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Jessica L. Bailey-Wheaton, Esq., Editor
Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, Publisher

Valuation of Neurology Services: Regulatory Environment

The previous installments of this series examined the competitive environment for neurology services and the Medicare reimbursement framework applicable to physician and telehealth services. This installment turns to the regulatory environment, focusing on the two federal fraud and abuse laws that most significantly shape the operation and transaction structures of neurology providers: the Anti-Kickback Statute and the physician self-referral law, commonly known as the Stark Law. This Health Capital Topics article is the third in a four-part series on the valuation of neurology services.

Healthcare provider organizations face federal and state constraints affecting their formation, operation, coding and billing, and transactions. While both the Anti-Kickback Statute (AKS) and the Stark Law address the financial motivation behind patient referrals, they differ in important respects. The AKS applies broadly to payments between providers or suppliers in the healthcare industry and reaches any item or service payable under any federal healthcare program. The Stark Law specifically addresses referrals from physicians to entities with which the physician has a financial relationship for the provision of defined services payable by Medicare.[1] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[2]

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,[3] even if only one purpose of the arrangement is to offer remuneration deemed illegal under the AKS.[4] Notably, a person need not have actual knowledge of the AKS or specific intent to commit a violation for the government to prove a kickback violation,[5] only an awareness that the conduct in question is "generally unlawful".[6] Further, a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).[7]

Criminal violations of the AKS are punishable by up to ten years in prison, criminal fines up to $100,000, or both; civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties, which currently reach $127,973 for conduct occurring after February 9, 2018, plus treble damages.[8] If an AKS violation triggers liability under the FCA, defendants may incur additional civil monetary penalties of $14,308 to $28,619 per claim, plus treble damages.[9]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[10] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to HHS to protect certain arrangements through the promulgation of safe harbors.[11] These safe harbors set out regulatory criteria that, if met, shield arrangements unlikely to result in fraud or abuse from liability.[12] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[13] To meet the requirements of many AKS safe harbors, compensation must not exceed the range of Fair Market Value and must be commercially reasonable.

In a December 2020 final rule, the HHS Office of Inspector General (OIG) released several revisions to the AKS, many of which parallel those made to the Stark Law by CMS, as discussed below.[14] Among the more notable revisions are new safe harbors for value-based arrangements and revisions to existing safe harbors.[15] The OIG also added flexibility to the safe harbor for Personal Services and Management Contracts, eliminating the requirement that aggregate compensation be set in advance and instead requiring only that the compensation methodology be set in advance. That methodology must, however, be consistent with Fair Market Value and must not take into account the volume or value of referrals or other business generated between the parties.[16]

Stark Law

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physicians or their immediate family members have a financial relationship for the provision of designated health services (DHS).[17] When a prohibited referral occurs, entities may not bill for services resulting from that referral.[18] Under the Stark Law, DHS includes clinical laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; outpatient prescription drugs; home health services; and inpatient and outpatient hospital services, among others.[19] CMS updates the code

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list defining four of these categories annually; the current list took effect January 1, 2026.[20]

Financial relationships subject to the Stark Law include ownership interests through equity, debt, or other means, as well as ownership interests in entities that also have an ownership interest in the entity that provides DHS.[21] Financial relationships also include compensation arrangements, defined as any arrangement involving remuneration, directly or indirectly, in cash or in kind, between physicians and entities.[22]

Civil penalties under the Stark Law include overpayment or refund obligations, a civil monetary penalty that currently reaches $31,670 for each service billed after a prohibited referral, plus treble damages, and exclusion from the Medicare and Medicaid programs; schemes to circumvent the referral prohibition carry penalties of up to $211,146 per scheme.[23] Similar to the AKS, a violation of the Stark Law can also trigger liability under the FCA.[24]

The Stark Law contains numerous exceptions describing ownership interests, compensation arrangements, and forms of remuneration to which the prohibition does not apply.[25] 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. Unlike the AKS safe harbors, an arrangement must fully satisfy one of the Stark Law exceptions to be shielded from enforcement, because the statute imposes strict liability.[26]

In December 2020, CMS released a number of significant revisions to the Stark Law in a final rule, including revised definitions for Fair Market Value, General Market Value, and Commercial Reasonableness, and new permanent exceptions for value-based arrangements.[27] The value-based exceptions protect full financial risk arrangements, arrangements in which the physician assumes meaningful downside financial risk, and arrangements at any level of risk, the last of which is intended to encourage participation by physicians assuming only upside risk.[28]

Fraud & Abuse Enforcement

Enforcement activity illustrates the fraud and abuse risks to neurology arrangements. In July 2021, an electroencephalography testing company and its private investment firm manager paid $15.3 million to resolve allegations that the company induced referrals by furnishing free electroencephalogram (EEG) test-interpretation reports, which allowed non-neurologist physicians to bill Medicare as though they had personally interpreted the studies.[29] In December 2024, an intraoperative neuromonitoring company, its founder, and a referring neurosurgeon paid a combined $2.008 million to resolve allegations that remuneration was routed to the surgeon through a joint venture in exchange for ordering neuromonitoring services.[30] Both matters proceeded under the AKS and the FCA rather than the Stark Law and both turned on remuneration flowing to a referral source outside any applicable safe harbor.

The regulatory framework governing neurology service arrangements is extensive, and the penalties for noncompliance are severe. The AKS, the Stark Law, and the FCA collectively create substantial exposure for providers. Central to compliance with many exceptions and safe harbors is the requirement that compensation not exceed Fair Market Value and be commercially reasonable. The fourth and final installment of this series will examine the technological environment, including health information technology, telehealth delivery systems, and artificial intelligence in neurology.

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1 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 8/12/26).

2 *Ibid.*

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

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, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 8/12/26), p. 4–5; "United States of America v. Greber" 760 F.2d 68, 69 (3d Cir., 1985).

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

6 "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview" By Jennifer A. Staman, Congressional Research Service, September 8, 2014, https://www.fas.org/sgp/crs/misc/RS22743.pdf (Accessed 8/12/26), p. 5.

7 "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, 124 Stat. 119, 759 (March 23, 2010).

8 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1); "Civil Monetary Penalties" 42 U.S.C. § 1320a-7a(a); "Penalty adjustment and table" 45 C.F.R. § 102.3.

9 "False claims" 31 U.S.C. § 3729(a)(1); "Civil monetary penalty inflation adjustment" 28 C.F.R. § 85.5; "Civil Monetary Penalties Inflation Adjustments for 2025" Federal Register, Vol. 90, No. 126 (July 3, 2025), p. 29445, 29448.

10 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 8/12/26), p. 5, legal complexity of broad AKS application.

11 *Ibid*.

12 "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.

13 "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 8/12/26), p. 1.

14 "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, Vol. 85, No. 232 (December 2, 2020), p. 77814–77815.

(Continued on next page)

15 *Ibid*.
16 Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77839.
17 "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; "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.
18 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn(a)(1)(A).
19 42 U.S.C. § 1395nn(h)(6); "Definitions" 42 C.F.R. § 411.351.
20 "Annual Update to the List of CPT/HCPCS Codes Effective January 1, 2026" Centers for Medicare & Medicaid Services, December 1, 2025, https://www.cms.gov/files/document/annual-update-list-cpt-hcpcs-codes-effective-january-1-2026.pdf (Accessed 8/12/26).
21 42 U.S.C. § 1395nn(a)(2).
22 42 U.S.C. § 1395nn(h)(1).
23 42 U.S.C. § 1395nn(g); "Penalty adjustment and table" 45 C.F.R. § 102.3.
24 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 8/12/26).
25 42 U.S.C. § 1395nn(b)-(e).
26 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 8/12/26).
27 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77492.
28 *Ibid*, p. 77510–77528.
29 "EEG Testing and Private Investment Companies Pay $15.3 Million to Resolve Kickback and False Claims Allegations" United States Department of Justice, Office of Public Affairs, Press Release, July 21, 2021, https://www.justice.gov/opa/pr/eeg-testing-and-private-investment-companies-pay-153-million-resolve-kickback-and-false (Accessed 8/12/26).
30 "$2 Million Resolves Kickback Allegations Relating to Denver Neuromonitoring Company" United States Attorney's Office for the District of Colorado, Press Release, December 3, 2024, https://www.justice.gov/usao-co/pr/2-million-resolves-kickback-allegations-relating-denver-neuromonitoring-company (Accessed 8/12/26).

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Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, 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 30 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 2,500 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*" [AICPA - 2015], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Guide to Valuing Physician Compensation and Healthcare Service Arrangements* (BVR/AHLA); *The Accountant's Business Manual* (AICPA); V*aluing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*. Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); the National Association of Certified Valuators and Analysts (NACVA); the American Health Lawyers Association (AHLA); the American Bar Association (ABA); the Association of International Certified Professional Accountants (AICPA); the Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute. He also serves on the Editorial Board of The Value Examiner and QuickRead, both of which are published by NACVA.

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 Certified Valuation Analyst (CVA) designation from NACVA. Mr. Zigrang also holds the Accredited in Business Valuation (ABV) designation from AICPA, and the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter. He is also a member of the America Association of Provider Compensation Professionals (AAPCP), AHLA, AICPA, NACVA, NSCHBC, and, the Society of OMS Administrators (SOMSA).

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 (American Bar Association); Physician Leadership Journal (American Association for Physician Leadership); The Journal of Vascular Surgery; St. Louis Metropolitan Medicine; Chicago Medicine; The Value Examiner (NACVA); and QuickRead (NACVA). She has previously presented before the American Bar Association (ABA), the American Health Law Association (AHLA), the National Association of Certified Valuators & Analysts (NACVA), the National Society of Certified Healthcare Business Consultants (NSCHBC), and the American College of Surgeons (ACS).

Janvi R. Shah, MBA, MSF, CVA, serves as Senior Financial Analyst of HCC. Mrs. Shah holds a M.S. in Finance from Washington University Saint Louis and the Certified Valuation Analyst (CVA) designation from NACVA. 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.

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