

Insights

OIG Advisory Opinion No. 18-03: Provision of Free Telemedicine Hardware & Services

July 16, 2018

By: Marc T. Quigley

On May 24, 2018, the Office of Inspector General (OIG) issued Advisory Opinion No. 18-03, which evaluated a proposed arrangement between a federally qualified health center look-alike (the "Provider") and a county health clinic (the "County Clinic"), whereby the Provider would supply telemedicine items and services, without charge, to the County Clinic to facilitate virtual encounters between the entities (the "Proposed Arrangement"). The OIG concluded that it would not impose administrative sanctions on the Provider or the County Clinic in connection with the Proposed Arrangement.

Under the Proposed Arrangement, the Provider would furnish certain telemedicine hardware items to the County Clinic, and would also assume financial responsibility for installation and maintenance of the items, train the County Clinic staff to use the items, and provide technical assistance for the items. The telemedicine items would be used for virtual encounters related to HIV prevention – primarily, consultations and prescribing services related to medications for the pre-exposure prophylaxis ("PrEP") and post-exposure prophylaxis ("PEP") – which the County Clinic was unequipped to provide to its patient population.

The Provider would finance the provision of the telemedicine items and services using grant funds from the State Department of Health AIDS Institute. The Proposed Arrangement would further the purpose of the grant funds because the telemedicine items and services will improve overall patient access to HIV prevention services and make it more likely that patients will seek out and receive such services.

Under the Proposed Arrangement, both the County Clinic and the Provider could submit claims to a federal health care program for virtual PrEP and PEP consultations and services. The County Clinic could submit claims for medically necessary preliminary items or services, as well as fees for serving as the originating site. Thus, the remuneration to the County Clinic under the Proposed Arrangement would consist of not only the free telemedicine items and services, but also the opportunity to earn originating site fees. In turn, the County Clinic could serve 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, and the Provider could submit claims as the distant site.

Given the circumstances and structure of the Proposed Arrangement, the remuneration to the County Clinic could operate to induce the Clinic to refer federal health care program business to the Provider – thus implicating the anti-kickback statute. Nevertheless, the OIG concluded that the Proposed Arrangement presents a low risk of fraud and abuse under the anti-kickback statute for the following reasons:

- The Proposed Arrangement includes several safeguards to prevent inappropriate patient steering: (a) the County Clinic would always be free to refer patients to a qualified provider or supplier other than the Provider; (b) the County Clinic would advise patients who wish to receive PrEP or PEP consultations that they could receive them virtually or in-person from the Provider or from another qualified provider; and (c) nothing in the telemedicine items would limit or restrict their use to particular software or other technology systems and networks.
- Neither the Provider nor the County Clinic would recommend a specific pharmacy to fill orders for the medications used for PrEP and PEP, and County Clinic patients could fill their prescriptions at the pharmacy of their choice. Further, it is unlikely that a patient would choose to use the Provider's pharmacy, as it is 80 miles away from the County Clinic and does not offer mail-order services.^[1]
- The Proposed Arrangement is unlikely to inappropriately increase costs to federal health care programs because (a) the County Clinic would have performed and billed to federal healthcare programs certain services for patients that sought PrEP and PEP consultations regardless of the Proposed Arrangement and (b) there is a limited risk of overutilization, as PrEP and PEP services and treatment are limited in scope and appropriate to prescribe only in limited clinical circumstances.
- The Proposed Arrangement would increase the chances that the County Clinic patients who already require PrEP and PEP consultations and services actually receive them. Increased access to HIV prevention services is consistent with the purpose of the Provider's grant funds and can reduce HIV prevalence and promote public health.
- The primary beneficiaries of the Proposed Arrangement will be County Clinic patients who will receive HIV prevention services more conveniently and efficiently because of the telemedicine items.

The OIG concluded 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 upon the Provider or the County Clinic pursuant to Sections 1128(b)(7) or 1128A(a)(7) of the Social Security Act (as those sections relate to the commission of acts described in the federal anti-kickback statute).

The OIG notes that this Advisory Opinion may only be relied on by the Requestors. Even so, the Opinion provides insight into the OIG's application of the law to arrangements in which telemedicine items or services is provided at no cost. The Advisory Opinion is consistent with CMS's view of telemedicine as part of its efforts to improve access to care for rural and underserved patient populations. It further demonstrates the OIG's willingness to balance concerns regarding the implication of federal fraud and abuse laws with substantial public health benefits, and to potentially view arrangements such as the one proposed here more favorably when the latter is an important factor in the analysis.

[1] The Advisory Opinion notes that the OIG's conclusion that the Proposed Arrangement presents a low risk of fraud and abuse under the anti-kickback statute may change if the Provider's pharmacy offered mail-order services or the Provider opened a pharmacy closer to the County Clinic.