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QUI TAM QUARTERLY

HEALTH CARE'S NEW WILDERNESS: THE INTERSECTION OF TELEHEALTH & ANCILLARY SERVICES

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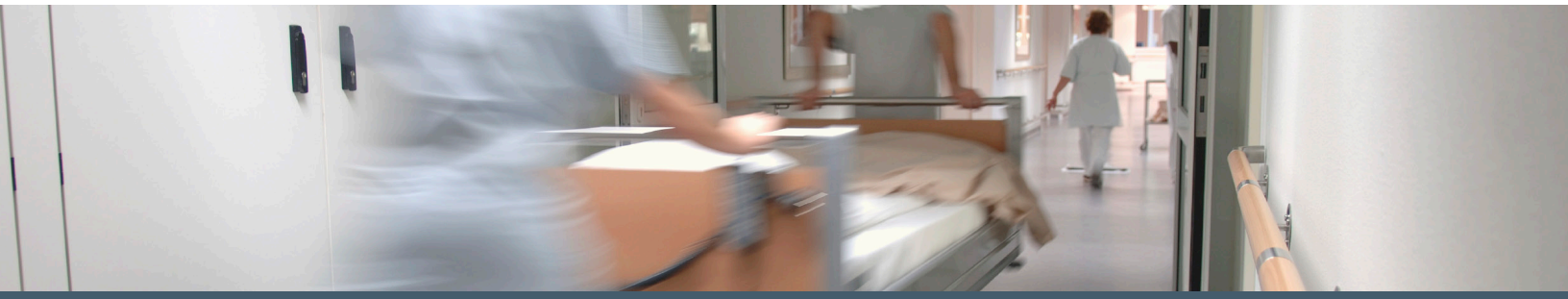

Qui Tam Quarterly is a quarterly publication authored by members of the K&L Gates Health Care Fraud & Abuse team highlighting emerging and pressing issues in health care fraud and abuse, including litigation and governmental investigations involving the False Claims Act, the Stark Law, the Anti-Kickback Statute, and other health care fraud related statutes.

Health care arrangements involving telehealth services to generate orders for reimbursable services have drawn increasing Government scrutiny for potential fraud and abuse over the last few years as the utilization of telehealth services has become more ubiquitous across the industry.

As a result, Government enforcement actions related to potentially fraudulent arrangements involving telehealth services have been on the rise. Such increased Governmental scrutiny and enforcement activities have been particularly apparent at the intersection of telehealth and ancillary services, such as pharmaceutical prescriptions, clinical laboratory testing, and durable medical equipment, orthotics, prosthetics, and supplies ("DME") sales. The Government's focus on arrangements involving these specific intersections is unsurprising, as these ancillary services have independently been fertile grounds for Government enforcement over the last several years.

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In particular, the introduction of telehealth services into arrangements involving ancillary services has heightened the potential for Government inquiry into and legal exposure for a range of health care companies under the False Claims Act, the federal Physician Self-Referral Law (the "Stark Law"), the federal Anti-Kickback Statute ("AKS"), the Civil Monetary Penalties ("CMP") Law, and other health care fraud related statutes. Through a series of actions in 2018, the Government has demonstrated a ready willingness to pursue criminal charges against companies and individuals using telehealth services to generate orders for ancillary services, particularly those involving alleged kickbacks to marketers and the telehealth companies or physicians. The Government has also oriented its enforcement efforts in this space to business practices that target potentially vulnerable segments of the nation's population, such as the elderly and veterans, and to those that the Government perceives as contributing to the nation's opioid epidemic.

Given the growing scrutiny of certain ancillary service arrangements involving telehealth, 2019 is likely to include significant civil and criminal enforcement against health care entities and individuals that utilize telehealth services, directly or indirectly, in a manner that the Government considers legally suspect or outright fraudulent. It is also likely that the health care industry will experience a rise in *qui tam* or whistleblower lawsuits brought under the False Claims Act in light of the Government's enhanced focus in this area and the growth of telehealth services to generate ancillary referrals nationwide.

In light of the increased scrutiny at the intersection of telehealth and ancillary services, it is essential for ancillary service providers—particularly those that bill federal and state health care programs—to engage health care regulatory counsel to review financial arrangements with marketing and telehealth companies to ensure compliance with the applicable federal and state health care fraud and abuse laws. In addition, ancillary service providers should work with health care regulatory counsel to perform due diligence reviews of the businesses and activities

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of third-party contractors prior to entering into financial arrangements. Such an approach helps ensure properly functioning compliance programs and places ancillary service providers in the best position to avoid potential costly litigation.

Overview: What is Telehealth?

According to the Health Resources & Services Administration ("HRSA"), the term "telehealth" means "the use of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration."[1] The technologies involved in telehealth services "include video conferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications."[2] In other words, telehealth allows for health care professionals to evaluate, diagnose, and treat patients remotely through the use of some form of technology.[3] From sophisticated academic medical centers to ancillary service providers, the utilization of telehealth services has begun to rapidly increase throughout the health care industry.[4]

Telehealth's burgeoning role in health care largely relates to the convenience that the use of technology provides. Ever-evolving technologies, including more sophisticated video conferencing services, allow health care professionals to treat patients remotely thereby eliminating barriers created by geography or certain other constraints presented by the patient's condition. For example, a general practitioner in California may be able to participate in a video conference with a patient in Iowa during which the physician determines that the patient suffers from a certain condition requiring ancillary services. Through this type of long distance encounter facilitated by telehealth services, the physician might order laboratory tests, DME items or supplies, or medication for the patient and, eventually, the patient's insurer—which might be a federal payor—is billed.

As this example underscores, telehealth technology allows health care providers to expand the populations of patients that the providers might not otherwise have the opportunity with which to connect. Such expanded relationships can offer providers an enhanced ability to generate business and associated revenue, which might be impossible without the use telehealth services. From a patient perspective, telehealth technology offers the potential to more conveniently connect with a range of providers that may be able to provide more effective clinical care and at a potentially lower cost.

Telehealth and Fraud and Abuse Considerations

Despite their potential benefits in facilitating more convenient, efficient, and effective health care solutions for providers and patients alike, telehealth services have proven to be fraught with regulatory risk for the health care industry. Companies across the industry have integrated telehealth services into a range of arrangements, including using telehealth to connect physicians with patients identified through the work of marketers and lead generation companies for the purposes of screening for various medical conditions and for generating orders. The rapid expansion of telehealth services throughout health care, particularly into ancillary services that have been traditional targets for Government enforcement, has occurred with very little applicable regulations or guidance. Indeed, while the growth of telehealth services seems almost exponential in recent years, Government regulations surrounding the appropriate use of such services in generating referrals for reimbursable items and services are, at most, in their infancy.

As set forth in detail below, the most significant telehealth-related enforcement actions to date involve arrangements that are largely on the fringe of the health care industry given the degree of egregious conduct alleged. However, the Government has also begun to actively probe arrangements involving telehealth

1 HRSA, Federal Office of Rural Health Programs, "Telehealth Programs," (January 2019), available at https://www.hrsa.gov/rural-health/telehealth/index.html.

2 *Id.*

3 Department of Justice, Press Release, "Burlington, New Jersey, Doctor Arrested for Role in $20 Million Telemedicine Compounded Medication Scheme," (November 16, 2018), https://www.justice.gov/usao-nj/pr/burlington-new-jersey-doctor-arrested-role-20-million-telemedicine-compounded-medication ("Telemedicine allows health care providers to evaluate, diagnose, and treat patients remotely–without the need for an in-person visit–by interacting with a patient using telecommunications technology, such as the internet or telephone.").

4 URAC, "URAC / Telemedicine Magazine Survey Finds Increased Usage of Telehealth Tools, Tactics," (December 28, 2017), available at https://www.urac.org/blog/urac-telemedicine-magazine-survey-finds-increased-usage-telehealth-tools-tactics (highlighting current and future rise of telehealth services).

services that appear less egregious on their face, but rather where the Government appears uncertain as to the nature and structure of the arrangements. Such arrangements often involve the Government's focus on the flow of remuneration between downstream entities—particularly payments to marketers, telehealth companies, and physicians—and whether the arrangements are designed to target Medicare, Medicaid, and TRICARE beneficiaries in a fraudulent manner.

Recent Telehealth Enforcement Actions

In recent years, one of the burgeoning areas for Government enforcement has been at the intersection of telehealth services and prescription drugs, particularly where compounding pharmacies are involved. Whether triggered by the ongoing opioid epidemic, the perceived prevalence of nefarious actors at this intersection, or both, the Government has demonstrated a ready willingness to pursue criminal charges against companies and individuals (including health care professionals) that have utilized telehealth services in the furtherance of alleged fraud. For example:

- "On October 12, 2018, the District Court for the Eastern District of Tennessee unsealed a 32-count indictment charging four individuals and seven companies in a $1 billion health care fraud scheme."[5] The defendants were charged with conspiracy to commit health care fraud, mail fraud, and introducing misbranded drugs into interstate commerce, based upon "an elaborate" telehealth "scheme" with several of the defendant-pharmacies.[6] At the center of the alleged fraud scheme was a telehealth company and its Chief Executive Officer.[7] Specifically, the telehealth company was alleged to have fraudulently solicited "insurance coverage information and prescriptions from consumers across the country for prescription pain creams and other similar products."[8] According to an indictment in the matter, 100 physicians hired by the telehealth company approved the prescriptions without knowing that the defendant-pharmacies "were massively marking up the prices of the invalidly prescribed drugs, which the defendants then billed to private insurance carriers."[9] The Government specifically "alleges that the defendants submitted not less than $931,000,000 in fraudulent claims for payment."[10]

- On November 16, 2018, a physician in New Jersey was charged with one count of conspiracy to commit health care fraud.[11] He is alleged to have been "paid by various telemedicine companies to prescribe exorbitantly expensive compounded medications, such as pain creams, scar creams, migraine creams, and metabolic supplements/'wellness capsules, regardless of whether they were medically necessary for the patient."[12] Specifically, the telemedicine company paid the physician on a per prescription basis.[13] The physician "signed the prescriptions without having established any prior doctor-patient relationship, speaking with the patient, or conducting any kind of medical evaluation."[14] The physician's alleged "participation in the conspiracy caused a loss to health care benefit programs of more than $20 million, at least $3 million of which was sustained by TRICARE."[15]

5 Department of Justice, Press Release, "Four Men and Seven Companies Indicted for Billion-Dollar Telemedicine Fraud Conspiracy, Telemedicine Company and CEO Plead Guilty in Two Fraud Schemes," (October 15, 2018), available at https://www.justice.gov/opa/pr/four-men-and-seven-companies-indicted-billion-dollar-telemedicine-fraud-conspiracy.

6 *Id.*

7 *Id.*

8 *Id.*

9 *Id.*

10 *Id.*

11 Department of Justice, Press Release, "Burlington, New Jersey, Doctor Arrested for Role in $20 Million Telemedicine Compounded Medication Scheme," (November 16, 2018), https://www.justice.gov/usao-nj/pr/burlington-new-jersey-doctor-arrested-role-20-million-telemedicine-compounded-medication

12 *Id.*

13 *Id.*

14 *Id.*

15 *Id.*

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- On November 27, 2018, the U.S. Attorney's Office for the Southern District of California announced that a Tennessee-based nurse practitioner pled guilty for participating "in a health care fraud scheme that bilked TRICARE … out of more than $65 million.[16] As part of her guilty plea, [the nurse practitioner] admitted to conducting sham 'telemedicine' evaluations that resulted in the prescription of exorbitantly expensive compounded medications to patients that she never saw or examined in person."[17] Specifically, as part of the scheme, current and former Marines and their family members were paid "to obtain compounded medications that would be paid for by TRICARE."[18] Their information was sent to the Tennessee medical clinic that employed the nurse practitioner, who "then conducted phone calls with the TRICARE beneficiaries, and recommended that they be prescribed compounded medications despite never examining the patients in person.[19] These prescriptions were then signed by doctors employed by the Tennessee medical clinic."[20] The prescriptions were then allegedly "sent directly to particular pharmacies controlled by co-conspirators, which filled the prescriptions and billed TRICARE at exorbitant prices."[21]
- On June 22, 2016, the U.S. Attorney's Office for the Central District of California announced health care fraud related charges against defendant compounding pharmacies in connection with a telehealth-based scheme.[22] Specifically, marketers working for the compounding pharmacies allegedly provided the compounding pharmacies "with large numbers of prescriptions, generally for pain medications, that carried huge reimbursements, often more than $15,000 for each prescription."[23] Physicians who "had little or no contact with patients" provided the prescriptions in exchange for "kickbacks from marketers or from 'telemedicine' websites."[24] According to the Government, "the prescriptions were written for 'patients' who, in many
cases, did not want the prescriptions, had never met the prescribing doctors or had no idea why they were receiving the medications."[25] The Government also alleged that, "[i]n many cases, the beneficiary information was being used without the knowledge of the 'patients' until the prescriptions showed up at their homes."[26] This telehealth scheme allegedly resulted in tens of millions of dollars in losses to TRICARE over the course of several months.[27]

While each of these matters is distinct on their facts, commonalities are clear. Specifically, the actors in many of these cases allegedly used sham telehealth services as the cornerstone of their fraudulent schemes. In most of the cases, health care practitioners were compensated to provide medically unnecessary prescriptions to patients who the provider never actually evaluated or with whom the practitioners had minimal contact. These medically unnecessary prescriptions were largely for high-dollar prescriptions, resulting in millions of dollars of payments from federal health care programs and/or private insurers.

The Government also emphasized in a number of these matters that—by virtue of the telehealth encounter—the practitioners and patients did not have a prior relationship with one another and were apparently isolated encounters. In other words, the physician-patient encounters via telehealth services did not appear to be for the sake of ongoing clinical care for the patient's benefit, but, instead, for a one time order for the ancillary service.

16 Department of Justice, Press Release, "Tennessee Nurse Practitioner Pleads Guilty for Role in $65 Million TRICARE Fraud," (November 28, 2018), *available at* https://www.justice.gov/usao-sdca/pr/tennessee-nurse-practitioner-pleads-guilty-role-65-million-tricare-fraud-0.

17 *Id.*

18 *Id.*

19 *Id.*

20 *Id.*

21 *Id.*

22 Department of Justice, Press Release, "22 Defendants Named in Health Care Fraud Cases involving over $161 Million in Fraudulent Bills to Government Health Care Programs," (June 22, 2016), *available at* https://www.justice.gov/usao-cdca/pr/22-defendants-named-health-care-fraud-cases-involving-over-161-million-fraudulent-bills

23 *Id.*

24 *Id.*

25 *Id.*

26 *Id.*

27 *Id.*

Fraud and Abuse (and Other) Laws Applicable to Telehealth Arrangements

When ancillary service providers bill federal and state health care programs, the financial relationships between ancillary service providers, marketers, telehealth companies, and referring physicians all implicate the federal and state fraud and abuse laws, including the AKS, the Stark Law, the CMP Law, and the False Claims Act. Even if ancillary service providers do not bill federal and state health care programs, there are state law restrictions that may be applicable to such financial arrangements. For example, many states also have their own anti-kickback statutes and fee-splitting prohibitions, which are often broader than their federal counterparts and are, in many instances, applicable to all payors (including self-pay patients). In addition, many states have consumer protection and similar commercial laws that are not limited to the health care context, which may also be applicable to ancillary service providers' arrangements.

1. The Federal Anti-kickback Statute

The AKS prohibits any individual from knowingly and willfully soliciting, receiving, offering, or paying, directly or indirectly, any remuneration to induce or reward the referral, order, lease, or recommendation of an item or service payable by a federal health care program (including Medicare and Medicaid).[28] The AKS is intent-based, which means remuneration for referrals is only subject to liability if the requisite intent to induce or provide referrals is present. However, certain federal circuit courts have held that the AKS is violated if one purpose (as opposed to a primary or sole purpose) of a payment or remuneration to a provider is to induce referrals.[29] Further, revisions to the AKS found in the Affordable Care Act, provide, "[w]ith respect to violations of [the AKS], a person need not have actual knowledge of this section or specific intent to commit a violation of this section."[30] The AKS provides a number of "safe harbors" that protect arrangements that satisfy all the requirements of the applicable safe harbor. Each requirement of an applicable safe harbor must be met in order to receive safe harbor protection. Arrangements that do not fit within a safe harbor are not *per se* violative but instead are analyzed based on their particular facts and circumstances.

a. Marketing Arrangements

Ancillary service providers often use marketing companies as a bridge between themselves, referring physicians, and patients. These marketing companies assist ancillary service providers to not only advertise the ancillary services to potential patients, but also often to interface directly with patients and the physicians prescribing the ancillary service. It is precisely these interactions between the marketers, patients and referring physicians that place ancillary service providers at risk with respect to running afoul of fraud and abuse laws, such as the AKS. In fact, two recent Department of Justice ("DOJ") settlements demonstrate Government regulators' willingness to vigorously pursue ancillary service providers and their marketers for violations of the AKS.[31]

The Office of the Inspector General ("OIG") has repeatedly stated that marketing and advertising services implicate the AKS because such activities, by their nature, are meant to recommend the use of a product or service and that such services should be pursuant to a flat, fair market value payment, which does not take into account the value or volume of referrals generated between the parties.[32] The Government will view any marketing services payments not connected to the value of the advertising services that the marketer provides as remuneration to steer patients—including potential federal health care program beneficiaries—to the health care provider or supplier. Even if the marketing arrangements are flat fee arrangements that otherwise reflect fair market value in an arms-length transaction, marketers may have relationships with the telehealth companies which involve steering telehealth orders back

28 42 U.S.C. § 1320a-7b(b)

29 *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).

30 U.S. Public Law 111-148, March 23, 2010, § 6402(f)(2). A violation of the AKS is a felony and may be punished by fines of up to $100,000 and/or imprisonment for up to ten years. In addition, the federal government may impose civil monetary penalties of up to $100,000 per kickback and damages calculated at three times the amount of the remuneration and exclude violators from participation in federal health care programs. Furthermore, violations of the AKS may also expose an individual or entity to liability under the federal False Claims Act, including via *qui tam* action, for knowingly presenting, or causing to be presented, to the government a false or fraudulent claim for payment or approval, which imposes penalties of not less than $11,181 and not more than $22,363 per claim, plus three times the amount of damages that the government sustains because of the submission of the false claim.

31 *See*, e.g., Department of Justice, Press Release, "Florida Compounding Pharmacy and its Owners to Pay at Least $775,000 to Resolve False Claims Act Allegations," (February 14, 2019), available at https://www.justice.gov/opa/pr/florida-compounding-pharmacy-and-its-owners-pay-least-775000-resolve-false-claims-act (resolving allegations that a compounding pharmacy and its owners paid kickbacks to a third-party marketing company to solicit prospective patients for compounded drugs prescriptions regardless of medical necessity); Department of Justice, Press Release, "Marketer Agrees to Pay Nearly $340,000 for Allegedly Engaging in an Illegal Kickback Scheme with OK Compounding," (February 8, 2019), available at https://www.justice.gov/usao-ndok/pr/marketer-agrees-pay-nearly-340000-allegedly-engaging-illegal-kickback-scheme-ok-0 (relating to allegations that a compounding pharmacy paid substantial kickbacks to marketers in the form a share of revenue generated by the marketers' referrals in exchange for those marketers referring prescriptions for compounded drugs to the pharmacy).

32 OIG, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35974 (July 29, 1991).

to the ancillary service providers with which the marketers have relationships. In such cases, Government regulators could allege that the ancillary service providers and the marketers are indirectly influencing patients to choose items and services sold by certain ancillary service providers over those of competitors. The Government could view payments from ancillary service providers to the marketing companies as prohibited remuneration under the AKS for a referral (or remuneration for "arranging for" a referral) and as having the effect of improperly influencing medical decision-making and precluding fair competition.

b. Arrangements between Ancillary Service Providers and Telehealth Companies

First and foremost, Government regulators expect that financial arrangements between all health care providers or suppliers and referral sources be commercially reasonable, meaning that the arrangement has a legitimate business purpose and would make commercial sense even if there were no potential business referrals generated between the parties to the arrangement. Typically, telehealth companies contract with physicians located in different states in order to serve patients located in those states. Medicare and Medicaid reimbursement for telehealth services is limited, and accordingly, telehealth companies generally receive reimbursement by billing the patient or the patient's third-party payor directly.

The Government is likely to view any financial relationship between an ancillary service provider and a telehealth company, whether direct or indirect through entities such as third party marketers, with intense scrutiny. Specifically, Government regulators could allege that the telehealth company is being paid to influence patients to choose items and services from the ancillary service provider paying for the telehealth consultation and therefore is paying prohibited remuneration under the AKS for a referral, even if the payment is a flat fee and would otherwise reflect fair market value in an arms-length transaction. In addition and as further discussed below, such arrangements are almost certain to implicate the Stark Law, which is a strict liability statute whereby violations require no illicit intent to induce referrals.

2. Beneficiary Inducement Prohibition under the Civil Monetary Penalties Law

Several Government enforcement actions involving telehealth have involved allegations that the ancillary service provider absorbed the cost of the telehealth consultation between the patient and the referring physician, either directly or indirectly through a marketing company. To the extent ancillary service providers pay for telehealth consultations instead of the telehealth company charging a patient or their third-party payors for the telehealth services, Government regulators could see such practices as a violation of the beneficiary inducement prohibition under the CMP Law.

The CMP Law prohibits health care providers from giving anything of value to a Medicare or Medicaid beneficiary that is likely to induce or encourage the patient to choose a particular provider for covered services.[33] For example, providing free or discounted items or services without regard to financial need could run afoul of this prohibition. Providers who violate the CMP Law by providing inducements to beneficiaries may be subject to penalties equal to $20,000 per occurrence and damages of three times the amount billed to Medicare or Medicaid as a result of the illegal acts, as well as exclusion from federal health care programs. [34]

Through the advisory opinion process, the OIG has expressly disapproved of the provision of free physician services to Medicare beneficiaries.[35] Furthermore, the OIG has repeatedly found that discounted or free items and services provided to federal health care beneficiaries are also a potential violation of the AKS as a prohibited kickback to patients, to the extent those items and services are offered as an inducement to the patients to self-refer in the future back to the entity providing the free or discounted item or service.[36] Accordingly, to the extent that Medicare and Medicaid

33 42 U.S.C. 1320a-7a(b).

34 Compliance guidance published by the OIG, which specifically identifies the provision of free services and other incentives or things of value to patients as a high-risk area for potential fraud and abuse and notes that routine waivers of deductibles and cost-sharing amounts may result in liability not only under the CMP Law, but also the AKS and the False Claims Act, as well as similar state statutes or regulations. The OIG notes that when ancillary service providers forgive financial obligations for reasons other than genuine financial hardship of a particular patient, they may be inducing the patient to use items or services that are not medically necessary, leading to overutilization. *See* OIG, Publication of OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, 64 Fed. Reg. 36,368, 36,378 (July 6, 1999).

35 *See, e.g.*, OIG Adv. Op. 00-3 (Apr. 7, 2000) (approving of an arrangement under which a hospice provide via unpaid volunteer certain support services to terminally ill patients who did not yet meet the Medicare definition of such or had not elected hospice, but specifically noting that the services did not include nursing, home health or physician professional services).

36 *See*, e.g., OIG Adv. Op. 07-08 (July 23, 2007).

beneficiaries are among the patients who are receiving telehealth consultations at no charge, this practice could be viewed by the Government as remuneration to beneficiaries to induce or encourage the beneficiaries to choose the ancillary service provider in violation of the CMP Law and the AKS.[37]

3. *The Stark Law*

As mentioned above, to the extent ancillary service providers have direct or indirect financial arrangements with referring physicians who refer designated health services payable by Medicare to the ancillary service provider, the Stark Law [38] is likely also implicated. The Stark Law generally prohibits a physician from making any referrals of Medicare patients to an entity for the furnishing of designated health services ("DHS"), including DME and supplies, clinical laboratory services, and outpatient prescription drugs, if the physician or the physician's immediate family member has a financial relationship with that entity, unless the arrangement meets an exception stated in the law or its accompanying regulations. A "financial relationship" includes both an ownership interest and/or a compensation arrangement with a physician. An ancillary service provider that receives a prohibited DHS referral may not seek payment from Medicare for any DHS performed as a result of such referral.

Unlike the AKS, which is intent based, the Stark Law is a strict liability statute. ***Any*** technical violation of the statute (i.e., the failure to fall squarely within the four corners of an enumerated Stark exception) requires repayment of all "tainted" referrals, regardless of the parties' intent. The Stark Law contains several enumerated exceptions that describe permissible financial relationships between a referring physician and an entity (which all require compliance with the AKS).[39]

4. *State Licensure Rules and Lack of Physician-Patient Relationships*

Violation of medical licensure rules are an additional opportunity for regulatory enforcement related to abusive telehealth arrangements that is beginning to receive attention from the Government and state medical boards. State medical boards require the establishment of a sufficient physician-patient relationship in accordance with the applicable standard of practice when providing treatment, rendering a diagnosis, prescribing, dispensing, or administering prescription drugs, including when medical services are provided via telehealth technology. For example, many state telehealth laws prohibit physicians from delivering health care services via an audio-only consultation or questionnaire.[40] Accordingly, failing to establish a sufficient physician-patient relationship clearly violates most states' medical board regulations and could subject the physicians to discipline by the applicable state medical board, including up to the loss of the physician's medical license.

37 While the AKS, CMP Law, and Stark Law are only applicable to the extent a federal or state health care program is billed as a result of a prohibited referral under those statutes, a newly enacted "all-payor" anti-kickback provision in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act may provide an additional enforcement mechanism for abusive financial arrangements involving clinical laboratory service providers that do not bill government programs, including those involving telehealth. SUPPORT for Patients and Communities Act, Pub. L. 115-271. Specifically, Section 8122 of the Act, codified at 18 U.S.C. § 220, contains prohibitions related to remuneration paid for any referral for clinical laboratory services, regardless of whether the laboratory test is connected to addiction treatment or recovery, including commission-based compensation paid to both W-2 employed and contracted marketers.

38 42 U.S.C. § 1395nn; 42 C.F.R. § 411.351 *et. seq.*

39 Penalties for violating the Stark Law are harsh and include the denial of payment to the DHS entity for the impermissible provision of DHS, the refund of any amounts collected related to all referrals made in violation of the Stark Law, and civil monetary penalties of up to $24,748 for each violation and $164,992 for each circumvention arrangement or scheme. 42 U.S.C. §1395nn(g). Furthermore, violations of the Stark Law may also expose an individual or entity to liability under the federal False Claims Act, including via *qui tam* action, for knowingly presenting, or causing to be presented, to the government a false or fraudulent claim for payment or approval. In addition, numerous courts have held that claims billed to federal health care payors in violation of the Stark Law also constitute a false claim. See, e.g., U*nited States ex rel. Drakeford v. Tuomey Health care Sys., Inc.*, 792 F.3d 364 (4th Cir. 2015) (affirming government damages and civil penalties of over $237M under the FCA based on Stark Law violations); *United States ex rel. Emanuele v. Medicor Assoc. Inc.*, 242 F.Supp.3d 409, (W.D. Pa. 2017) (denying defendants" motion for summary judgement and permitting *qui tam* complaint to move forward alleging FCA violations based on non-compliance with the Stark Law).

40 *See*, e.g., N.Y. Pub. Health Law § 2999-cc ("Telehealth shall not include delivery of health care services by means of audio-only telephone communication, facsimile machines, or electronic messaging alone, though use of these technologies is not precluded if used in conjunction with telemedicine, store and forward technology, or remote patient monitoring."); N.J. Stat. Ann 45:1-61 (" 'Telemedicine' does not include the use, in isolation, of audio-only telephone conversation, electronic mail, instant messaging, phone text, or facsimile transmission.").

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More notably, the Government can use the lack of a sufficient physician-patient relationship as further evidence of false and fraudulent claims related to medically unnecessary items and services reimbursed by a federal or state health care program. As one of many examples, in June 2016, six (6) defendants, including a physician and physician assistant, were indicted on various charges, including conspiracy to commit health care fraud and wire fraud, receiving illegal kickbacks, paying illegal kickbacks, and money laundering. According to the indictment, several of the defendants operated a telemarketing call center located inside a pharmacy, whereby the call center and pharmacy owners paid the physician and the physician assistant kickbacks in exchange for signing prescriptions for compounded drugs for TRICARE beneficiaries "even though they did not have legitimate provide-patient interactions with the TRICARE beneficiaries."[41] In another example, on June 28, 2018, the DOJ announced the prosecution of multiple individuals, including sales representatives of a marketing company, in connection with "medically unnecessary compounded prescriptions."[42] As described by the DOJ, the marketing company was paid a percentage of prescriptions sent to a particular compounding pharmacy. Importantly, the DOJ stated that "[t]o ensure physicians prescribed compounded medications regardless of medical necessity, [the sales representative] referred MTA beneficiaries to telemedicine physicians who were paid by the marketing company or its affiliates," and specifically noted that, in some instances, the physician signed prescriptions without examining or speaking with the patients. Recent enforcement actions, such as the cases discussed above, among others, evidence the Government's concern that connections between ancillary service providers and referring physicians—whether directly or through a marketing company acting as a facilitator—raise questions of medical necessity of orders for ancillary items and services and prescription drugs, and legitimate physician-patient relationships.

Projections in Telehealth Enforcement for 2019

The rapid and continued emergence of telehealth services in health care arrangements involving ancillary services—and the potential legal and regulatory issues at play at this intersection—increases the likelihood of significant Government enforcement actions in 2019. From a potential rise in the number of *qui tam*s filed involving such arrangements to the Government's continued pursuit of criminal health care fraud-related charges against entities and individuals involved in these arrangements, 2019 is likely to significantly define the contours of telehealth arrangements for the foreseeable future.

1. Telehealth and Prescription Drugs

As noted above, the latter half of 2018 saw major enforcement efforts involving compounding pharmacies and telehealth companies, including an alleged billion-dollar telehealth fraud scheme. While these cases can be deemed as being "extreme" or "on the fringe" based on the conduct alleged, the Government's apparent focus on the latter types of arrangements strongly suggests that it will continue to probe these arrangements in the coming year.

This position is reinforced by the clear commitment that the Government has shown recently to combatting the opioid epidemic.[43] As part of this process, Congress and law enforcement agencies have worked to eradicate the problem at its perceived sources, which include entities and individuals that dispense and distribute opioids.[44] Telehealth arrangements involving pharmacies will likely remain a prime Government target for enforcement as telehealth can help facilitate the quicker and widespread dispensing of opioids to patients across the country. If the Government perceives

41 Department of Justice, Press Release, "Fifteen Charged in Middle District As Part of Largest National Health Care Fraud Takedown in History," (June 22, 2016), https://www.justice.gov/usao-mdfl/pr/fifteen-charged-middle-district-part-largest-national-health-care-fraud-takedown.

42 Department of Justice, Press Release, "U.S. Attorney's Office Prosecutes Five Individuals Responsible For Over $15 Million In Health Care Fraud And Three Members Of South Jersey Oxycodone Ring As Part Of National Takedown," (June 28, 2018), *available at* https://www.justice.gov/usao-nj/pr/us-attorney-s-office-prosecutes-five-individuals-responsible-over-15-million-health-care.

43 Department of Justice, Press Release, "National Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over $2 Billion in Fraud Losses," (June 28, 2018), available at https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over.

44 *See* id.; SUPPORT for Patients and Communities Act, Pub. L. 115-271.

The Government has shown an increased interest in how and by whom the telehealth physicians are compensated and whether the telehealth physicians have been sufficiently evaluating patients for medical necessity.

that certain telehealth arrangements are contributing to the proliferation of drug prescriptions, including opioids and drugs marketed as safe opioid substitutes, in a medically unnecessary manner, or are otherwise resulting in fraudulent claims submission to federal health care programs, action is likely to be swift.

2. Telehealth and Durable Medical Equipment

In addition to enforcement actions involving telehealth services and prescription drugs, the last few years have seen an increased focus on the use of telehealth services in the DME industry; a trend that is likely to continue in 2019. For example, there has been a significant uptick in federal health program audits involving Medicare claims specifically aimed at DME suppliers that provide orthotics or supplies, such as catheters and other urologic supplies. The role of telehealth services in DME-related arrangements has often been through utilizing telehealth physicians to generate the physicians' orders necessary to bill federal health care programs for the DME supplied. The Government has shown an increased interest in how and by whom the telehealth physicians are compensated and whether the telehealth physicians have been sufficiently evaluating patients for medical necessity.[45] Consequently, such arrangements potentially implicate the False Claims Act, the Stark Law, the AKS, and other laws, depending on the specific facts involved.

The potential for a significant increase in enforcement activity surrounding arrangements at the intersection of telehealth and DME services is largely due to the high level of scrutiny the DME industry has independently and historically drawn. Specifically, traditional areas of scrutiny in the DME space have included DME sales to beneficiaries of federal health care programs where the DME was not actually provided, but the federal payor was billed; the practice of "slamming," or the provision of and billing for equipment not requested or prescribed; and/or unlawful marketing practices specifically targeting beneficiaries of federal health care programs.[46] The relatively recent overlay of telehealth services onto heavily scrutinized DME sales activities naturally heightens the possibility that the Government will intently probe these arrangements and counsel for relators will look to file further *qui tam*s. In other words, it will be unsurprising if the telehealth-DME intersection proves to be fertile ground for health care fraud allegations this year.

3. Telehealth and Laboratories

Finally, for many of the same reasons that telehealth's role in DME sales will likely garner attention this year, arrangements employing telehealth in generating laboratory orders may find themselves more consistently on the Government's radar. Some laboratories that screen for, *inter alia*, cancer, genetic abnormalities, and/or potential reactions to specific medications have utilized telehealth services to connect physicians with patients interested in preventative health information, including whether they have an increased likelihood for a certain illness and/or disease. However, because these screens are typically reimbursed by federal payors at high levels and because telehealth physicians, in some instances, may have no prior relationships with the patients for whom they are ordering the screens, intense scrutiny on whether medical necessity criteria have been met is likely.

Of potential concern for the Government in these arrangements is that telehealth physicians may serve merely as a "rubber stamp" for these high-cost screens. However, given the fact that the screens are largely preventative in nature, the threshold for medical necessity is often simply a certain historical pattern of the disease within a patient's family tree, which means medical necessity may be appropriately determined via a telehealth encounter.

Conclusion

Unsurprisingly, new frontiers are emerging in health care as burgeoning technologies merge with health care's ever-evolving landscape. While these new frontiers provide seemingly endless possibilities and opportunities for improving the quality of health care, they also present a constantly changing regulatory and legal environment that individuals and entities operating in the space must navigate. Telehealth's intersection with traditionally scrutinized ancillary services exemplifies this challenge and also demonstrates the risks of intense governmental scrutiny when regulations and the law do not keep pace with technological changes

45 Katie LaGrone, "The new face of medical equipment fraud in Florida: Telemedicine now used to target patients," (November 1, 2018), available at https://www.abcactionnews.com/long-form/the-new-face-of-medical-equipment-fraud-in-florida (quoting an HHS-OIG Special Agent as stating, "[y]ou have a whole group of doctors who are willing to write prescriptions for patients they don't have a relationship with, who they've never seen and then you're cutting out the patient's real provider who knows better").

46 *See*, e.g., *United States ex rel. Yarbrough v. Am-Med Diabetic Supplies, Inc.*, Case No. 15-81520-CIV (S.D. Fla.) (alleging, through *qui tam* action, similar practices).

in an already complex industry. The uncharted territory that telehealth currently represents in health care creates an environment—largely at its extremes—where fraud and other nefarious conduct for the sake of financial gain can become rampant. As such, it will be unsurprising if 2019 becomes the year when telehealth arrangements take center stage in the Government's continual quest to eradicate fraud and abuse from health care.

Given these realities, all ancillary service providers that have relationships with outside marketing companies and telehealth providers should engage health care regulatory counsel to review existing and proposed arrangements to ensure compliance with the applicable federal and state health care fraud and abuse laws. Ancillary service providers should also conduct comprehensive due diligence on third party marketing companies, especially the financial arrangements between the marketing companies and telehealth companies or telehealth physicians and terminate arrangements with marketers that engage in questionable business practices. Written agreements with marketers should clearly outline the duties and obligations of the marketers, and should contain regulatory guardrails and indemnities, and avoid suspect characteristics as specifically outlined by the OIG. Additionally, marketing arrangements should ideally be structured to squarely fit into an AKS regulatory safe harbor, if possible. If not possible, the arrangement should track the safe harbor requirements as closely as possible and, in any case, the compensation to marketers should not be based on the value or volume of federal health care business (or any business) referred to the ancillary service provider, but rather based on the actual amount and cost of services provided by the marketers.

As discussed above, Government regulators will expect that financial arrangements between ancillary service providers and referral sources (i.e., telehealth companies and physicians) be commercially reasonable, have a legitimate business purpose, and make commercial sense even in the absence of referrals generated between the parties. Accordingly, any arrangement between an ancillary service provider and a telehealth company or physician, whether direct or indirect, would likely be subject to intense scrutiny by Government regulators.

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