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Coordinated Actions Indicate Growing Scrutiny of Telemedicine

On July 20, 2022, the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services (HHS) released a Special Fraud Alert on telemedicine. On the same day, the U.S. Department of Justice (DOJ) announced a "nationwide coordinated law enforcement action" against 36 defendants, and the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity announced administrative actions against 52 providers, related to alleged telemedicine arrangements.[1] These coordinated actions indicate a growing scrutiny of telemedicine arrangements by federal government regulators.

With the rapid shift in the utilization of telehealth during the COVID-19 pandemic, the number of OIG investigations and enforcement actions related to Medicare payments for telehealth services have similarly grown. Fraudulent telemedicine arrangements may implicate numerous federal fraud and abuse laws, including the Anti-Kickback Statute, which prohibits any person from "*knowingly and willfully*" soliciting or receiving, or offering or paying, any "*remuneration*", directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[2] Additionally, a violation of the Anti-Kickback Statute is sufficient to state a claim under the False Claims Act, which prohibits any person from knowingly submitting false claims to the government.[3]

Since 1988, the OIG has periodically published special fraud alerts to alert and provide general guidance to healthcare industry stakeholders regarding "specific trends of health care fraud and certain practices of an industry-wide character."[4] In this most recent Special Fraud Alert, the OIG noted a common theme among most of the telehealth arrangements they have investigated: telemedicine companies arranging with practitioners "to order or prescribe medically unnecessary items and services for individuals [i.e., patients]…who are solicited and recruited by Telemedicine Companies."[5] This is compounded by the limited communication the practitioners have with the patient – typically not at all, or only by phone.[6] The practitioners are then paid "per review, audit, consult, or assessment of medical charts," i.e., via a methodology that contemplates the volume or value of referrals.[7]

Specifically, the OIG identified seven "suspect characteristics" in arrangements between healthcare practitioners and companies providing telehealth, telemedicine, or telemarking services, which, if present, "could suggest an arrangement that presents a heightened risk of fraud and abuse":

1. "The purported patients for whom the Practitioner orders or prescribes items or services were identified or recruited by the Telemedicine Company, telemarketing company, sales agent, recruiter, call center, health fair, and/or through internet, television, or social media advertising for free or low out-of-pocket cost items or services";
2. "The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed";
3. "The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed";
4. "The Telemedicine Company only furnishes items and services to Federal health care program beneficiaries and does not accept insurance from any other payor";
5. "The Telemedicine Company claims to only furnish items and services to individuals who are not Federal health care program beneficiaries but may in fact bill Federal health care programs";
6. "The Telemedicine Company only furnishes one product or a single class of products (e.g., durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a Practitioner's treating options to a predetermined course of treatment";
7. "The Telemedicine Company does not expect Practitioners (or another Practitioner) to follow up with purported patients nor does it provide Practitioners with the information required to follow up with purported patients (e.g., the Telemedicine Company does not require Practitioners to discuss genetic testing results with each purported patient)."[8]

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This list, which "is illustrative, not exhaustive," was developed based on the OIG's and DOJ's experience in telehealth investigations and enforcement activities. The OIG also clarifies that not all of these characteristics need be present for an arrangement to be considered high-risk. Nevertheless, this alert "is not intended to discourage legitimate telehealth arrangements," as the OIG has previously noted that "[f]or most, telehealth expansion is viewed positively, offering opportunities to increase access to services, decrease burdens for both patients and providers, and enable better care, including enhanced mental health care."[9]

On the same day that the Special Fraud Alert was released, the DOJ announced a "nationwide coordinated law enforcement action," wherein 36 defendants (one of which was a telemedicine company executive) were criminally charged for approximately $1.2 billion in alleged fraud between telemedicine companies and genetic testing laboratories and durable medical equipment (DME) manufacturers.[10] Specifically, the enforcement action involved alleged kickbacks to induce medically unnecessary orders and prescriptions.[11] In addition, the CMS Center for Program Integrity "took administrative actions against 52 providers involved in similar schemes."[12]

The regulatory scrutiny of telehealth services and arrangements is at "an all-time high."[13] With this Special Fraud Alert and latest enforcement action, the OIG appears to be sending a clear message – providers need to ensure that telemedicine arrangements are justified and have appropriate guardrails. Any payments under these arrangements should also be consistent with Fair Market Value and not fluctuate with the volume and value of referrals.

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1 "Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud" Department of Justice, Press Release, July 20, 2022, https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud (Accessed 7/26/22)
2 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
3 "The False Claims Act" U.S. Department of Justice, February 2, 2022, https://www.justice.gov/civil/false-claims-act (Accessed 7/26/22).
4 "Publication of OIG Special Fraud Alerts" Federal Register, Vol. 59, No. 242 (December 19, 1994), available at: https://www.govinfo.gov/content/pkg/FR-1994-12-19/html/94-31157.htm (Accessed 7/26/22).
5 "Special Fraud Alert: OIG Alerts Practitioners to Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies" Department of Health and Human Services, Office of Inspector General, July 20, 2022, available at: https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf (Accessed 7/26/22).
6 *Ibid.*
7 *Ibid.*
8 *Ibid.*
9 *Ibid.*
10 Department of Justice, Press Release, July 20, 2022.
11 *Ibid.*
12 *Ibid.*
13 "U.S. DOJ and HHS-OIG Scrutiny of Telehealth Services and Arrangements at an All-Time High" Sidley Austin, July 25, 2022, https://www.sidley.com/en/insights/newsupdates/2022/07/us-doj-and-hhs-oig-scrutiny-of-telehealth-services-and-arrangements-at-an-all-time-high (Accessed 7/26/22).

(Continued on next page)

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