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Valuation of Internal Medicine Services: Regulatory

This third installment of the internal medicine series will discuss the regulatory environment of the provision of internal medicine services. Healthcare providers 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 greatest impact on the operations of healthcare providers. It is crucial to understand these laws because violating them can result in criminal penalties, civil fines, and/or exclusion from federal healthcare programs.[1]

The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. 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. In contrast, 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.[2] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[3]

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.[4] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[5] Congress amended the original statute with the passage of the Medicare and Medicaid Patient & Program Protection Act of 1987 to include exclusion from the Medicare and Medicaid program as an alternative civil remedy to criminal penalties.[6] The Balanced Budget Act of 1997 added a civil monetary penalty of treble damages, or three times the illegal remuneration, plus a fine of $50,000 per violation.[7] Additionally, 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 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 commit a violation of the AKS for the government to prove a kickback violation.[9] Therefore, in order 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.[10] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).[11] The amended AKS points out that liability under the FCA is "[i]n addition to the penalties provided for in [the AKS]…"[12] This suggests 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 created a number of statutory exceptions and delegated authority to the U.S. Department of Health & Human Services (HHS) to protect certain business arrangements by means of promulgating several safe harbors.[15] 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.[16] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[17] 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.[18]

Of note, in December 2020, the HHS Office of Inspector General (OIG) released new revisions to the AKS in a final rule.[19] Included among the more notable revisions are new safe harbors for value-based arrangements (the safe harbor requirements for which arrangements lessen as the participants take on more financial risk).[20] See below for more information on those arrangements.

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Stark Law

The Stark Law, originally passed as the Ethics in Patient Referral Act of 1989, as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989, prohibits physicians from referring Medicare or Medicaid patients to entities with which the physicians or their family members have a financial relationship for the provision of designated health services (DHS).[21] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[22] 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.[23]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities which then have an ownership interest in the entity that provides DHS.[24] Additionally, financial relationships include compensation arrangements, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.[25] 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.[26] 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.[27] Unlike the AKS safe harbors, an arrangement must fully fall within one of the exceptions in order to be shielded from enforcement of the Stark Law.[28]

As previously mentioned, 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.[29]

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 10%[30] 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.[31]

Also of note is CMS's new exception for limited remuneration to a physician. Under this new exception, a physician may be paid an aggregate remuneration up to $5,000 within a calendar year without having the arrangement set forth in writing or the amount consistent with Fair Market Value; however, the arrangement must be commercially reasonable.[32]

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 False Claims Act (which law may be triggered by a violation of the AKS or Stark) will likely raise a hypothetical investor's estimate of the risk related to the valuation of the internal medicine services.

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1 "Fraud and Abuse Laws" U.S. Department of Health and Human Services, Office of Inspector General, https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/ (Accessed 11/15/21).
2 "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, accessed via: 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 (Accessed 10/14/21), p. 4-6, 17, 19, 42.
3 Scielzo, American Health Lawyers Association, Fundamentals of Health Law: Washington, DC, November 2014, p. 42.
4 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
5 *Ibid.*
6 "Medicare and Medicaid Patient and Program Protection Act of 1987" Pub. L. No. 100-93, § 2, 101 Stat. 680, 680-681 (August 18, 1987).
7 "The Balanced Budget Act of 1997" Pub. L. 105-33, § 4304, 111 Stat. 251, 384 (August 5, 1997).
8 "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 10/14/21), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 69 (3d Cir. 1985).
9 "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).
10 "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 10/14/21), p. 5.
11 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).
12 "Liability under subchapter III of chapter 37 of title 31" 42 U.S.C. § 1320a-7b(g).

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13 "False claims" 31 U.S.C. § 3729(a)(1); "Civil Monetary Penalties Inflation Adjustment: Final Rule" Federal Register Vol. 83, No. 19 (January 29, 2018), p. 3945.
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, http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf (Accessed 10/14/21), p. 1.
18 Scielzo, American Health Lawyers Association, Fundamentals of Health Law: Washington, DC, November 2014, p. 9-13, 42.
19 "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.
20 *Ibid*. For more information on the AKS final rule changes, see "Stark & Anti-Kickbacks Revisions Finalized: New Safe Harbors" By Jessica L. Bailey-Wheaton and Todd A. Zigrang, et al., Health Capital Topics, Vol. 14, No. 1 (January 2021), https://www.healthcapital.com/hcc/newsletter/01_21/HTML/STARK/convert_stark-aks-final-rules---new-safe-harbors-1.25.21.php (Accessed 11/15/21).
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 10/14/21); "Limitation on certain physician referrals" 42 U.S.C. §1395nn.
22 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1)(A).
23 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1)(B); "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 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)."
24 "Limitation on certain physician referrals" 42 U.S.C. §1395nn (a)(2).
25 "Limitation on certain physician referrals" 42 U.S.C. §1395nn (h)(1).
26 "Limitation on certain physician referrals" 42 U.S.C. §1395nn.
27 Scielzo, American Health Lawyers Association, Fundamentals of Health Law: Washington, DC, November 2014, p. 28-38.
28 "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.
29 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77492.
30 This percentage is greater under the AKS. For more information on the AKS value-based arrangement safe harbors, see "Stark & Anti-Kickbacks Revisions Finalized: New Safe Harbors" By Jessica L. Bailey-Wheaton and Todd A. Zigrang, et al., Health Capital Topics, Vol. 14, No. 1 (January 2021), https://www.healthcapital.com/hcc/newsletter/01_21/HTML/STARK/convert_stark-aks-final-rules---new-safe-harbors-1.25.21.php (Accessed 11/15/21).
31 Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77510-77528.
32 "New Limited Remuneration Exception and Additional Tools to Ensure Compliance With the Stark Law" Jones Day, January 2021, https://www.jonesday.com/en/insights/2021/01/new-limited-remuneration-exception-and-additional-tools-to-ensure-compliance-with-the-stark-law (Accessed 10/18/21).

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