



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 8, 2020

Posted: January 13, 2020

[Name and address redacted]

Re: OIG Advisory Opinion No. 20-01

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a hospital's provision of discounted training to a specified fire department's personnel at the hospital's facility (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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. 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

[Name redacted] (“Requestor”) is a nonprofit healthcare system with locations throughout the greater [city redacted] metropolitan area. Its charitable mission is to provide high-quality, cost-effective healthcare to its patients. According to Requestor, this mission aligns with the statutory requirement for nonprofit hospitals in [state redacted] (“State”) to offer charity care and community benefits,¹ the latter of which includes research and educational opportunities for healthcare professionals. Requestor certified that—consistent with its mission and statutory obligations—it operates a variety of community benefit programs.

A. The Training Facility

In addition to several hospitals and other healthcare entities, Requestor operates the [name redacted] (the “Training Facility”). According to Requestor, the Training Facility is a state-of-the-art facility designed to provide hands-on clinical training to healthcare professionals seeking to refine existing clinical skills and to acquire new skills. A range of healthcare providers, including physicians, nurses, and paramedics, may train at the Training Facility. Requestor certified that no other hospital in the greater [city redacted] metropolitan area has a comparable facility or offers similar training opportunities.

By way of example, Requestor certified that the Training Facility is the only facility in the greater [city redacted] metropolitan area that has the resources to allow emergency personnel to train in conditions that simulate complex rescue scenarios. During sessions at the Training Facility, emergency personnel learn how to deal with challenging situations in the field (*e.g.*, when a patient is suspended upside down in a car) and to manage unusual or difficult cases while transporting the patient to the appropriate trauma center.

Requestor certified that it incurs both fixed costs and variable costs when operating the Training Facility for a training session. Fixed costs include the facility fees, the costs for

¹ [Citation redacted].

the use of certain areas in the Training Facility (e.g., operating rooms), and the related costs of using the Training Facility. Variable costs fluctuate on a session-by-session basis, depending on the amount of Requestor's supplies and personnel required for a given training session. If healthcare providers that use the Training Facility bring in certain equipment and personnel to facilitate the training, Requestor does not include such items in the calculation of its costs.

As part of Requestor's community benefit programs, Requestor offers a discount on certain costs for sessions at the Training Facility that are in furtherance of its charitable mission. To determine whether a session qualifies for the discount, Requestor first evaluates whether the session educates healthcare providers who have a direct impact on patient care in the community. This analysis informs whether the training session is consistent with Requestor's nonprofit charitable mission and its statutorily required duties to provide community benefits and charity care. Second, Requestor considers whether the session constitutes an education-related cost under the State's statutory definition of community benefits. If both criteria are met, a training session is eligible for a discount equal to the fixed costs for the session (the "Training Facility Discount"). In other words, Requestor only charges for the variable costs for the session.

B. The Fire Department

[Name redacted] (the "Fire Department") is a department of [city redacted] ("City") and operates an emergency medical services ("EMS") system that provides emergency medical care and transportation in the City.² To furnish these services, the Fire Department uses paramedics who must be certified by the State and must meet credentialing standards. Given these certification and credentialing requirements, the Fire Department seeks out training opportunities for its paramedics. The Fire Department also maintains a fleet of ambulances, some of which can provide basic life support transports only and others of which can provide advanced life support transports as well. A City ordinance stipulates that only the Fire Department may operate emergency ambulances for the purposes of furnishing emergency ambulance services within City limits.³

According to Requestor, State licensure regulations require that every EMS provider submit treatment and transport protocols that have been approved by its medical director. To that end, the Fire Department's medical director developed, approved, and implemented specific protocols that the Fire Department's personnel must follow when selecting the destination for emergency ambulance transports. Requestor certified that

² Requestor certified that the Fire Department does not provide any non-emergency ambulance services.

³ [Citation redacted].

the protocols require decisions regarding hospital destination to be based on objective standards; specifically, the protocols require the Fire Department’s personnel to evaluate the patient’s chief complaint, the urgency of care needed, the specific care needed, the status of hospital diversions, the status of EMS resources, and the patient’s preference (if available). After considering these factors, the personnel transport the patient to the most appropriate facility.

C. The Arrangement

The Fire Department has used the Training Facility since 2014 for purposes of training its emergency personnel on advanced airway management techniques. Requestor concluded that these training sessions qualified for the Training Facility Discount using the criteria described above; as a result, the Fire Department has received the Training Facility Discount for these training sessions.

During the course of the Arrangement, the City (on behalf of the Fire Department) and Requestor formally memorialized the Arrangement in a written agreement that allows the Fire Department to hold no more than 24 advanced airway management training sessions per year at the Training Facility. Requestor certified that the written agreement expressly disclaims any referral requirements and that the offer and amount of the Training Facility Discount is not tied directly or indirectly to the volume or value of referrals between the Fire Department and Requestor. Requestor certified that there have been no statistically significant changes to the Fire Department’s transports to Requestor, and the Fire Department’s protocols with respect to hospital-destination decisions have not been substantively modified since Requestor began offering the Training Facility Discount.

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.

B. Analysis

The OIG's position on the provision of free or below-market items or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the Federal anti-kickback statute, depending on the circumstances. Requestor's provision of the Training Facility Discount to a current and future referral source implicates the anti-kickback statute. Nonetheless, for the combination of the reasons set forth below, we conclude that the Arrangement presents a low risk of fraud and abuse under the anti-kickback statute.

First, the Arrangement poses little risk of overutilization or increased costs to any Federal health care program. Requestor certified that the only medical transportation services the Fire Department provides are emergency transport services. Neither the number of Federal health care program beneficiaries who require such services from the Fire Department nor the treatment these patients may receive at a hospital is related to the existence or implementation of the Arrangement.

Second, several factors, in combination, sufficiently mitigate the risk that the Fire Department will steer patients to Requestor as a result of the Arrangement. Requestor certified that, as required by the State's licensure regulations, the Fire Department's medical director developed, approved, and implemented specific protocols for Fire Department personnel to follow when selecting destinations for emergency ambulance transports. These protocols require hospital-destination decisions to be based on objective standards (e.g., urgency of care needed), and those protocols have not been substantively modified since the Arrangement commenced. In addition, the written agreement expressly disclaims any referral requirements, and Requestor certified that the offer and amount of the Training Facility Discount provided under the Arrangement are not tied directly or indirectly to the volume or value of referrals between the parties. Requestor certified that, since the Arrangement commenced, there have been no statistically significant changes to the Fire Department's transports to Requestor. We note that a kickback does not have to be successful to violate the anti-kickback statute, and any changes in referral patterns are not dispositive in an anti-kickback statute

analysis. However, this fact supports Requestor's certification that the remuneration is not tied to the volume or value of referrals by the Fire Department to Requestor and supports our conclusion that the Arrangement is low risk.

Third, the Arrangement may benefit the community by improving the quality of emergency ambulance services in the City, which is consistent with Requestor's certification that it offers the Training Facility Discount in accordance with the State's statutory requirement for nonprofit hospitals to offer community benefits. Given that a City ordinance places sole responsibility on the Fire Department to furnish emergency ambulance services within City limits, it is important that its paramedics receive training that will expand their skills to care for patients in the field. Requestor certified that no other training facility in the area has a comparable facility or offers similar training opportunities, and the Fire Department's personnel can train in conditions that simulate complex rescue scenarios. Patients in the community, including those who ultimately do not receive care at Requestor, may receive higher-quality services from paramedics who are more equipped to manage unusual or difficult cases during transport.

Finally, the putative prohibited remuneration (*i.e.*, the Training Facility Discount) inures to the public, and not private, benefit. The public receives the financial benefit of the Arrangement because the Training Facility Discount reduces the funds the City must allocate for clinical training of the Fire Department's personnel. The fact that the City (acting on behalf of the Fire Department) receives the financial benefit of the Arrangement reduces the risk that the Training Facility Discount is improper remuneration to the Fire Department to induce referrals.

For the combination of reasons set forth above, we conclude that the Arrangement presents a low risk of fraud and abuse under the anti-kickback statute.

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. 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