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Valuation of Telemedicine: Regulatory

Introduction

The third installment in this five-part *Health Capital Topics* series on the valuation of telemedicine will focus on the regulatory environment for telemedicine, with a specific focus on fraud and abuse laws.[1] The first installment in this series introduced telemedicine and its increasing importance to, and popularity among, providers and patients. It also discussed the current and future challenges related to telemedicine, many of which hinge upon reimbursement restrictions and regulations.[2] The second installment took a deeper dive into the growth, new payment rules, and future uncertainties surrounding reimbursement for telemedicine services.[3]

Federal Fraud and Abuse Laws

Healthcare service organizations face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Fraud and abuse laws, specifically those related to the federal *Anti-Kickback Statute* (AKS) and physician self-referral laws (the "*Stark Law*"), may have the most significant impact on the operations of those organizations.

The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between providers or suppliers in the healthcare industry and relates to any item or service that may receive funding from any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to entities with which the physician has a financial relationship for the provision of defined services that are paid for by the Medicare program.[4] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[5]

Anti-Kickback Statute

Enacted in 1972, the federal AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[6] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[7] Additionally, interpretation and application of the AKS under case law have created a precedent for a regulatory hurdle known as the *one purpose* test. Under the *one purpose* test, healthcare providers violate the AKS if even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[8]

The *Patient Protection and Affordable Care Act* (ACA) made two noteworthy changes to the intent standards related to the AKS. First, the legislation amended the AKS by stating that a person need not have *actual knowledge* of the AKS or *specific intent* to violate the AKS for the government to prove a kickback violation.[9] However, the ACA did not remove the requirement that a person must "*knowingly and willfully*" offer or pay remuneration for referrals to violate the AKS.[10] Therefore, to prove a violation of the AKS, the government must show that the defendant was aware that the conduct in question was "*generally unlawful*," but not that the conduct specifically violated the AKS.[11] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[12] This means that in addition to *civil monetary penalties* paid under the AKS, violation of the AKS would create additional liability under the FCA, which itself carries *civil monetary penalties* of over $21,500 plus treble damages.[13]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[14] In response to these concerns, Congress promulgated several *safe harbors*,[15] which set out regulatory criteria that, if met, shield an arrangement from regulatory liability, and are meant to protect transactional arrangements unlikely to result in fraud or abuse.[16] Failure to comply with all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[17] Some of the safe harbors most applicable to a telemedicine arrangement include the space and equipment rental safe harbors, for the purposes of leasing telemedicine equipment or space, and the personal services and management contracts safe harbor, for the arrangement for the provision of telemedicine services between an entity and a physician.[18]

Of note, in November 2020, the HHS *Office of Inspector General* (OIG) made several revisions to the AKS in a final rule, many of which are similar to those revisions to the Stark Law proposed by CMS. Among the more notable changes related to the AKS includes a new safe harbor related to *cybersecurity technology and services*.

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This safe harbor protects the nonmonetary donation of cybersecurity technology and services subject to several conditions, including that the agreement is in writing and that the donation (or receipt thereof) does not directly take into account the volume or value of referrals or other business between the parties.[19]

Stark Law

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physicians or their family members have a financial relationship for the provision of *designated health services* (DHS).[20] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[21]

Under the Stark Law, DHS include, but are not limited to, the following:

(1) Certain therapy services, such as physical therapy;
(2) Inpatient and outpatient hospital services;
(3) Radiology and certain other imaging services;
(4) Radiation therapy services and supplies;
(5) Durable medical equipment; and,
(6) Outpatient prescription drugs.[22]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and compensation arrangements, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or "*in kind*."[23]

Similar to the AKS *safe harbors*, the Stark Law contains a large number of *exceptions*, which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[24] However, unlike the AKS safe harbors, an arrangement must entirely fall within one of the *exceptions* to shield from enforcement of the Stark Law.[25] Some of the exceptions most applicable to a telemedicine arrangement include the space and equipment leasing arrangement exception, for the purposes of leasing telemedicine equipment or space; the bona fide employment arrangement exception, for the employment of a physician who is providing services through telemedicine; fair market value (FMV) compensation arrangements, for compensation that is paid at fair market value; and, the personal services arrangements exception, for the arrangement for the provision of telemedicine services between an entity and a physician.[26] Note that, generally, these exceptions require that: the arrangement be memorialized in a signed, written agreement; the compensation not exceed FMV and be commercially reasonable; and the compensation not reflect the volume or value of referrals.[27]

In November 2020, CMS finalized revisions to the Stark Law, including:

(1) Revised definitions for Fair Market Value;
(2) A definition for Commercial Reasonableness (as this term was previously undefined);
(3) New permanent exceptions for value-based arrangements; and,
(4) A new exception for limited remuneration to a physician.[28]

These rule changes seek to make it easier for healthcare providers to provide value-based care without running afoul of the Stark Law.

Licensure

The growth in reimbursable telemedicine services varies widely across payor types, as well as across states.[29] Much of this geographic variance can be attributed to the current state of medical licensure rules for each state. While many state legislatures have debated increasing reimbursement for telemedicine services,[30] the *American Telemedicine Association's* (ATA's) 2019 report on coverage and reimbursement reported that ten states have not yet enacted substantive policies for telemedicine reimbursement.[31] Additionally, coverage, payment parity, geographic restrictions for both patients and physicians, and restrictions on provider types all vary by state, and this inconsistency has made cost-effective telemedicine service offerings difficult to achieve across provider locations.

In 2014, the *Federation of State Medical Boards* (FSMB) issued a *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine* (Model Policy) requiring those practicing telemedicine to be licensed in the state where a patient is located.[32] FSMB cited overriding concerns for patient welfare as the reason for their conservative position on this issue.[33] As of July 2020, 49 states require physicians providing telemedicine to be licensed in the state in which the patient is located.[34] Additionally, 12 states allow for a special license or certificate for physicians to practice across state lines for the purpose of providing telemedicine services, and six states require registration for practicing telemedicine across state lines.[35]

As of November 2020, 29 states, as well as the District of Columbia, have signed the *Interstate Medical Licensure Compact* (IMLC), an "*expedited pathway to licensure for qualified physicians who wish to practice in multiple states*."[36] The IMLC expedites licensure, but only for physicians that meet certain eligibility requirements – approximately 80% of physicians meet this criteria sufficient for obtaining IMLC licensure.[37] Thirty-four states have signed onto a somewhat analogous agreement – the *Nurse Licensure Compact* (NLC).[38] The NLC was launched in 2015, and has effectively allowed for nurses to practice in other NLC states physically, telephonically, and electronically.[39]

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Corporate Practice of Medicine (CPOM)

The CPOM doctrine prohibits unlicensed individuals or corporations from engaging in the practice of medicine by employing licensed physicians.[40] The CPOM is regulated on a state level, with regulations varying significantly by state.[41] Some states expressly prohibit the practice, including laws restricting unlicensed individuals from owning or operating a business in which medical services are provided to patients. Other restrictions include placing limitations on physicians and their ability to enter into professional relationships with unlicensed individuals or nonprofessional business entities. Further, some states except tax-exempt healthcare entities from liability under the CPOM,[42] with the rationale that the lack of a "profit incentive" eliminates the dangers associated with the CPOM.

As a result of changes in the delivery of healthcare, new practice areas have surfaced that may be prone to running afoul of current statutes restricting the CPOM, e.g., telemedicine companies. Telemedicine companies are often owned by non-providers and operate (and provide services) across state lines, both of which issues may implicate CPOM. Consequently, in order to refrain from CPOM violations, these companies may set up their corporate structure utilizing a "friendly PC" or "captive PC" model, wherein physicians own the legal entity, typically a professional corporation (PC) or professional limited liability company (PLLC), that provides healthcare services, and that "captive" or "friendly" entity contracts with a management services organization (MSO), which provides the management services to the PC/PLLC.[43]

Regulations During and After the COVID-19 Pandemic

Many of the federal and state regulations and licensing requirements have been temporarily suspended during the COVID-19 *public health emergency* (PHE). For example, FSMB reports that, as of October 30, 2020, 41 states have enacted waivers for out-of-state physicians, preexisting relationships, and audio-only requirements in response to the COVID-19 PHE.[44] Further, the *Department of Health and Human Services* (HHS) and the *Office for Civil Rights* (OCR) have temporarily suspended regulations under the *Health Insurance Portability and Accountability Act of 1996* (HIPAA). HHS and OCR announced in early Spring 2020 that they would not enforce penalties on providers who violated HIPAA rules, but acted in good faith in providing telemedicine during the COVID-19 PHE.[45] Other telemedicine visit regulations that have been suspended during the PHE include requiring an initial in-person visit, geographic restrictions that required the telemedicine visit to take place at a clinical facility, and obtaining special training before conducting these visits.[46]

As providers speculate as to the future of healthcare post-COVID-19, many suggest that simplifying the complex regulatory system may be key to the continued success of telemedicine.[47] Post-pandemic regulations will be critical in determining the future of telemedicine, and many believe that permanently relaxing or eliminating regulations that were waived during the PHE and creating a single, federal regulatory framework (in contrast to a state-by-state approach) would be important steps toward making the investment into telemedicine feasible and cost effective for many providers, especially smaller providers who have not yet implemented this technology into their practice.[48]

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1 For the purposes of this series, the terms "telemedicine" and "telehealth" will be considered to be synonymous, with the former used exclusively for the sake of consistency.

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5 *Ibid*, p. 42.

6 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).

7 *Ibid.*

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9 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 6402, 10606, 124 Stat. 119, 759, 1008 (March 23, 2010).

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13 "False claims" 31 U.S.C. § 3729(a)(1).

14 Demske, July 28, 2015, p. 5.

15 *Ibid.*

16 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520.

17 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, https://oig.hhs.gov/fraud/docs/alertsandbulletins/malpracticeprogram.pdf (Accessed 11/2/20), p. 1.

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19 "HHS Makes Stark Law and Anti-Kickback Statute Reforms to Support Coordinated, Value-Based Care" Centers for Medicare & Medicaid Services, November 20, 2020, https://www.hhs.gov/about/news/2020/11/20/hhs-makes-stark-law-and-anti-kickback-statute-reforms-support-coordinated-value-based-care.html (Accessed 11/21/20).

20 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 11/2/20); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.

21 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(a)(1)(A).

22 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1)(B); "Definitions" 42 C.F.R. § 411.351 (2015). Note the distinction in 42 C.F.R. § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."

23 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.

24 *Ibid.*

25 "Health Care Fraud and Abuse: Practical Perspectives" By Linda A. Baumann, Health Law Section of the American Bar Association, Washington, DC: BNA Books, 2002, p. 106.

26 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn; "Telemedicine: A review of the fraud and abuse landscape" By Douglas Grimm and Hillary Stemple, Arent Fox, https://www.arentfox.com/sites/default/files/2019-03/Telemedicine-A-review-of-the-fraud-and-abuse-landscape.pdf (Accessed 11/21/20).

27 42 U.S.C. § 1395nn; "Telemedicine Fraud and Abuse Under the Microscope" By Douglas Grimm and Hillary Stemple, HCCA Louisville Regional Conference, November 1, 2019, slide 8.

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