Requestor does not cover any expenses related to the cost of care provided during the patient's hospital stay that is in addition to the Drug, e.g., the hospital facility fee. The patient would remain financially responsible for the costs of any services provided by the Treatment Center, subject to any independent financial arrangement between the Treatment Center and the patient. We have not been asked to opine on, and we express no opinion regarding, any arrangements involving allocation of financial risk between and among the Treatment Center, the patient, or any other persons for the cost of care provided during the patient's hospital stay that is in addition to the Drug.

[14] Requestor reported that theoretical circumstances in which an insurer could provide written approval indicating that treatment with the Drug is covered for the patient and then later deny coverage of the Drug include: (i) the Treatment Center making a material administrative error in filing the claim that cannot be cured; or (ii) a commercial insurer using a stop-loss or reinsurance plan providing written approval indicating that treatment with the Drug is covered without first

addition, in Requestor's experience with the Refund Program, Requestor has not waived, refunded, or delayed requiring receipt of payment for the Drug because the conditions for doing so have not been met, and Requestor believes that it is unlikely that the conditions for doing so will be met in the future.

2. Discount Program

Under the Discount Program, Requestor offers a discount on the price of the Drug to the Treatment Center when certain conditions are met.[15] Currently, there are many months between the date that the Treatment Center first seeks Clinical and Financial Clearance for a patient—which includes the Treatment Center signing a Special Pricing Agreement with the patient's insurer specifying how the insurer will reimburse the Treatment Center for the Drug—and the date that a lot of the Drug is delivered to the Treatment Center for implantation in the patient. The latter date is the date that payment for the Drug is due to Requestor. Requestor reported that it is possible that the WAC of the Drug could change during the months that pass between the date that a Special Pricing Agreement is signed and the date that a lot of the Drug is delivered.[16] Requestor created the Discount Program to give the Treatment Center more predictability regarding the price of the Drug during this timeframe.

The Discount Program applies when the WAC in effect on the date of execution of the Special Pricing Agreement is lower than the WAC for the Drug in effect on the date of delivery of the Drug to the Treatment Center. When this occurs, Requestor reduces the price it charges the Treatment Center for the Drug in an amount equal to the positive difference between the respective WAC amounts on those two dates, which is the amount not reimbursed by the insurer (since the Special Pricing Agreement contemplated the lower WAC amount).[17] Requestor certified that this price reduction is based on an arms-length transaction. The Discount Program is available to the Treatment Center regardless of whether the relevant patient is covered by a Federal health care program or by another payor.

Requestor certified that: (i) the Discount Program involves a "discount" meeting the definition of that term in the discount safe harbor, 42 C.F.R. § 1001.952(h); and (ii) Requestor meets the

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confirming coverage with the stop-loss or reinsurance plan, later determining the Drug is not covered by such plan, and being unable to afford to pay the claim.

[15] Requestor certified that part of its service obligations to the Manufacturer include promoting the purchase of the Drug by the Treatment Center at this discounted price.

[16] Requestor is required to provide notice to the Treatment Center at least 90 days in advance of any change to the WAC for the Drug, which allows the Treatment Center to incorporate the updated price into future Special Pricing Agreements. Requestor recently provided the Treatment Center with 90 days' notice of a price increase.

[17] The Discount Program does not apply, however, when a Special Pricing Agreement provides for insurance reimbursement that adjusts based on changes in the WAC of the Drug; the insurer covers any increased price of the Drug in that instance.

applicable obligations of an "offeror" under that safe harbor. Requestor also certified that it: (i) notifies the Treatment Center—both in the procurement agreement related to the purchase of the Drug and in the Drug's invoice—of its obligations to reflect any discount in an applicable cost report and to provide information about the discount upon request by HHS or a State agency; and (ii) refrains from doing anything that would impede such obligations.

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.[18] 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.[19] 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.[20] 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, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[21] In addition, HHS has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an

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

[19] Id.

[20] 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).

[21] Section 1128B(b)(3) of the Act.

exclusion.[22] However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis.

The safe harbor for discounts[23] potentially applies to the Discount Program. This safe harbor interprets and expands upon a statutory exception that protects "a discount or other reduction in price obtained by a provider of services or other entity under [Medicare or a State health care program] if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under [Medicare or a State health care program]."[24] The discount safe harbor specifies different requirements for sellers, buyers, and offerors of discounted items and services.[25] As explained in more detail below, for the remuneration offered under the Discount Program to be protected under the discount safe harbor, Requestor would have to comply with the requirements for offerors.

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. 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. Refund Program

a) Federal Anti-Kickback Statute

The Refund Program implicates the Federal anti-kickback statute in two ways. First, in exchange for the Treatment Center's agreement to purchase the Drug (which may be paid for by a Federal health care program), Requestor offers or pays remuneration to the Treatment Center in the form of a reimbursement guarantee, i.e., waiving or refunding the WAC of the Drug if the patient's insurer denies reimbursement, or delaying the payment date if the insurer delays

[22] 42 C.F.R. § 1001.952.

[23] Id. § 1001.952(h).

[24] Section 1128B(b)(3)(A) of the Act.

[25] See 42 C.F.R. § 1001.952(h)(1)–(3).

reimbursement. Second, Requestor indirectly offers or pays remuneration to patients who receive treatment with the Drug, some of whom are Federal health care program beneficiaries, in the form of a guarantee, i.e., assuming the financial risk that otherwise would be held by the patient if the insurer denies coverage of the Drug. Specifically, a patient who receives treatment with the Drug and whose claim for the Drug is subsequently denied normally would incur a financial obligation to the Treatment Center for the WAC of the Drug; but under the Refund Program, if a payor denies a claim for the Drug, Requestor provides a refund or waiver for the WAC of the Drug to the Treatment Center, and the Treatment Center returns to the patient any cost-sharing amounts that the patient had paid for the Drug. Ultimately, this results in the patient receiving the Drug for free.

No safe harbor applies to the Refund Program. Because the Refund Program implicates the Federal anti-kickback statute and is not protected by a safe harbor, we evaluate the Refund Program based on the totality of the facts and circumstances. For the combination of the following reasons, we believe the risk of fraud and abuse presented by the Refund Program is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion with respect to this program.[26]

First, the Refund Program is limited in scope and time. The Drug is a one-time, potentially curative treatment, meaning that the Refund Program, if triggered, would occur only once per patient. In addition, because the Condition is an ultra-rare disorder (affecting only 17 to 24 out of every 4 million children born each year in the United States), the potential universe of patients who may be eligible for the Refund Program is quite small. Moreover, conditions of the Refund Program include that the Treatment Center must have received written approval from the patient's insurer indicating that treatment with the Drug is covered for the patient. For this reason, it is likely that the Treatment Center will receive reimbursement from insurers for the Drug in most instances during the Refund Program Term, so the Refund Program is unlikely to be triggered. Indeed, in Requestor's experience with the Refund Program, no insurer has provided written approval indicating that treatment with the Drug is covered for the patient and then later denied coverage of the Drug, and Requestor believes the risk of an insurer doing so in the future is very low. Finally, the timeframe of the Refund Program is limited—i.e., to be eligible for the Refund Program, the Drug must have been purchased during the 3-year period of the Purchase Term, with the possibility of a waiver or refund under the Refund Program extending for the 18-month period of the Reconciliation Term.

Second, the nature of the Condition and the Drug reduces the risk that the Refund Program would result in interference with clinical decision-making, overutilization, or inappropriate utilization. The Drug is a one-time, potentially curative treatment, and it is the only treatment option available to rebuild the immune system of a patient diagnosed with the Condition; there are no competing treatment options. The Condition is identified through nationally required newborn screening and confirmed by additional laboratory testing, and it affects only 17 to 24

[26] We emphasize that this conclusion is based on the combination of the reasons stated herein, and that we may have reached a different conclusion if, for example, the Drug was not one-time and potentially curative, the Condition was not ultra-rare, or there were competing treatment options.

out of every 4 million children born each year in the United States. The Drug is made from thymus tissue that is obtained from donors who are 9 months of age or younger and who are undergoing cardiac surgery, and it then is aseptically processed and cultured for 12 to 21 days to produce the Drug; this is not a mass-produced Drug and does not appear to be subject to risks of inappropriate utilization. In addition, except in the exceedingly rare and unlikely situation that the Referring Physician is affiliated with the Treatment Center and is also the surgeon who administers the Drug, the Referring Physician would receive no financial benefit related to the Refund Program or the procedure to implant the Drug.

Third, the risk of inappropriate utilization of the Drug by the Treatment Center is lowered because it is in the Treatment Center's financial interest to administer the Drug only in circumstances that satisfy the requirements for coverage (as specified by the insurer in writing). This is because Requestor does not: (i) provide a refund or waiver for the WAC of the Drug to the Treatment Center based on only partial reimbursement denials (as opposed to full reimbursement denials) of the Drug by the insurer; or (ii) cover any expenses related to the cost of care provided during the patient's hospital stay that are in addition to the Drug, and it is possible that the Treatment Center ultimately could be responsible for these costs.

Finally, the Refund Program is unlikely to increase costs inappropriately to Federal health care programs. Patients with the Condition have extensive health care needs, with an associated average total economic burden of over $5.5 million—or significantly higher—in the first 3 years of life. Because the Drug is a one-time, potentially curative treatment that may rebuild the immune system of a patient diagnosed with the Condition, it ultimately has the potential to offset some of the costs that these patients might otherwise incur for their supportive care. Furthermore, there are a number of transparency measures taken under the Refund Program, including that Requestor reports the existence of the Refund Program on invoices for the Drug delivered to the Treatment Center; the Treatment Center reports to the insurer, and reflects in its cost reports, any waiver or refund issued by Requestor; and the Treatment Center and Requestor provide to Federal and state health care officials upon request all information related to waivers and refunds for the Drug. These measures reduce the likelihood of the Refund Program inappropriately increasing costs to Federal health care programs.

b) Beneficiary Inducements CMP

Under the Beneficiary Inducements CMP, we must analyze whether Requestor knows or should know that the remuneration it provides under the Refund Program is likely to influence a 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 facts here potentially implicate the Beneficiary Inducements CMP because the Treatment Center is a provider that Refund Program beneficiaries could be induced to select.

As described in the Federal anti-kickback statute analysis above, Requestor indirectly offers or pays remuneration to patients who receive treatment with the Drug, some of whom are Federal health care program beneficiaries, in the form of a guarantee, i.e., assuming the financial risk that otherwise would be held by the patient if the insurer denies coverage of the Drug. Having established that Requestor is offering or paying remuneration, the next question under the Beneficiary Inducements CMP is whether this remuneration is likely to influence patients to

select the Treatment Center as their provider of items and services payable by Medicare or a State health care program. We believe the answer is no. Because the Drug can be administered only at the Treatment Center (due to limitations related to its manufacturing and distribution), all patients treated with the Drug must obtain it at this location, regardless of the Refund Program. In other words, patients do not have the ability to select from among a choice of providers; they must obtain it at the Treatment Center. Therefore, we conclude it is the limitations related to the manufacturing and distribution of the Drug, rather than the remuneration offered or transferred to a patient under the Refund Program, that would be likely to influence a patient to select the Treatment Center for items and services for which payment may be made, in whole or in part, by Medicare or a State health care program. As such, we conclude that any remuneration offered or transferred to a patient under the Refund Program is unlikely to influence a patient to select the Treatment Center for items and services for which payment may be made, in whole or in part, by Medicare or a State health care program.[27] Having reached that conclusion, it is not necessary to analyze whether Requestor knows, or should know, that the Refund Program is likely to influence patients to select the Treatment Center as their provider of the Drug.

For the foregoing reasons, we conclude that the Refund Program does not generate prohibited remuneration under the Beneficiary Inducements CMP.

2. Discount Program

The Discount Program implicates the Federal anti-kickback statute because, in exchange for the Treatment Center's agreement to purchase the Drug (which may be paid for by a Federal health care program), Requestor offers remuneration to the Treatment Center in the form of a discount on the price of the Drug. That is, when the WAC in effect on the date of execution of the Special Pricing Agreement (when reimbursement for the Drug was determined with the insurer) is lower than the WAC for the Drug in effect on the date of delivery of a lot of the Drug to the Treatment Center (when payment is due), Requestor reduces the amount owed by the Treatment Center to the lower amount. For the reasons described below, we conclude that Requestor's offer of remuneration under the Discount Program is protected by the statutory exception and regulatory safe harbor for discounts. Therefore, Requestor's offer of remuneration under the Discount Program does not generate prohibited remuneration under the Federal anti-kickback statute.[28]

[27] While we believe the lack of choice in provider (entirely unrelated to the remuneration offered by Requestor under this program) is dispositive to this conclusion, there is another reason that supports our conclusion that the remuneration is not likely to influence patients. Specifically, because Requestor does not advertise the Refund Program to patients or Referring Physicians, Requestor believes it is unlikely that patients or their caregivers would learn of the existence of the Refund Program until after the insurer denies coverage of the Drug and all conditions of the Refund Program have been met, at which point the patient already would be a patient of the Treatment Center and already would have received the Drug.

[28] As stated below, this advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person—including the Treatment Center as the buyer of the Drug and the Manufacturer as the seller of the Drug.

First, Requestor certified that the Discount Program involves a "discount" meeting the definition of that term in the discount safe harbor. The term "discount" is defined there as "a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction."[29] This definition includes certain exceptions, including that the discount cannot be in the form of cash or a cash equivalent and cannot be a reduction in price applicable to one payor but not to Federal health care programs.[30] Here, Requestor potentially provides a reduction in the amount a buyer (i.e., the Treatment Center) is charged for an item (i.e., the Drug), and Requestor certified that this reduction is based on an arms-length transaction. Additionally, this reduction in price does not meet any exceptions to the definition of "discount" because, for example, it is not in the form of cash or a cash equivalent and is applicable regardless of whether the relevant patient is covered by a Federal health care program or by another payor.

Second, Requestor certified that it meets the applicable obligations of an "offeror" under the discount safe harbor.[31] Requestor is an "offeror" under that safe harbor because, as Requestor certified, it promotes the purchase of an item (i.e., the Drug) by a buyer (i.e., the Treatment Center) at a reduced price, and the Drug is an item for which payment may be made, in whole or in part, under a Federal health care program. The Treatment Center is a cost-reporting entity, so Requestor must comply with the standards applicable when the buyer is a cost-reporting entity, which are that Requestor must: (i) inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request as specified under the safe harbor; and (ii) refrain from doing anything that would impede the buyer's ability to meet its obligations under the safe harbor.[32] These requirements are met here because Requestor certified that it: (i) informs the Treatment Center of its reporting obligations (i.e., its obligations to reflect any discount in an applicable cost report and to provide information about the discount upon request by HHS or a State agency) in the procurement agreement for the Drug and in the Drug's invoice; and (ii) refrains from doing anything that would impede the Treatment Center from meeting such obligations.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, with respect to the Refund Program, we conclude that: (i) although this program would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, OIG will not impose administrative sanctions on Requestor in connection with the Refund Program 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) this program does not generate prohibited remuneration under the Beneficiary Inducements CMP, so OIG will not impose administrative sanctions on Requestor in connection with the Refund

[29] 42 C.F.R. § 1001.952(h)(5).

[30] See id.

[31] See id. § 1001.952(h)(3).

[32] See id. § 1001.952(h)(3)(ii).

Program 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. In addition, based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, with respect to the Discount Program, we conclude that Requestor's offer of remuneration under this program does not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG will not impose administrative sanctions on Requestor in connection with the Discount Program 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.

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 HHS.

- 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.

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. 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, 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 OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs