## **PUBLICATION**

## **Advisory Opinion 18-03 Confirms OIG's Focus on Telehealth**

**June 2018** 

In prior articles regarding the OIG's Work Plan (July 2017 and November 2017) and its recent telehealth claim audit, we have noted how telehealth is clearly on the OIG's radar. Now, the first advisory opinion addressing telemedicine services since 2011 gives further evidence of OIG's increasing attention to this growing area.

OIG Advisory Opinion 18-03, issued on May 24, delivered a favorable opinion addressing an arrangement between a federally qualified health center look-alike (FQHC) and a clinic operated by a County Department of Health (Clinic). The arrangement involves the FQHC's provision of telehealth equipment and services funded by a state grant, to the Clinic, for the purpose of facilitating access to HIV preventive care. The OIG determined that, based on the presence of certain safeguards, the arrangement posed a low risk of fraud and abuse under the Anti-Kickback Statute and that it would not impose administrative sanctions based on the arrangement.

Under the proposed arrangement, the FQHC would furnish the Clinic with certain items, including a computer, telemedicine software, and a camera used in telemedicine examinations. The FQHC would remain financially responsible for all aspects of installing, maintaining, and updating the telemedicine system. These services would include maintaining "communication links and connectivity" required by the system and providing technical assistance for its use. The FQHC would also train Clinic staff on the telemedicine items and facilitate access to telemedicine services

The Clinic would use the telemedicine equipment to facilitate consultations and follow-up with Clinic patients related to HIV prevention, specifically consultations regarding prescriptions for pre-exposure prophylaxis (Prep.) and post-exposure prophylaxis (Pep.). While the Clinic currently offers testing and evaluations for sexually transmitted infections, its scope of services is limited to legally mandated services, which do not include Prep and Pep services. Although another provider located within a mile of the Clinic does provide such services, it only offers them to adult women. The next closest provider of Prep and Pep consultations and follow-up services is 25 to 30 minutes away from the Clinic by car. The FQHC operates a pharmacy where patients could fill prescriptions for Prep and Pep medications, but patients would not be required to fill prescriptions there; furthermore, the pharmacy is 80 miles from the Clinic and does not offer mail-order services.

The telemedicine items and services provided by the FQHC would be funded by an HIV prevention grant from the state Department of Health, which would retain actual title to the items used in the arrangement. According to the OIG, the FQHC would not limit or restrict the ability of the telemedicine equipment and software to be used with other systems or prevent users from doing so. The Clinic would not require its patients to receive telemedicine services from the FQHC and would advise them of the availability of services from other providers, either in person or via telemedicine. Furthermore, the Clinic's patients could receive such services from other remote providers using the equipment and software provided by the FQHC. While OIG declined to assess whether the arrangement was acceptable under billing rules applicable to telemedicine services, it did note that both the FQHC and the Clinic could potentially submit claims to federal payers for services rendered under the arrangement; accordingly, federal health care program dollars were at play.

In its analysis, OIG identified four reasons for its favorable opinion.

First, it noted that the arrangement included safeguards to prevent patient steering. The Clinic would be free to refer patients to any provider for PrEP and PEP consults, including via telemedicine.

Second, patients could fill prescriptions at any pharmacy, and neither the Clinic nor the FQHC would recommend a specific pharmacy. Added to that was the unlikelihood that patients would use the FQHC's pharmacy due to the distance and lack of mail order services. The OIG did note, however, that its opinion could change if the pharmacy did commence mail order services or opened a location closer to the Clinic.

Third, the OIG determined that the arrangement would be unlikely to increase costs to federal health care programs. The arrangement would not affect the volume of the Clinic's billable tests and other services provided to the subject patients. In addition, while the arrangement would likely increase utilization of PrEP and PEP services due to better access, OIG noted that the increase of such services is consistent with the purpose of the grant and are only appropriate in limited clinical circumstances, making the risk of overutilization low.

Fourth and finally, the OIG noted that while both the Clinic and the FQHC could potentially benefit from the arrangement, the greatest potential benefit would be to the patients themselves. In particular, OIG noted that rapid access to PEP treatment is essential because it must be administered within 72 hours of exposure to HIV.

Interestingly, the OIG recognized that the telemedicine consultations could be billable to federal health care programs but did not convey such with any negative connotation. Somewhat to the contrary was the OIG's regard for the absence of federal health care reimbursable services as a good safeguard in the 2011 telehealth advisory opinion (Adv. Op.11-12). It is also unknown how much of an impact the nature of the services had to the OIG's view of this arrangement. HIV is a known public health issue. With so much attention to other public health issues, such as opioid abuse, we question whether the OIG's view of this arrangement would change if the services were for less severe conditions. Finally, as noted in the beginning of this article, the OIG's attention and activity in relation to telehealth has significantly increased in the last year. We expect that this will only continue, and Baker Donelson will continue to monitor and provide information regarding any such developments.