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: March 1, 2019

Posted: March 6, 2019

[Name and address redacted]

Re: OIG Advisory Opinion No. 19-03

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a program offered by a medical center that provides free, in-home follow-up care to eligible individuals with congestive heart failure (the "Current Arrangement") and the proposed expansion of this program to include certain individuals with chronic obstructive pulmonary disease (the "Proposed Arrangement," and with the Current Arrangement, the "Arrangements"). Specifically, you have inquired whether the Current Arrangement constitutes, or the Proposed Arrangement would constitute, 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 Current Arrangement and the Proposed 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, and would not, respectively, 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 Current Arrangement or the Proposed Arrangement. In addition, the OIG will not, and would not, respectively, impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Current Arrangement or the Proposed Arrangement. This opinion is limited to the Arrangements 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 medical center located in [city redacted, state redacted], that provides a range of inpatient and outpatient hospital-based services. [Name redacted] (the "Clinic") is an affiliate of Requestor that offers primary care and certain specialty services at several facilities located in the geographic region that Requestor serves. Requestor and the Clinic are under the sole control of [name redacted] (the "Health System"), an integrated health system operating in three states.

Requestor has developed a program to provide free, in-home follow-up care to certain patients who it certifies are at higher risk of admission or readmission to a hospital. Under the Current Arrangement, Requestor offers in-home care to patients with congestive heart failure ("CHF") who qualify for participation, and under the Proposed Arrangement, Requestor would expand the program to qualifying patients with chronic obstructive pulmonary disease ("COPD"). According to Requestor, the goals of both Arrangements are to increase patient compliance with discharge plans, improve patient health, and reduce hospital inpatient admissions and readmissions.[1]

[1] Requestor certified that the Arrangements ultimately are expected to decrease utilization of services by improving patient health.

A. Eligibility Requirements

Clinical nurse leaders[2] screen patients to determine if they meet the following eligibility criteria for the Current Arrangement. First, a patient must have CHF and be (i) currently admitted as an inpatient to Requestor, or (ii) a patient of Requestor's [name redacted] ("CHF Center"), a part of Requestor's outpatient cardiology department, who was admitted as an inpatient to Requestor within the previous 30 days. Second, the clinical nurse leader must identify the patient as high risk for hospital inpatient readmission using a risk assessment tool utilized throughout the industry to predict the risk of unplanned readmission or emergency department visits subsequent to a hospital discharge. Third, the patient must have arranged to receive follow-up care at the CHF Center. If a patient does not plan to seek follow-up care, intends to receive follow-up services elsewhere, or expresses uncertainty about where he or she will receive follow-up care, the patient is not informed of the Current Arrangement.[3] Fourth, the patient must be willing to enroll in the Current Arrangement after consultation with the clinical nurse leader. Finally, the patient must be discharged to—or reside at—a personal residence or an assisted living facility ("ALF") in the Health System's service area.

The Proposed Arrangement generally would have the same eligibility requirements as the Current Arrangement. Instead of screening patients with CHF who are admitted as an inpatient to Requestor or who are a patient of the CHF Center, however, clinical nurse leaders would screen patients with COPD who have presented for care at Requestor or at one of the Clinic facilities. Second, the patient must be identified by a clinical nurse leader as (i) high risk for hospital inpatient readmission, using the assessment tool described above, or (ii) high risk for hospital inpatient admission, using a predictive analytics tool. Third, the patient must have arranged to receive follow-up care at Requestor or a Clinic facility. As in the Current Arrangement, if a patient does not plan to seek follow-up care, intends to receive follow-up services elsewhere, or expresses uncertainty about where he or she will receive follow-up care, the patient would not be informed of the Proposed Arrangement.[4] Fourth, as in the Current Arrangement, the patient must be willing to enroll in the Proposed Arrangement after consultation with the clinical nurse leader. Finally, as in the Current Arrangement, the patient must be

---

[2] According to Requestor, a clinical nurse leader is an individual who manages and promotes group processes to achieve integration of care.

[3] Requestor certified that it does not, and will not, attempt to persuade uncertain patients to select the CHF Center for follow-up services by offering them the Current Arrangement.

[4] Requestor certified that it would not offer uncertain patients the Proposed Arrangement as a means to encourage these patients to select Requestor or the Clinic for follow-up care.

discharged to—or reside at—a personal residence or an ALF in the Health System's service area.

Requestor offers the Current Arrangement, and would offer the Proposed Arrangement, to any patient who meets the eligibility criteria, regardless of the patient's health insurance status or his or her ability to pay for medical services. Requestor certified that it does not, and would not, advertise or market the Arrangements to the public. Further, Requestor does not, and would not, publicize the Arrangements on its website.

B. Program Services

Under the Arrangements, patients who meet all eligibility criteria and who choose to participate receive two visits from a community paramedic each week for approximately 30 days following enrollment. Each visit takes place in the patient's home or ALF and lasts approximately 60 minutes, during which time the community paramedic may perform some or all of the following activities (collectively, the "Services"):

i. Review the patient's medication;
ii. Assess the patient's need for follow-up appointments;
iii. Monitor the patient's compliance with the discharge plan of care or the patient's disease management;
iv. Perform a home safety inspection; and
v. Perform a physical assessment, which may include checking the patient's pulse and blood pressure, listening to the patient's lungs and heart, checking any wounds, running an electrocardiogram, drawing blood and running blood tests using a portable blood analyzer, or administering medication.

The community paramedic uses a clinical protocol to deliver interventions and to assess whether a referral for follow-up care is necessary. The community paramedic documents all activities and interventions he or she performs during the course of the visit in the patient's electronic medical record. If a patient requires care that falls outside the community paramedic's scope of practice, the community paramedic directs the patient to follow up with his or her established provider. For urgent but non-life-threatening medical needs, the community paramedic calls the patient's established provider, and such provider follows up with the patient as he or she deems appropriate.

Requestor certified that in many cases Requestor or the Clinic is the patient's established provider. If a patient requires care unrelated to his or her CHF or COPD for which he or she has no established provider, the community paramedic contacts Requestor or the Clinic, as applicable, to determine if Requestor or the Clinic can address any immediate needs, but Requestor explained that the patient may obtain care from the provider of his or her choice, and the community paramedic informs the patient of this fact. Requestor

certified that this approach fosters integrated care delivery for patients and improves patients' adherence to their treatment plans, which is particularly important for patients with chronic diseases. Requestor and the Clinic bill, and would bill, for any follow-up services they provide outside the scope of the Arrangements at the same rate that they would bill for such services if the patient were not participating in the Arrangements.

Requestor certified that it employs, on either a full-time or part-time basis, the community paramedics who provide the Services. Neither Requestor nor the Clinic compensates, or would compensate, any employee or contractor based on the number of patients who enroll in the Arrangements. Further, all costs associated with the community-paramedic visits (e.g., supplies, vehicle use, equipment) provided under the Arrangements are, and would be, allocated to Requestor. With one exception, Requestor certified that the Services provided under the Arrangements are not covered or reimbursed by Federal health care programs when performed by a community paramedic. Specifically, one Medicaid program in the Health System's service area reimburses for community-paramedic services that Requestor certified are similar to the Services, but Requestor certified that it does not, and would not, bill this Medicaid program for the Services provided under the Arrangements. Neither patients nor any payors are, or would be, billed for the Services, and Requestor does not, and would not, shift any costs related to the Current Arrangement or the Proposed Arrangement to Medicare, Medicaid, other payors, or individuals.

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 "Beneficiary Inducement 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). 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 Beneficiary Inducement 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 could apply in the context of the Arrangements. Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducement CMP, the term "remuneration" does not include "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)" (the "Promotes Access to Care Exception"). We have interpreted this provision to apply to:

> [i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns . . . .[5]

B. Analysis

Under the Arrangements, Requestor provides the Services to qualifying patients, some of whom may be Federal health care program beneficiaries. The Services provide a significant benefit to patients in the form of free health care services and care

[5] 42 C.F.R. § 1003.110 (defining "remuneration").

management furnished in their home. While not dispositive, the fact that a Medicaid program in the Health System's service area reimburses for similar community-paramedic services also indicates their value. For these reasons, we believe the Services constitute remuneration from Requestor to patients participating in the Arrangements.

We also conclude that this remuneration could influence a patient to select Requestor or the Clinic for federally reimbursable items and services. It is true that Requestor offers the Current Arrangement, and would offer the Proposed Arrangement, only to those patients who plan to receive follow-up care from Requestor (including its CHF Center) or at one of the Clinic facilities, i.e., the Arrangements are limited to patients who already have selected Requestor or its affiliated Clinic as their care provider. However, patients who receive the Services may be more likely to order reimbursable services unrelated to their CHF or COPD from Requestor or its affiliated Clinic in the future. Accordingly, the Arrangements implicate the Beneficiary Inducement CMP as well as the Federal anti-kickback statute.

Once the Beneficiary Inducement CMP is implicated, we next analyze whether an exception applies. We conclude the Promotes Access to Care Exception does not protect the Current Arrangement or the Proposed Arrangement. For the Promotes Access to Care Exception to apply, the remuneration must (i) improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid and (ii) pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs. With respect to the first prong, we previously have stated that "some forms of remuneration that remove impediments to compliance with a treatment plan"[6] and some types of post-discharge support could promote access to care.[7] While we continue to believe these categories of remuneration could be protected under the Promotes Access to Care exception in certain circumstances if they are low risk, we do not believe that the full suite of Services offered under the Arrangements promotes a patient's access to care. By way of example, the home safety assessment performed by the community paramedic does not improve the patient's ability to obtain federally reimbursable items or services. In addition, we fail to see how such an assessment removes socioeconomic, educational, geographic, or other barriers that could prevent the patient from receiving care.

Although we conclude that neither the Current Arrangement nor the Proposed Arrangement satisfies the Promotes Access to Care Exception, in an exercise of our discretion we will not impose sanctions under the Beneficiary Inducement CMP for the combination of the following reasons.

---

[6] Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88,368, 88,394 (Dec. 7, 2016).

[7] Id. at 88,397.

First, although the remuneration provided under the Arrangements implicates the Beneficiary Inducement CMP because it could influence a patient to select Requestor or the Clinic for federally reimbursable items or services, we believe that the Arrangements' benefits outweigh any risk of inappropriate patient steering that the statute was designed to prevent. Before learning about the Current Arrangement or the Proposed Arrangement, patients already must have selected Requestor or the Clinic for follow-up services related to their CHF or COPD. In other words, the risk that the remuneration will induce patients to choose Requestor or the Clinic for CHF- or COPD-related services is negligible because patients already have made this selection. With respect to future services unrelated to their CHF or COPD, Requestor certified that the community paramedics direct patients to follow up with their established provider—whether or not that established provider is Requestor or the Clinic—if they require care outside the community paramedics' scope of practice. And while the community paramedics contact Requestor or the Clinic in those instances where a patient does not have an established provider, the patient may obtain care from the provider of his or her choosing, and the community paramedic informs the patient of this freedom of choice. Given that the patient already has selected Requestor or the Clinic for his or her CHF- or COPD-related care, it is reasonable to expect that he or she may choose the same provider for continuity of care. Moreover, Requestor certified that this approach fosters integrated care delivery, which is particularly important for individuals with chronic diseases because it improves their adherence to their treatment plans. The numerous safeguards in the Arrangements that protect patients (e.g., the ability to select their preferred provider), combined with Requestor's stated goal to improve patient health by offering free follow-up care to patients with chronic conditions, allow us to conclude that the remuneration poses a low risk of harm to patients and Federal health care programs.

Second, if the Arrangements work as intended, they are unlikely to lead to increased costs to Federal health care programs or patients through overutilization or inappropriate utilization. With the exception of one Medicaid program in the Health System's service area, the Services provided by the community paramedic are not covered or reimbursed by Federal health care programs.[8] To the extent the Arrangements increase utilization of health care services (e.g., by reminding patients to take their medications or identifying the need for a follow-up appointment during the physical assessment), such an increase likely would reflect appropriate utilization from patients receiving medically necessary care as a result of the Arrangements. Moreover, the Arrangements could result in overall savings to Federal health care programs if they successfully achieve Requestor's stated goals of improving patient health and reducing hospital inpatient admissions and

[8] Requestor certified that it does not, and would not, bill the Medicaid program in the Health System's service area that covers the Services, which mitigates the risk of increased costs stemming from Federal health care program reimbursement.

readmissions, which ultimately could lead to Requestor's expected decrease in overall utilization of federally reimbursable services.

Third, the risk that the Arrangements will interfere with or skew clinical decision making is low. Requestor certified that it does not, and would not, compensate any employee or contractor based on the number of patients who enroll in the Arrangements.

Fourth, Requestor certified that it does not, and would not, advertise or market the Arrangements to the public, and Requestor does not, and would not, publicize them on its website. These factors lower the risk that the Arrangements are designed to induce patients to select Requestor or the Clinic because they make it less likely that patients will learn about the Arrangements before they have selected Requestor or the Clinic for their CHF- or COPD-related care.

Finally, the scope and duration of the Services provided by the community paramedics appear reasonably tailored to accomplish Requestor's goals of increasing patient compliance with discharge plans, improving patient health, and reducing hospital inpatient admissions and readmissions. It is reasonable to assume these patient populations—who Requestor certified are at higher risk of hospital inpatient admission or readmission—will benefit from the continuity of care offered by the Arrangements. For instance, the Arrangements make available a health care professional who can assist patients with following the discharge plan or treatment plan developed by Requestor or the Clinic, as applicable. In addition, the community paramedics can keep patients' providers apprised of patients' health by documenting all activities and interventions in their electronic medical records between discharge and a follow-up appointment. Access to free care also may foster patient safety and improve quality of care by preventing or detecting health care issues after discharge or after a treatment plan has been developed.

As we explained in our August 27, 2018, request for information, "OIG has identified the broad reach of the anti-kickback statute and [Beneficiary Inducement CMP] as a potential impediment to beneficial arrangements that would advance coordinated care."[9] We are mindful that health care providers may wish to offer the type of services provided under the Arrangements to deliver higher quality care that improves the health of patients and may decrease overall costs to Federal health care programs. With the combination of safeguards described above, we believe the Current Arrangement is, and the Proposed Arrangement would be, sufficiently low risk and may help further these goals. Thus, in an exercise of our discretion, we will not subject Requestor to sanctions under the Beneficiary Inducement CMP in connection with the Arrangements. For the same

[9] Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 Fed. Reg. 43,607, 43,608 (Aug. 27, 2018).

reasons, we also will not subject Requestor to sanctions under the anti-kickback statute in connection with the Arrangements.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Current Arrangement and the Proposed 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, and would not, respectively, 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 Current Arrangement or the Proposed Arrangement. In addition, the OIG will not, and would not, respectively, impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Current Arrangement or the Proposed Arrangement. This opinion is limited to the Arrangements 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 Current Arrangement or 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.

- 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 Current Arrangement or 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 Current Arrangement and the Proposed Arrangement in practice comport 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 Current Arrangement or 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