DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: January 9, 2019

Posted: January 14, 2019

[Name and address redacted]

Re: OIG Advisory Opinion No. 19-01

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a charitable pediatric clinic's arrangement under which the clinic waives cost-sharing amounts in certain circumstances (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

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

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General ("OIG") will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

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

I. FACTUAL BACKGROUND

A. The Clinic and Its Patients

[Name redacted] ("Requestor") is a charitable pediatric clinic that furnishes medical, psychiatric, and dental care to children residing in [redacted] (the "County"), which includes [redacted] (the "City"), where Requestor is located. Requestor's mission is to improve health outcomes for at-risk children in the County, which contains disproportionately large numbers of children living in poverty.[1] Requestor is located in HRSA-designated Health Professional Shortage Areas for Primary Care, Dental Care, and Mental Health and sits only a few blocks outside of an HRSA-designated Medically Underserved Area.

Requestor maintains eligibility guidelines that are consistent with its mission. To be eligible to receive continuing services from Requestor, patients must: (1) reside in the County, (2) meet Requestor's age guidelines (from birth to 19 years old), and (3) satisfy

[1] At the time Requestor submitted the advisory opinion request, the most recently available U.S. Census data showed that 58.5 percent of the City's children, and 30 percent of the County's children, live in households reporting incomes below the Federal poverty guidelines (the "Poverty Level") defined by the Health Resource Services Administration ("HRSA") of the U.S. Department of Health & Human Services.

Requestor's financial need standard (the "Need Standard"). To satisfy the Need Standard, a patient must either participate in Medicaid, [program name redacted], or [program name redacted] (the "State Insurance Programs")[2] or present evidence that his or her family's income does not exceed 200 percent of the Poverty Level. Requestor certified that more than 90 percent of the patients whom it deems eligible to receive continuing services ("Enrolled Patients") participate in at least one of the State Insurance Programs. Requestor individually verifies that its remaining Enrolled Patients (i.e., the fewer than 10 percent of Enrolled Patients who do not participate in a State Insurance Program) meet the Need Standard and reevaluates their financial need on an annual basis. Requestor certified that fewer than one percent of its Enrolled Patients are covered by TRICARE, the insurance program for members of the military and their families and that it treats very few, if any, Enrolled Patients covered by Medicare[3] at any given time.

In certain circumstances, Requestor provides limited health care services to pediatric patients whose families have not satisfied the Need Standard ("Non-Enrolled Patients").[4] For example, Requestor provides emergency dental care ("Emergency Dental Care") needed to stabilize the conditions of Non-Enrolled Patients. Requestor certified that it refers Non-Enrolled Patients who have received the limited services Requestor makes available in such circumstances to other providers for necessary subsequent or follow-up care. At the time Requestor submitted the advisory opinion request, Requestor had provided Emergency Dental Care to fewer than 50 Non-Enrolled Patients, in total, over the past few years. Requestor certified that the limited services that it provides Non-Enrolled Patients represent only a small percentage of the aggregate care that it provides. Requestor does not

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[2] Requestor certified that the three State Insurance Programs all represent "State health care programs" as defined by section 1320a-7(h) of the Act. Prior to the issuance of this advisory opinion, State Insurance Programs temporarily increased the family income threshold from 200 percent of the Poverty Level to 400 percent of the Poverty Level due to a public health crisis in the City.

[3] Requestor's patients can qualify for Medicare coverage if they are eligible individuals from the comparatively small population of children with end-stage renal disease. See, e.g., 42 C.F.R. § 406.13(c)(2).

[4] According to Requestor, many Non-Enrolled Patients' families have incomes at or below 200 percent of the Poverty Level but are designated as Non-Enrolled Patients because their families did not satisfy the Need Standard by participating in a State Insurance Program or provide Requestor with adequate proof of their limited incomes. Requestor's social workers counsel such families, after which many successfully demonstrate need and obtain Enrolled Patient status for their children.

expect to provide care to significantly greater numbers of patients who do not meet the Need Standard in the future.

B. Federal Beneficiary Cost-Sharing Waivers

Under the Arrangement, Requestor waives any applicable patient cost-sharing amounts but bills and accepts payments from third party payors, including Federal health care programs.[5] The vast majority of Requestor's patients who are Federal health care program beneficiaries participate in the State Insurance Programs and owe no cost-sharing amounts.[6] Typically, a patient receiving care from Requestor would owe Federal health care cost-sharing amounts only in connection with services paid for by TRICARE or Medicare, and then only if the patient's services are not also covered by one of the State Insurance Programs.[7] Because TRICARE covers fewer than one percent of Requestor's patients and Medicare covers no more than a handful of Requestor's patients at a given time, very few of Requestor's patients owe Federal health care cost-sharing amounts. As a consequence, in practice, Requestor waives Federal health care program cost-sharing obligations for very few patients.

C. Other Pertinent Facts

Requestor certified that it does not consider a patient's medical condition or insurance status (including whether the patient is insured by a Federal health care program or private payors, or is uninsured) when determining whether a patient is eligible to receive its services or deciding on a course of treatment. Requestor certified that it does not offer waivers of cost-sharing amounts as part of any advertisement or solicitation. Requestor does not compensate physicians, dentists, and other staff (including independent contractors) in a manner that varies based on the volume or value of services performed or referrals made. Requestor certified that it never ties the delivery of services (directly or indirectly) to the provision of other services reimbursed in whole or in part by any Federal health care

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[5] Requestor waives the total cost of services that it provides to uninsured patients.

[6] Requestor certified that its patient pool is almost entirely under 19 years of age and that the State Insurance Programs require no cost-sharing amounts from their beneficiaries under 19. See, e.g., section 1916(a)(2)(A) of the Act (prohibiting state Medicaid programs from requiring cost-sharing amounts from children).

[7] Because Requestor serves low-income patients, many of its patients who are covered by TRICARE or Medicare are also covered by a State Insurance Program and, as a result, owe no cost-sharing amounts for any care that is paid for by a State Insurance Program.

program. Finally, Requestor certified that it does not report waived cost-sharing amounts as bad debt on cost reports, nor does it shift those amounts to third party payors, including Federal health care programs.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to ten years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act (the "CMP") provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). (This provision does not apply to TRICARE.) The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the CMP as including "the waiver of coinsurance and

deductible amounts (or any part thereof)," except in certain circumstances that include financial need.

Section 1128(A)(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 not offered as part of any advertisement or solicitation; are not routine; and are made following an individual determination of financial need. 42 C.F.R. § 1003.110 (defining "remuneration").

B. Analysis

Cost-sharing waivers may constitute prohibited remuneration under the anti-kickback statute if the amounts waived relate to federally reimbursable items or services. Similarly, cost-sharing waivers may constitute prohibited inducements under the CMP if they are offered or paid to induce a Medicare beneficiary to select a particular provider, practitioner, or supplier. Under the Arrangement, Requestor waives Federal health care program cost-sharing amounts only for the small percentage of TRICARE and Medicare beneficiaries who receive services not covered by a State Insurance Program. Thus, the Arrangement implicates the anti-kickback statute only in connection with the comparatively few services that Requestor provides to these particular patients. The Arrangement implicates the CMP to an even more limited extent because the CMP does not apply to TRICARE. Thus, the Arrangement implicates the CMP only with respect to services that are not covered by a State Insurance Program that Requestor provides to Medicare beneficiaries.

The Arrangement does not meet all of the requirements of the exception to the CMP for the waiver of cost-sharing amounts offered to patients in financial need. Requestor waives cost-sharing amounts routinely,[8] and, although it verifies the financial need of some patients, it does not do so for all patients who may have cost-sharing obligations.

Nonetheless, for the combination of reasons discussed below, we conclude that the Arrangement presents a minimal risk of fraud and abuse under the anti-kickback statute. For similar reasons, in combination with the limited extent to which Requestor's conduct

[8] Whether an entity waives cost-sharing amounts routinely depends on the facts and circumstances. See, e.g., 81 Fed. Reg. 88,368, 88,373 (Dec. 7, 2016). We consider Requestor's waiver of cost-sharing amounts under the Arrangement to be routine because it waives cost-sharing amounts for 100 percent of its patients to whom they apply. The fact that Requestor waives Federal health care program cost-sharing obligations for very few patients in the aggregate does not make the waivers any less routine.

implicates the CMP, in an exercise of our discretion, we will not impose sanctions under the CMP in connection with the Arrangement.

First, Requestor waives Federal health care program cost-sharing amounts for very few patients absent individually verified need. Indeed, it is possible that, in a given year, no such patients exist. Enrolled Patients receive the vast majority of Requestor's services, and Requestor certified that it individually verifies need for every Enrolled Patient who does not participate in a State Insurance Program. Although Requestor provides limited services, such as Emergency Dental Care, to Non-Enrolled Patients who may not satisfy the Need Standard, these offerings make up a small percentage of Requestor's aggregate services.

Second, Requestor certified that it does not offer waivers of cost-sharing amounts as part of any advertisement or solicitation. In the context of the Arrangement's other features, this safeguard reduces risks arising from routine cost-sharing waivers.

Third, Requestor offers no financial incentives to its physicians, dentists, or other health care providers to order unnecessary care or to steer patient referrals to Requestor. All of Requestor's physicians, dentists, and other staff, including independent contractors, receive compensation that does not vary based on the volume or value of services provided or referrals made.

Fourth, when assessing the risk posed by the Arrangement, we also consider the circumstances of Requestor's service area and of Requestor's specific patient pool. Multiple overlapping HRSA-designated Health Professional Shortage Areas evidence the depleted state of local health care infrastructure, and a large number of area children live in poverty. In this particular context, the lack of other provider options for an especially vulnerable patient population, and not any improper inducement under the Arrangement, appears likely to draw patients to Requestor.[9]

Fifth, Requestor has minimized the risk posed by the Arrangement by implementing certain other safeguards. Requestor does not consider a patient's medical condition or insurance status when determining whether the patient is eligible to receive its services or deciding on a course of treatment. Requestor is therefore unlikely to use the Arrangement to attract highly profitable patients. Requestor never ties the delivery of services (directly or indirectly) to the provision of other services reimbursed in whole or in part by a Federal health care program. These aspects of the Arrangement reduce the risks of overutilization, unnecessary services, and increased Federal health care program costs. Requestor does not

[9] We stress that the lack of alternative sources of care would not, standing alone, justify the routine waiver of cost-sharing amounts, but we consider this factor, among others, in evaluating the risk posed by the Arrangement.

claim the patient cost-sharing amounts it waives as bad debt or otherwise shift the burden to Federal health care programs. This also reduces the risk that the Arrangement contributes to increased Federal health care program costs.

For the combination of the foregoing reasons, we conclude that the Arrangement presents a minimal risk of fraud and abuse under the anti-kickback statute. For similar reasons, in combination with the limited extent to which Requestor's conduct implicates the CMP, in an exercise of our discretion, we will not impose sanctions under the CMP in connection with the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement,

including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

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

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

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs