Health Capital Topics
Volume 15
Issue 9
September 2022
©
Jessica L. Bailey-Wheaton, Esq., Editor
Todd A. Zigrang MBA, MHA, CVA, ASA, FACHE, Publisher

Valuation of Remote Therapeutic Monitoring: Regulatory Considerations

Healthcare organizations and providers are increasingly seeking partnerships (often with healthcare tech companies that have developed a compatible medical device) to facilitate their provision of remote therapeutic monitoring (RTM) services to eligible patients. Because only a licensed healthcare provider can bill for RTM services, these arrangements often involve the provider compensating the device manufacturer for the devices used to perform the RTM. Such arrangements typically fall under the purview of federal fraud and abuse laws such as the Anti-Kickback Statute (AKS) and the Stark Law. This third installment of the five-part series on the valuation of RTM will discuss these regulatory hurdles.

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 be paid for under 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. Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.

The 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.[1] Notably, a person need not have *actual knowledge* of the AKS or *specific intent* to commit a violation of the AKS for the government to prove a kickback violation.[2] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, and/or exclusion from Medicare and Medicaid as an alternative civil remedy to criminal penalties.[3] Interpretation and application of the AKS under case law has created 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 illegal remuneration.[4]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[5] In response, the law contains a number of statutory exceptions called *safe harbors*.[6] These *safe harbors* 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.[7] However, failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[8] It should be noted that, in order for a payment to meet the requirements of many AKS *safe harbors*, the compensation must not exceed the range of *Fair Market Value* and must be *commercially reasonable*.[9]

Of note, in December 2020, the Department of Health & Human Services (HHS) Office of Inspector General (OIG) released new revisions in a final rule, many of which are similar to those revisions to the Stark Law proposed by the Centers of Medicare & Medicaid Services (CMS), as discussed below.[10] Among the more notable revisions included are new safe harbors for value-based arrangements, wherein the safe harbor requirements lessen as the participants take on more financial risk. Additionally, several already-established safe harbors, such as personal services and management contracts and outcomes-based payment arrangements, were modified by this final rule.[11] These arrangements were changed to add more flexibility, e.g., by adding protections to certain outcomes-based payments.[12] Notably, the OIG also eliminated the requirement that aggregate compensation under these agreements is set in advance, instead of requiring the compensation methodology in advance; however, that methodology must be consistent with Fair Market Value and not directly take into account the volume or value of referrals or other business generated between the parties.[13]

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physician or their family members have a financial relationship for the provision of *designated health services* (DHS).[14] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[15] Under the Stark Law, DHS include, but are not limited to, the following:

(1) Certain therapy services, such as physical therapy;
(2) Radiology and certain other imaging services;
(3) Radiation therapy services and supplies;
(4) Durable medical equipment;
(5) Outpatient prescription drugs; and,
(6) Inpatient and outpatient hospital services.[16]

(Continued on next page)

Under the Stark Law, financial relationships include: (1) *ownership interests* through equity, debt, other means, and ownership interests in entities which then have an ownership interest in the entity that provides DHS;[17] and (2) *compensation arrangements*, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.[18] Notably, 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.[19] Similar to the AKS *safe harbors,* without these *exceptions,* the Stark Law may prohibit legitimate business arrangements. It must be noted that in order to meet the requirements of many *exceptions* related to compensation between physicians and other entities, compensation must: (1) not exceed the range of *Fair Market Value*; (2) not take into account the *volume* or *value of referrals* generated by the compensated physician; and, (3) be *commercially reasonable*.[20] Unlike the AKS safe harbors, an arrangement must fall within one of the *exceptions* in order to be legally permissible under the Stark Law.[21]

As noted above, in December 2020, CMS released a number of revisions to the Stark Law in a final rule, including:

(1) Revised definitions for Fair Market Value, General Market Value, and Commercial Reasonableness; and,
(2) New permanent exceptions for value-based arrangements.[22]

Importantly, the new value-based arrangements exceptions protect the following arrangements:

(1) Full financial risk arrangements: Includes capitated payments and predetermined rates or a global budget;
(2) Value-Based Arrangements with Meaningful Downside Financial Risk: Where a physician pays no less than 25% of the value of the remuneration the physician receives when he or she does not meet pre-determined benchmarks; and,
(3) Value-Based Arrangements: Applies regardless of risk level to encourage physicians to enter value-based arrangements, even if they only assume upside risk.[23]

Notably, a violation of the AKS or Stark is sufficient to state a claim under the *False Claims Act* (FCA); which prohibits individuals from knowingly submitting false claims to the government. Therefore, in addition to *civil monetary penalties* paid under the AKS and/or Stark, violation would create additional liability under the FCA, which itself carries *civil monetary penalties* of up to $25,076 plus treble damages.[24]

It is important to note that, the regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased in recent years. Therefore, under current regulation, the severe penalties that may be levied against healthcare providers under the AKS, the Stark Law, and/or the FCA will likely raise a hypothetical investor's estimate of the risk of paying for RTM services.

---

1 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
2 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 3; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6402, 119, 124 Stat. 119, 759 (March 23, 2010).
3 42 U.S.C. § 1320a-7b(b)(1); "Medicare and Medicaid Patient and Program Protection Act of 1987" Pub. L. No. 100-93, § 2, 101 Stat. 680, 680-681 (August 18, 1987).
4 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, http://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 4/24/18), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 72 (3d Cir. 1985).
5 "Demske, Chief counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, p. 5.
6 *Ibid.*
7 "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.
8 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf (Accessed 5/3/21), p. 1.
9 "Fundamentals of the Stark Law and Anti-Kickback Statute" By Asha B. Scielzo, American Health Lawyers Association, Fundamentals of Health Law: Washington, DC, November 2014, https://docplayer.net/17313708-Ahla-fundamentals-of-the-stark-law-and-anti-kickback-statute-asha-b-scielzo-pillsbury-winthrop-shaw-pittman-llp-washington-dc.html f (Accessed 5/3/21), p. 9-13, 42.
10 "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" Federal Register, December 2, 2020, Vol. 85, No. 232, p. 77814-77815.
11 *Ibid*, p. 77686.
12 *Ibid*.
13 *Ibid*.
14 "Avoiding self-referral: Understanding the Stark laws" By Hayden S. Wool, Medical Economics, April 1, 2015, http://www.medicaleconomics.com/medical-economics/news/avoiding-self-referral-understanding-stark-laws?page=full (Accessed 5/3/21); "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, https://www.policyarchive.org/handle/10207/2137 (Accessed 5/3/21), p. 1-5; "Limitation on certain physician referrals" 42 U.S.C. §1395nn.
15 "Limitation on certain physician referrals" 42 U.S.C. §1395nn(a)(1)(B).
16 *Ibid*; "Definitions" 42 C.F.R. § 411.351 (October 1, 2014). 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

©HEALTH CAPITAL CONSULTANTS
(Continued on next page)

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)."

17 "Limitation on certain physician referrals" 42 U.S.C. §1395nn (a)(2).

18 *Ibid,* §1395nn (h)(1).

19 *Ibid,* §1395nn.

20 "Fundamentals of the Stark Law and Anti-Kickback Statute" By Asha B. Scielzo, American Health Lawyers Association, Fundamentals of Health Law: Washington, DC, November 2014, https://docplayer.net/17313708-Ahla-fundamentals-of-the-stark-law-and-anti-kickback-statute-asha-b-scielzo-pillsbury-winthrop-shaw-pittman-llp-washington-dc.html f (Accessed 5/3/21), p. 28-38.

21 "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.

22 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77492.

23 *Ibid*, p. 77510-77528.

24 "Civil Monetary Penalties Inflation Adjustments for 2022" Federal Register, Vol. 87, No. 89 (May 9, 2022), p. 27515; "The False Claims Act" The United States Department of Justice, February 2, 2022, https://www.justice.gov/civil/false-claims-act (Accessed 9/23/22).

FREE EBOOK DOWNLOAD

HEALTH CAPITAL Topics 2021

DOWNLOAD HERE

(Continued on next page)

(800)FYI - VALU

Providing Solutions in the Era of Healthcare Reform

Founded in 1993, HCC is a nationally recognized healthcare economic financial consulting firm

- **HCC Home**
- **Firm Profile**
- **HCC Services**
- **HCC Experts**
- **Clients & Projects**
- **HCC News**
- **Upcoming Events**
- **Contact Us**
- **Email Us**

HCC Services

- **Valuation Consulting**
- **Commercial Reasonableness Opinions**
- **Commercial Payor Reimbursement Benchmarking**
- **Litigation Support & Expert Witness**
- **Financial Feasibility Analysis & Modeling**
- **Intermediary Services**
- **Certificate of Need**
- **ACO Value Metrics & Capital Formation**
- **Strategic Consulting**
- **Industry Research Services**

Todd A. Zigrang, MBA, MHA, CVA, ASA, FACHE, is the President of HEALTH CAPITAL CONSULTANTS (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 25 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 2,000 transactions and joint ventures. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.

Mr. Zigrang is the co-author of "*The Adviser's Guide to Healthcare – 2nd Edition*" [2015 – AICPA], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*. In addition to his contributions as an author, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); American Health Lawyers Associate (AHLA); the American Bar Association (ABA); the National Association of Certified Valuators and Analysts (NACVA); Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter, and is current Chair of the ASA Healthcare Special Interest Group (HSIG).

Jessica L. Bailey-Wheaton, Esq., is Senior Vice President and General Counsel of HCC. Her work focuses on the areas of Certificate of Need (CON) preparation and consulting, as well as project management and consulting services related to the impact of both federal and state regulations on healthcare transactions. In that role, Ms. Bailey-Wheaton provides research services necessary to support certified opinions of value related to the Fair Market Value and Commercial Reasonableness of transactions related to healthcare enterprises, assets, and services.

Additionally, Ms. Bailey-Wheaton heads HCC's CON and regulatory consulting service line. In this role, she prepares CON applications, including providing services such as: health planning; researching, developing, documenting, and reporting the market utilization demand and "need" for the proposed services in the subject market service area(s); researching and assisting legal counsel in meeting regulatory requirements relating to licensing and CON application development; and, providing any requested support services required in litigation challenging rules or decisions promulgated by a state agency. Ms. Bailey-Wheaton has also been engaged by both state government agencies and CON applicants to conduct an independent review of one or more CON applications and provide opinions on a variety of areas related to healthcare planning. She has been certified as an expert in healthcare planning in the State of Alabama.

Ms. Bailey-Wheaton is the co-author of numerous peer-reviewed and industry articles in publications such as: The Health Lawyer; Physician Leadership Journal; The Journal of Vascular Surgery; St. Louis Metropolitan Medicine; Chicago Medicine; The Value Examiner; and QuickRead. She has previously presented before the ABA, the NACVA, and the NSCHBC. She serves on the editorial boards of NACVA's QuickRead and AHLA's Journal of Health & Life Sciences Law.

Janvi R. Shah, MBA, MSF, serves as Senior Financial Analyst of HCC. Mrs. Shah holds a M.S. in Finance from Washington University Saint Louis. She develops fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition she prepares, reviews and analyzes forecasted and pro forma financial statements to determine the most probable future net economic benefit related to healthcare enterprises, assets, and services and applies utilization demand and reimbursement trends to project professional medical revenue streams and ancillary services and technical component (ASTC) revenue streams.

© HEALTH CAPITAL CONSULTANTS