



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 4, 2022

**Posted:** February 9, 2022

[Name and address redacted]

**Re: OIG Advisory Opinion No. 22-02**

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 proposed arrangement between Requestor and two individuals, pursuant to which Requestor and the individuals would reduce and subsidize certain costs incurred by qualifying patients of Requestor’s children’s hospital (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

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 Proposed 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 Proposed 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 Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed 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) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement 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<sup>1</sup> 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 Children’s Hospital and Its Patients**

Requestor, a tax-exempt organization under section 501(c)(3) of the Internal Revenue Code, operates multiple hospitals, including the [name redacted] (“Children’s Hospital”). Most Federal health care program beneficiaries treated at Children’s Hospital face no out-of-pocket expenses related to their care because they are under the age of 18 and covered by Medicaid, which does not impose cost-sharing obligations for Medicaid-billable items and services provided to children. Requestor certified that approximately [number redacted] percent of children treated at Children’s Hospital are either Medicaid beneficiaries or not Federal health care program beneficiaries.<sup>2</sup> Requestor also certified that this Federal health care program payor mix has been relatively consistent in recent years.

### **B. The Proposed Arrangement**

Two individuals, [name redacted] and [name redacted] (“Donor A” and “Donor B,” respectively) have entered into an agreement (the “Contribution Agreement”) with Requestor under which Donor A and Donor B would make a donation to Requestor with an estimated value between [number redacted] and [number redacted] (the “Donation”).<sup>3</sup> The Donation would be made via a

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<sup>1</sup> 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.

<sup>2</sup> Requestor certified that its payor mix of Federal health care programs that may have cost-sharing obligations includes Medicare, TRICARE, Dual Eligible Special Needs Plans, the Civilian Health and Medical Program of the Department of Veterans Affairs, State Children’s Health Insurance Program (“S-CHIP”), and Health Resources and Services Administration’s Ryan White HIV/AIDS Program.

<sup>3</sup> Requestor certified that the actual Donation amount is uncertain because the Donation would be made as the remainder of Donor A’s estate, and multiple factors would impact the amount of the contribution between now and the time that it is made, including changes to the overall value of the estate itself (e.g., through increases and decreases in the various investments constituting the estate), as well as any changes Donor A may make to the distributions from the estate.

testamentary gift from Donor A’s estate, which would name Requestor as a beneficiary. Requestor certified that neither Donor A nor Donor B (nor any defined representative of Donor A’s estate) are providers or suppliers of health care items or services, and they are not otherwise involved in the health care industry aside from other charitable endeavors in which they may engage by making donations individually or through foundations.

The Donation would be used to establish a restricted endowment fund (the “Fund”) that would: (i) be subject to specific rules governing how Requestor can use monies from the Fund; and (ii) be used to subsidize patient bills for families with children who have an established treatment relationship with physicians at Children’s Hospital and who receive services provided by one or more of the programs described below (“Qualified Families”). The terms of the Contribution Agreement condition Requestor’s receipt of the Donation on Requestor making certain reductions in a Qualified Family’s bills before the Fund can be used to subsidize that bill. Under the Proposed Arrangement, Requestor and the Fund would pay all out-of-pocket costs owed to Requestor incurred by Qualified Families for their child’s medical care from specified programs, as detailed below. These out-of-pocket costs would include inpatient and outpatient hospital costs and any professional fees for items and services provided by Requestor’s employed physicians.<sup>4</sup>

Initially, under the Proposed Arrangement, monies from both Requestor and the Fund would be used to pay out-of-pocket expenses that otherwise would be owed to Requestor by Qualified Families whose children receive treatment in the cancer, cardiac, or neurosurgical programs at Children’s Hospital (the “Initial Supported Programs”). If there are remaining sums in the Fund after monies are allocated for all Qualified Families that receive services through the Initial Supported Programs, Requestor may use monies in the Fund to pay for Qualified Families’ out-of-pocket expenses for other services provided at Children’s Hospital, after consultation with and consent by Donor B or a defined representative of Donor A’s estate (the “Supported Programs”) and up to an annual limit determined by Requestor.<sup>5</sup>

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<sup>4</sup> Requestor certified that compensation for its employed physicians is fixed and does not (directly or indirectly) take into account, or vary based on, the volume or value of referrals to or from these physicians. Approximately 85 percent of the physicians on Requestor’s active medical staff are employed by Requestor. Further, under the Proposed Arrangement, neither Requestor nor the Fund would: (i) pay non-employed physicians for their professional services; or (ii) cover any cost-sharing obligations incurred by Qualified Families that are due to non-employed physicians.

<sup>5</sup> Requestor certified that it would invest the Donation, and the amount available to be expended from the Fund each year would be determined in accordance with the endowment spending policy adopted by Requestor’s Board of Trustees. For example, if the Donation is [number redacted], and an average distribution from investment earnings is [number redacted] percent annually in the first year of the Proposed Arrangement, Requestor would anticipate up to [number redacted] in available annual funding from the Fund for the Proposed Arrangement.

Pursuant to the Proposed Arrangement, after a patient at Children’s Hospital receives inpatient or outpatient services from an Initial Supported Program or Supported Program, as applicable, Requestor would determine the Qualified Family’s cumulative bill for hospital fees and professional fees (the “Bill”) and submit a claim for reimbursement to the appropriate third-party payor (including Federal health care programs), if any. After payment by the appropriate payor, Requestor would calculate the remaining balance on the patient’s Bill. Qualified Families who satisfy the criteria of Requestor’s financial assistance policy (the “Financial Assistance Policy”)<sup>6</sup> would receive a financial need reduction, and then all Bills, regardless of financial need, would receive a percentage reduction from Requestor (the “Reduction”).<sup>7</sup> Finally, Requestor would use monies from the Fund to pay any balance remaining on the Bill (the “Subsidy”).<sup>8</sup>

Requestor would not advertise the existence of the Proposed Arrangement. Rather, the Reduction and the Subsidy under the Proposed Arrangement would be discussed with patients’ families only after Requestor establishes the patient as an inpatient or outpatient in one of the Initial Supported Programs or Supported Programs, as applicable. Requestor certified that the criteria for clinical determinations regarding the appropriateness of inpatient or outpatient care would not change. Further, Requestor certified that it would not consider insurance coverage, type of insurance, or a patient’s diagnosis or medical condition (provided that such patient receives services in connection with an Initial Supported Program or Supported Program, as applicable) in determining which families are Qualified Families. In addition, the reduction or subsidization of cost-sharing amounts through the Proposed Arrangement would not be part of any price reduction agreement with third-party payors. Requestor also certified that it would not report unbilled cost-sharing amounts under the Proposed Arrangement as bad debt on cost reports, nor would it shift those amounts to third-party payors, including Federal health care programs. Finally, Requestor certified that neither the Reduction nor the Subsidy would be earmarked to cover only cost sharing for Federal health care program beneficiaries.

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<sup>6</sup> In general, Requestor’s Financial Assistance Policy assesses the income of the patient’s household in comparison to the poverty guidelines published by the U.S. Department of Health and Human Services and reduces the amount owed by a patient on a sliding scale.

<sup>7</sup> The Contribution Agreement requires this reduction and defines this percentage as the greatest three-year moving average write-off and uncollected amount for the Initial Supported Programs for both Children’s Hospital and all physician fees combined, for the period beginning 3 years prior to the date of the Contribution Agreement and ending on the date of the Donation. Requestor certified that, based on current figures, the percentage reduction if the Proposed Arrangement were implemented today would be [number redacted] percent.

<sup>8</sup> The process would remain the same for an uninsured Qualified Family but without the submission of a claim to a third-party payor. Additionally, pursuant to Requestor’s Financial Assistance Policy, all uninsured patients receive a discount regardless of financial need, which discount would be applied to the Bill before the Reduction would be applied.

## 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.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> 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.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.<sup>12</sup> In addition, the U.S. Department of Health and Human Services 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 exclusion.<sup>13</sup> 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.

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<sup>9</sup> Section 1128B(b) of the Act.

<sup>10</sup> Id.

<sup>11</sup> 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).

<sup>12</sup> Section 1128B(b)(3) of the Act.

<sup>13</sup> 42 C.F.R. § 1001.952.

The safe harbor for waiver of beneficiary copayment, coinsurance, and deductible amounts<sup>14</sup> is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the safe harbor allows hospitals to waive cost-sharing amounts that are owed to a hospital for inpatient hospital services for which a Federal health care program pays under the prospective payment system, if all of the following three standards are met: (i) the hospital does not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payors, or individuals; (ii) the hospital offers to reduce or waive the cost-sharing amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for reimbursement is filed; and (iii) the hospital's offer to reduce or waive the cost-sharing amounts must not be made as part of a price reduction agreement between a hospital and a third-party payor.<sup>15</sup>

## 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." Section 1128A(i)(6) of the Act contains an exception to the definition of "remuneration" that may apply in the context of the Proposed Arrangement. Section 1128A(i)(6)(A) of the Act includes an exception that carves out from the definition of remuneration under the CMP certain waivers of cost-sharing amounts offered to patients in financial need. The exception protects waivers of cost-sharing amounts that are: (i) not offered as part of any advertisement or solicitation; (ii) not routine; and (iii) made following an individual determination of financial need.<sup>16</sup>

### **B. Analysis**

The Proposed Arrangement involves several streams of remuneration from the Requestor and Donor A and Donor B that may implicate the Federal anti-kickback statute and the Beneficiary Inducements CMP. Specifically, removing the cost-sharing obligation—both through the Reduction and the Subsidy—would constitute remuneration to Federal health care program

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<sup>14</sup> 42 C.F.R. § 1001.952(k).

<sup>15</sup> 42 C.F.R. § 1001.952(k)(1).

<sup>16</sup> See also 42 C.F.R. § 1003.110 (defining "remuneration").

beneficiaries that would implicate the Federal anti-kickback statute.<sup>17</sup> Similarly, the Proposed Arrangement would implicate the Beneficiary Inducements CMP because the Reduction and the Subsidy would be likely to influence a Medicare or S-CHIP beneficiary to select Requestor.

As a preliminary matter, we note that the Proposed Arrangement would implicate the Federal anti-kickback statute only in connection with the comparatively few services that Requestor provides to a subset of Federal health care program beneficiaries who could incur cost sharing as part of being treated at Children’s Hospital. The vast majority of pediatric Federal health care program beneficiaries treated at Children’s Hospital are covered by Medicaid, which does not impose cost-sharing obligations for covered items and services furnished to children.

Accordingly, the only remuneration stream under the Proposed Arrangement that implicates the Federal anti-kickback statute would be assistance provided to pediatric patients covered by other Federal health care programs. The Proposed Arrangement would implicate the Beneficiary Inducements CMP to an even more limited extent because the Beneficiary Inducements CMP applies in this case only to children covered by Medicare or S-CHIP.

With regard to the Subsidy and the Reduction, the Proposed Arrangement would not fall squarely within any safe harbor to the Federal anti-kickback statute or exception to the definition of “remuneration” for purposes of the Beneficiary Inducements CMP. First, with regard to the Subsidy, the Proposed Arrangement would not meet the Federal anti-kickback statute safe harbor at 42 C.F.R. § 1001.952(k) nor the exception to the Beneficiary Inducements CMP at section 1128A(i)(6)(A) of the Act for certain waivers of beneficiary cost-sharing obligations because, among other reasons, the safe harbor applies only to a “reduction or waiver” of cost-sharing obligations, and the exception applies only to a “waiver” of cost-sharing obligations. Insofar as the Fund would pay cost-sharing amounts Children’s Hospital otherwise would have collected from beneficiaries, the remuneration is a payment on behalf of the beneficiary by a third party—not a waiver of cost sharing by the provider.

While the Reduction constitutes a “waiver” of certain cost-sharing obligations, the Proposed Arrangement would not meet the safe harbor for waivers of beneficiary copayment, coinsurance, and deductible amounts at 42 C.F.R. § 1001.952(k) because the Proposed Arrangement—which is limited to patients receiving treatment through specified programs—would not meet the safe harbor requirement that the waiver is offered without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for reimbursement is filed. Additionally, the Reduction would not meet all of the requirements of the exception to the Beneficiary Inducements CMP for the waiver of cost-sharing amounts offered to patients in financial need. Specifically, Requestor would implement the Reduction routinely, and although some Qualified Families may meet the criteria established in Requestor’s Financial Assistance Policy, financial need would not be a requirement to qualify for the

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<sup>17</sup> We note that the Donation itself could implicate the Federal anti-kickback statute to the extent that Requestor is receiving the Donation from Donor A and Donor B in return for arranging for purchasing or ordering an item or service that may be payable by a Federal health care program. However, for the same reasons discussed herein, we believe that the Donation, to the extent that it implicates the Federal anti-kickback statute, is sufficiently low risk.

Reduction in the Proposed Arrangement. We note that our concerns regarding routine waivers of cost-sharing amounts are longstanding, and providers and suppliers that routinely waive cost-sharing amounts for reasons unrelated to individualized, good faith assessments of financial hardship may be held liable under the Federal anti-kickback statute.<sup>18</sup> Such waivers may constitute prohibited remuneration to induce referrals. However, for the combination of reasons discussed below, we conclude that the Proposed Arrangement would present a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute. For similar reasons, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP in connection with the Proposed Arrangement.

First, the Proposed Arrangement would cover care-related expenses incurred by all Qualified Families, regardless of payor, for the treatment of their children at Children’s Hospital, including all remaining costs on the Bill of an uninsured Qualified Family. Neither the Reduction nor the Subsidy would be earmarked to cover only cost sharing for Federal health care program beneficiaries. Moreover, the Reduction and the Subsidy would cover cost-sharing amounts for few Federal health care program beneficiaries. These facts reduce the risk that the Proposed Arrangement would be a vehicle leading to overutilization and increased Federal health care program costs.

Second, Requestor certified that it would not advertise the Proposed Arrangement. Requestor would inform Qualified Families that their cost-sharing amounts would be covered only after their children already were established as inpatients or outpatients in one of the Initial Supported Programs or Supported Programs, as applicable. This safeguard reduces some of the risks typically associated with routine cost-sharing waivers, such as overutilization and inappropriate steering.

Third, Requestor certified that it would not report unbilled cost-sharing amounts under the Proposed Arrangement as bad debt on cost reports or shift those amounts to third-party payors, including Federal health care programs, which reduces the risk that the Proposed Arrangement would contribute to increased Federal health care program costs.

Fourth, other safeguards reduce the risk that Requestor would use the Proposed Arrangement to attract highly profitable patients or that the Proposed Arrangement would result in overutilization, unnecessary services, or increased Federal health care program costs. For example, Requestor certified that the usual clinical criteria for inpatient or outpatient care would not change because of the Proposed Arrangement. In addition, Requestor would not consider insurance coverage, type of insurance, or a patient’s diagnosis or medical condition (provided the patient would receive treatment from an Initial Supported Program or Supported Program, as applicable) when determining whether the Qualified Family is eligible to receive cost-sharing support.

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<sup>18</sup> See, e.g., OIG, Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).



Finally, Requestor certified that neither Donor A nor Donor B are health care providers or suppliers and that they are not involved in health care aside from other charitable endeavors in which they may engage individually or through their foundation. Accordingly, Donor A and Donor B are not in a position to make or receive referrals for health care items or services.

### **III. CONCLUSION**

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed 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) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement 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 limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person 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 Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

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

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against Requestor with respect to any action that is part of the Proposed 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 Proposed 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 Proposed 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