



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: May 24, 2018

Posted: May 31, 2018

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 18-03

Dear [Names redacted]:

We are writing in response to your request for an advisory opinion regarding a federally qualified health center look-alike's proposal to provide information technology items and services, without charge, to a county Department of Health's clinic to facilitate telemedicine encounters (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute 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 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”) would not impose administrative sanctions on [names 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 Proposed Arrangement. This opinion is limited to the Proposed 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 [names redacted], the requestors 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] (the “Provider”) is a not-for-profit federally qualified health center look-alike located in [city redacted, state redacted]. [Name redacted] (the “County Clinic”) is a division of the [county redacted] County Department of Health and furnishes certain confidential sexually transmitted infection testing, treatment, and counseling. The Provider’s primary location is approximately 80 miles, by car, from the County Clinic. The Provider and the County Clinic (collectively, “Requestors”) propose to enter into an arrangement under which the Provider would furnish to the County Clinic, without charge, certain information technology-related equipment and services intended to facilitate telemedicine encounters with the County Clinic’s patients.

Under the Proposed Arrangement, the Provider would furnish the following items to the County Clinic for free: (i) a laptop or computer with high-quality speakers; (ii) a webcam; (iii) a microphone; (iv) a GlobalMed TotalExam 3 Camera; and (v) videoconferencing software (collectively, the “Telemedicine Items”). Requestors certified that nothing inherent to the Telemedicine Items would: (i) limit or restrict the use or compatibility of the Telemedicine Items with different information technology systems, software applications, or networks; or (ii) inhibit the ability of any users of the Telemedicine Items to communicate or exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks. Requestors further certified that they would not use the Telemedicine Items to inappropriately limit or restrict the flow of information. The Provider also would: (i) assume financial responsibility for installing, maintaining, and updating the communication links and connectivity necessary to provide telemedicine services; (ii) train the County Clinic staff to use the Telemedicine Items and facilitate telemedicine encounters; (iii) maintain the Telemedicine Items, as necessary; and (iv) provide technical assistance for the use of the Telemedicine Items, as necessary (collectively, the “Telemedicine Services”).

The Provider would use grant funds it received from the [state redacted] State Department of Health, AIDS Institute (the “State Department of Health”) to pay for the Telemedicine Items and Telemedicine Services. The Provider stated that the primary purpose of the grant funds is to increase access to human immunodeficiency virus (“HIV”) prevention services in the state. The State Department of Health would retain title to the Telemedicine Items and would have the authority to recover them at any time.

Under the Proposed Arrangement, the Telemedicine Items would be used only for telemedicine encounters related to HIV prevention, namely, consultations regarding the prescription of medications for pre-exposure prophylaxis (“PrEP”) and post-exposure prophylaxis (“PEP”).¹ According to Requestors, the County Clinic currently is unequipped to provide PrEP and PEP consultations and prescribing services to its patient population and refers patients to outside specialists for such consultations when clinically appropriate.² Under the Proposed Arrangement, the County Clinic could use the Telemedicine Items to refer patients to the Provider, or other qualified providers, for virtual PrEP and PEP consultations and, if appropriate, prescription of PrEP and PEP medications. Requestors certified that, under the Proposed Arrangement: (i) the County Clinic would not be required to refer patients to the Provider for PrEP and PEP consultations or follow-up items or services; and (ii) the County Clinic would advise patients it deems appropriate for, and who wish to receive, PrEP or PEP consultations that they could receive such consultations either virtually from the Provider or another qualified provider, using the Telemedicine Items, or in-person from the Provider or another qualified provider. If a patient opts to receive a virtual PrEP or PEP consultation, the County Clinic would be responsible for performing preliminary tests and information gathering, scheduling the consultation with the Provider or another qualified provider,

¹ PrEP is when an individual who is at high risk for HIV infection takes certain medications daily to lower his or her chances of becoming infected with HIV. The U.S. Food and Drug Administration has approved a combination of two medications, tenofovir and emtricitabine, sold under the name Truvada®, for daily use as PrEP. If used as prescribed, PrEP may be highly effective in preventing HIV. PEP means taking antiretroviral medicines after being potentially exposed to HIV to prevent becoming infected with HIV. PEP should be used only in emergency situations and must be started within 72 hours after a possible exposure to HIV. The Centers for Disease Control and Prevention (“CDC”) recommends a 28-day course of a three-drug antiretroviral regimen for PEP. See CDC, Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016, available at <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>.

² The County Clinic currently focuses on providing services mandated by law. The County Clinic explained that PEP and PrEP are not considered a mandated service.

and facilitating the telemedicine encounter with the Provider or another qualified provider. Finally, to the extent that a prescribing practitioner orders PrEP or PEP medications, Requestors certified that the patient would be permitted to fill the necessary prescriptions at the pharmacy of his or her choice and that neither the County Clinic nor the Provider would recommend a specific pharmacy.³

According to Requestors, some County Clinic patients seeking in-person PrEP and PEP consultations and follow-up services similar to those that the Provider could furnish virtually via the Telemedicine Items would need to travel approximately 25 to 30 minutes by car.⁴ Requestors indicated that the Proposed Arrangement is intended to improve patient access to HIV prevention services, making it more likely that patients will seek out and receive such services.

Both the County Clinic and the Provider could submit claims to a Federal health care program for virtual PrEP and PEP consultations and follow-up services.⁵ In particular, the County Clinic could submit claims to a Federal health care program for: (i) any medically necessary preliminary items or services (e.g., an HIV test); and (ii) fees for serving as the originating site (i.e., the location of the Federal health care program beneficiary when the service furnished via a telecommunications system occurs). The Provider could submit claims to a Federal health care program as the distant site (i.e., the location where health services and health related services are provided via telecommunications technology).⁶

³ The Provider operates a pharmacy that is located 80 miles, by car, from the County Clinic. The Provider's pharmacy does not currently offer mail-order services.

⁴ Requestors informed us that another provider that also provides PrEP and PEP consultation and follow-up services is located less than a mile from the County Clinic. However, that provider typically furnishes services to female patients and does not offer PrEP or PEP to minors. In contrast, the County Clinic furnishes services to both male and female patients, and under the Proposed Arrangement, the County Clinic would make PrEP and PEP consultation and follow-up services available to minors.

⁵ The County Clinic is not enrolled in Medicare, but it may submit claims to the state Medicaid program.

⁶ We express no opinion regarding the Proposed Arrangement's compliance with applicable laws, regulations, and billing guidance regarding services furnished via telecommunications technology.

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

Under the Proposed Arrangement, the Provider would use grant funds it received from the State Department of Health to give the County Clinic free Telemedicine Items and Telemedicine Services for use in telemedicine encounters related to HIV prevention. The remuneration to the County Clinic would consist of both the free Telemedicine Items and Telemedicine Services and the opportunity to earn the originating site fees for the services furnished using the Telemedicine Items.⁷ In turn, the County Clinic could serve

⁷ While the County Clinic also could receive Federal health care program reimbursement for preliminary items or services furnished in advance of a patient’s telemedicine encounter, such reimbursement would not constitute improper remuneration under the analysis above, as Requestors indicated that the County Clinic would perform and bill for these services regardless of whether it used the Telemedicine Items to facilitate a telemedicine encounter.

as a potential source of referrals of Federal health care program business to the Provider for virtual PrEP and PEP consultations and follow-up items and services. One purpose of the remuneration to the County Clinic could be to induce referrals of Federal health care program business to the Provider and, therefore, the Proposed Arrangement implicates the anti-kickback statute. Nevertheless, for the combination of the reasons set forth below, we conclude that the Proposed Arrangement would present a low risk of fraud and abuse under the anti-kickback statute.

First, the Proposed Arrangement would include certain safeguards intended to prevent inappropriate patient steering. In particular, the County Clinic would remain free at all times to refer its patients to a qualified provider or supplier other than the Provider for PrEP and PEP consultations and follow-up items and services. Requestors certified that the County Clinic would not be required to refer patients to the Provider for PrEP and PEP consultations. The County Clinic would advise all patients who wish to receive PrEP or PEP consultations that they could receive them either virtually from the Provider or another qualified provider, or in-person from the Provider or another qualified provider. Furthermore, nothing inherent to the Telemedicine Items would: (i) limit or restrict the use or compatibility of the Telemedicine Items with different information technology systems, software applications, or networks; or (ii) inhibit the ability of any users of the Telemedicine Items to communicate or exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks. In addition, the Requestors would not use the Telemedicine Items to inappropriately limit or restrict the flow of information. Therefore, through the Telemedicine Items, the County Clinic could facilitate telemedicine encounters with qualified PrEP and PEP providers other than the Provider.

Second, the Proposed Arrangement would be unlikely to result in inappropriate patient steering to the Provider's pharmacy. Requestors certified that neither the Provider nor the County Clinic would recommend a specific pharmacy to fill orders for the medications used for PrEP and PEP and that County Clinic patients would be free to fill their prescriptions at the pharmacy of their choice. In addition, it seems unlikely that a patient would choose to use the Provider's pharmacy to fill a prescription, given that the Provider's pharmacy is located 80 miles, by car, from the County Clinic and does not currently offer mail-order services.⁸

Third, the Proposed Arrangement would be unlikely to inappropriately increase costs to Federal health care programs. While some of the preliminary tests, consultations, and follow-up items and services could be billed to a Federal health care program, the County

⁸ Our conclusion that the Proposed Arrangement presents a low risk of fraud and abuse under the anti-kickback statute may change should the Provider's pharmacy offer mail order services or should the Provider open a pharmacy closer to the County Clinic.

Clinic would have performed the preliminary tests and referred clinically appropriate patients for consultations and, potentially, follow-up items and services regardless of the Proposed Arrangement. The Proposed Arrangement would increase the chances that the County Clinic patients who already require PrEP and PEP consultations and follow-up items and services actually would receive them. This increased access to HIV prevention services is consistent with what Requestor has stated is the purpose of the State Department of Health's grant funds. Further, PrEP and PEP treatments are limited in scope and are appropriate to prescribe only under limited clinical circumstances, lessening the risk of overutilization. Finally, increased access to preventative HIV services could reduce the prevalence of HIV and promote public health.

Fourth, although both the County Clinic and the Provider might benefit from the Proposed Arrangement, the primary beneficiaries would be certain County Clinic patients who, through the use of the Telemedicine Items, could receive HIV prevention services more conveniently and efficiently. The Proposed Arrangement likely would improve access to HIV prevention services for the County Clinic's patients, which is especially important in PEP administration, where the medication must be taken within 72 hours after exposure to HIV.

For the combination of the reasons set forth above, we conclude that the Proposed Arrangement would present 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 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 would not impose administrative sanctions on [names 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 Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors 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 [names 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 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 [names redacted] 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 [names redacted] 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/

Assistant Inspector General for Legal Affairs