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Telemedicine: A review of the fraud and abuse landscape

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The practice of telemedicine saw continued advancements in 2018 including, importantly, passage of the Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act (CHRONIC Act or the Act) as part of the 2018 Congressional Bipartisan Budget Act.[1] The measures passed as part of this bill will help pave the way for Medicare reimbursement for a wider range of telemedicine services, which ultimately may result in further expansion of the availability of these services.

Historically, Medicare reimbursement for telemedicine services has been limited, primarily due to Medicare's conditions for coverage of telemedicine services.[2] These conditions include requiring patients to be located in qualifying rural areas and qualifying "originating sites" (e.g., a hospital or physician's office, but not the patient's home), restrictions on covered Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS) codes, provision of services by eligible "distant site" practitioners, and communication requirements (i.e., real-time audio visual communications). Loosening these limitations, over the next two years, the Act phases in revisions to Medicare's telemedicine reimbursement requirements including: (1) eliminating geographic restrictions on telestroke consultation services; (2) expanding telemedicine coverage under Medicare Advantage plans; (3) permitting Accountable Care Organizations more flexibility in the use of telemedicine services; and (4) permitting monthly telemedicine assessments by a nephrologist from a patient's home for patients receiving home dialysis treatment.

With an increase in federal healthcare spending on telemedicine services, providers can expect increased scrutiny on compliance with federal healthcare program billing and coding requirements, as well as with the requirements of the various fraud and abuse laws that may be implicated by telemedicine arrangements. (For purposes of this article, we are using the term "telemedicine" interchangeably with the term "telehealth.")

For example, in April 2018, the U.S. Department of Health and Human Services Office of Inspector General (OIG) released a report entitled "CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements," a title directly stating the report's conclusion. The report detailed the OIG's findings with respect to whether telemedicine services reimbursed by Medicare met all of the Medicare reimbursement conditions. Medicare paid a total of $17.6 million in telemedicine payments in 2015 out of a total of $540 billion in payments.[3] Based on a review of 100 telemedicine claims, the OIG found that 31 out of 100 claims were improperly paid. The OIG's extrapolation of this result showed that Medicare improperly paid an estimated $3.7 million during the audit period (2014-2015). Although not a large sum in comparison to overall Medicare spending, nevertheless the amount accounts for approximately 27% of all Medicare dollars spent on telemedicine services during this period.

In addition to the OIG's findings, the Department of Justice (DOJ) also appears to be turning its focus to telemedicine-related matters. In October 2018, the DOJ announced an investigation into a nearly $1 billion healthcare fraud scheme involving fraudulent telemedicine services and improperly solicited insurance coverage

information and prescriptions.[4] HealthRight LLC, a telemedicine company, and its CEO pleaded guilty to, among other things, felony conspiracy charges for their roles in the scheme. Charges also were announced against four other individuals and seven companies related to the scheme, which allegedly involved HealthRight fraudulently soliciting insurance coverage information and prescriptions from consumers for prescription pain creams and other similar products. The companies allegedly engaged physicians to prescribe medications via telemedicine encounters, then massively marked up the price of the prescriptions. The prescriptions were then billed to private insurers. Although the scheme described in the DOJ's announcement is a fairly garden-variety case of fraud, the DOJ's announcement is instructive of its increasing interest in oversight of telemedicine activities. Moreover, this interest is likely to increase as more federal healthcare dollars are spent on telemedicine.

It is, therefore, vital that healthcare providers and suppliers that are currently involved in the provision of telemedicine services, and providers and suppliers that are interested in moving into this space, understand the rules of the road under which they will operate their telemedicine programs. Numerous federal and state laws and regulations govern the provision of, and reimbursement for, telemedicine services. One primary example is the varying state licensure requirements for the provision of services. Compliance with these laws is not optional. Start-up companies may not be aware of these laws, and therefore, it is incumbent upon healthcare providers that contract with these entities to ensure that the entities are in compliance. In addition to licensure concerns, telemedicine implicates all of the federal fraud and abuse laws. The effect of those laws on telemedicine arrangements is the focus of this article.

The Anti-Kickback Statute

The federal Anti-Kickback Statute (AKS) is a wide-reaching statute that prohibits the knowing and willful offer or payment of, or the solicitation or receipt of, "remuneration" to induce or reward patient referrals or generation of business involving any item or service payable by the federal healthcare programs (i.e., drugs, supplies, or healthcare services provided to Medicare, Medicaid, or TRICARE beneficiaries).[5] Broken down into its individual elements, the AKS requires: (1) remuneration; (2) that is offered, paid, solicited, or received; (3) to induce or reward referrals of Medicare, Medicaid, or TRICARE beneficiaries. The mental state required for a violation of the AKS is "knowing and willful," but there can be a violation where "one-purpose" of the remuneration was to induce or reward referrals.[6] "Remuneration" is broadly defined as "anything of value" and can include free rent or equipment, discounts, provision of office assistance, certain reimbursement services (e.g., pre-authorization assistance), and excessive compensation for medical directorships or consultancies.

Penalties under the AKS include criminal penalties (i.e., jail), as well as civil monetary penalties, and violations of the AKS are per se violations of the federal False Claims Act (FCA, discussed in more detail below).

To help facilitate legitimate business arrangements that may nevertheless implicate the AKS, Congress included several safe harbors in the statute and granted the OIG authority to promulgate additional safe harbors by regulation. The safe harbors offer protection for arrangements that fit squarely within the requirements of the safe harbor. To the extent an arrangement meets all of the requirements of the safe harbor, the AKS is not violated and the arrangement is considered "safe." If, however, an arrangement does not meet all of the requirements of a safe harbor, the arrangement does not automatically violate the AKS. Rather, whether the statute has been violated will depend on an assessment of the facts and circumstances surrounding the arrangement, including whether there is any nexus between the remuneration and any referrals. The closer an arrangement can be structured to fitting into a safe harbor, the less AKS risk there will be associated with the arrangement.

Although there are numerous safe harbors, some will be more beneficial than others to parties interested in

entering into arrangements related to the provision of telemedicine services. Several of the most helpful safe harbors include the space and equipment rental safe harbors, which can be used to facilitate arrangements in which one party leases telemedicine equipment or space for the equipment to another; and the personal services and management contracts safe harbor, which can be used to facilitate arrangements between an entity and a practitioner for the provision of remote services.

These safe harbors generally require that the arrangement: (1) be set out in writing and signed by the parties; (2) cover all of the services, space, or equipment for the term of the arrangement; (3) if the services, space, or equipment are to be provided on a periodic basis, specify the exact schedule, length, and payment for such intervals; (4) not be for a term of less than one year; (5) have compensation (or rent) that is set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties for which payment may be made by Medicare, Medicaid, or other federal programs; and (6) the services (or space or equipment) do not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the arrangement.

Other safe harbors that may be beneficial to entities entering into arrangements related to the provision of telemedicine services include the electronic health records and electronic prescribing items and services safe harbors, and the employment safe harbor. There may be more than one way to structure a compliant arrangement. (We provide the references to these safe harbors by way of example only.)

One example of an arrangement that may implicate the AKS is a scenario in which a pharmacy engages a group practice to provide assessments for the pharmacy's patients via telemedicine as part of the pharmacy's expansion into primary care services. The pharmacy compensates the physicians and provides equipment to facilitate the telemedicine consultations. The physicians may refer patients to the pharmacy for fulfillment of prescriptions, but referrals to the pharmacy are not required under the terms of the arrangement. In this example, the parties could potentially rely upon the personal services safe harbor and the equipment safe harbor to structure the arrangement so that it complies with the AKS.[7]

The Stark Law

The Stark Law, which is similar (though not identical) to the AKS, prohibits a physician from referring Medicare or Medicaid patients for designated health services (DHS) to an entity with which the physician or physician's immediate family member has a financial relationship, unless an exception applies.DHS includes clinical lab services, inpatient and outpatient hospital services, physical therapy, occupational therapy, outpatient speech-language pathology services, outpatient prescription drugs, and durable medical equipment and supplies. A complete list of DHS can be found at 42 C.F.R. § 411.351. In addition to the restriction on the physician, the entity is also prohibited from submitting claims to Medicare or Medicaid resulting from any prohibited referral.

In contrast to the AKS, penalties under the Stark Law are limited to civil, as opposed to criminal, penalties. The penalties include an overpayment or refund obligation, civil monetary penalties, and possible exclusion from participation in the federal healthcare programs. Importantly, a violation of the Stark Law also can lead to FCA liability.

Similar to the AKS, there are "exceptions" that protect certain business arrangements from Stark Law liability. However, unlike the AKS, a failure to meet all of the requirements of a Stark Law exception results in an automatic violation of the statute, because the Stark Law is a "strict liability" statute where the intent of the parties is irrelevant. The Stark Law exceptions include exceptions for physician ownership interest, as well as for compensation.

As with the AKS, certain exceptions may be more useful with respect to establishing telemedicine arrangements,

including the employment relationships exception, the personal services arrangements exception, the space and equipment leasing arrangements exception, the fair market value compensation arrangements exception, and the electronic prescribing and electronic health records items and services exceptions. Although each Stark Law exception has its own requirements, generally the exceptions require a written agreement signed by the parties, where the arrangement is commercially reasonable and any compensation paid under the arrangement is fair market value and does not reflect the volume or value of referrals. There may be more than one way to structure a compliant arrangement. (We provide the references to these exceptions by way of example, only.)

One example of an arrangement that implicates the Stark Law involves a hospital engaging a physician to provide on-call telestroke services for the hospital. The arrangement includes compensation for the physician's services and provision of the equipment to facilitate the telestroke assessment. To the extent the physician refers DHS to the hospital (regardless of whether the referrals are related to the telestroke services), the Stark Law is implicated. Therefore, if referrals are expected, the arrangement must be structured to fit one or more Stark Law exceptions. Here, the personal services exception and the equipment lease exceptions are the most likely candidates for use to ensure the arrangement complies with the Stark Law.

The False Claims Act

The federal False Claims Act prohibits, among other things, the knowing submission of false or fraudulent claims, and knowingly making, using, or causing to be made or used, false records or statements material to a false or fraudulent claims.[8] As discussed under the AKS and Stark Law sections, violations of these statutes can (or, in the case of the AKS, will) lead to a violation of the FCA as well. However, FC A violations also commonly occur when providers knowingly improperly bill for services, for example, by upcoding (i.e., coding for a higher level of patient visit than actually provided). The FCA could be violated in the telemedicine space if a provider billed Medicare for a telemedicine encounter where the encounter was conducted via telephone; therefore, the encounter did not meet the requirement that the physician assess the patient using real-time audio visual communication. Another example involves a patient's assessment while the patient is located in her home, which generally is not permitted for purposes of Medicare telemedicine encounters.

FCA penalties include treble damages calculated based on the value of the improper claim and per claim penalties, which, as of December 2018, range between $11,181 and $22,363, subject to annual adjustment. Because the penalties are assessed on each improperly filed claim, penalties assessed in FCA settlements or cases can quickly accumulate to truly significant amounts. Moreover, Medicare reimbursement for telemedicine services is currently somewhat limited, but the FCA applies to other federal healthcare programs such as Medicaid, where reimbursement for telemedicine services is much more robust and common.

Other considerations

In addition to the federal AKS, Stark Law, and FCA, most states have enacted their own versions of these laws; and depending on their scope, those laws may apply to a wider range of arrangements. Although the federal laws are generally limited to claims submitted to federal payers, some states have enacted laws that apply not only to state programs such as Medicaid, but also to claims submitted to commercial payers doing business in that state. And some states have enacted "all-payer" laws where the laws apply to claims involving private pay arrangements. Therefore, simply limiting the reimbursement accepted by a telemedicine company to commercial payers or private pay patients does not necessarily mitigate all risk associated with a business arrangement.

States may also maintain unique laws that could be implicated by a telemedicine arrangement. For example, many states have corporate practice of medicine laws that prohibit lay corporations from employing or contracting with physicians to practice medicine. Such laws can significantly affect arrangements for a

provider's practice of telemedicine.

In short, physicians and corporate entities should determine the states in which they will provide or facilitate the provision of telemedicine services and closely review the applicable laws of those states to determine whether there are any requirements in addition to those established by federal law.

Summary

As the telemedicine industry continues to expand, the companies and practitioners planning to join the industry, whether by operating a new company or joining an existing company as a practitioner, should be aware of the rules governing this rapidly-growing industry. As federal reimbursement for telemedicine services continues to increase, expect to see a growing emphasis on enforcement of both federal and state fraud and abuse laws. To ensure compliance with these laws, parties entering into arrangements related to the provision of telemedicine services should closely consider the federal and state laws that may be implicated and how to structure those arrangements to comply with any applicable safe harbors or exceptions. Although such steps may seem onerous, failing at the outset to ensure an arrangement is structured in a compliant manner could ultimately result in the parties to the arrangement violating the law and being subject to civil, and in some instances criminal, penalties.

Takeaways

- 2018 had several important advancements for the provision of telemedicine services, but also a new emphasis on future risk of increased enforcement.
- As federal dollars spent on telemedicine increase, so will government enforcement.
- Federal laws governing telemedicine arrangements and services include the Anti-Kickback Statute, the Stark Law, and the False Claims Act
- Many states maintain laws governing telemedicine arrangements that apply to arrangements involving the submission of claims to commercial payers and private pay patients.
- Parties entering into telemedicine arrangements involving the employment of or contracting with physicians must comply with state corporate practice of medicine laws.

1 Bipartisan Budget Act of 2018, Pub. L. No. 115-123, §§ 50207-50354 (2018).
2 DHHS, Office of Inspector General, "CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements" April 2018. https://bit.ly/2qQTmQM
3See H.J. Kaiser Family Foundation, The Facts on Medicare Spending and Financing (published June 22, 2018). https://bit.ly/2BTku4o
4 U.S. Deparrtment 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.) https://bit.ly/2Ag7Q1T
5 42 U.S.C. § 1320a-7b(b).
6U.S. v. Greber, 760 F.2d 68 (3d. 1985).
7See 42 C.F.R. § 411.357(a)-(d), (l), and (v)-(w)
8 31 U.S.C. § 3729 et seq.