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The Regulatory Landscape Surrounding Physician Referrals

The Anti-Kickback Statute and the Stark Law Regulate Physician Referral Practices

The healthcare industry has long been subject to a complex set of federal regulations aimed at ensuring high-quality patient care. Among these are regulations that specifically apply to physician referrals, most notably the AKS and the Physician Self-Referral Law, commonly known as the “Stark Law.”

The AKS is a statute that makes it illegal to pay, solicit, or receive kickbacks for medical referrals, though only in connection with any item or service payable by the federal health care programs (e.g., Medicare or Medicaid).¹ Instituted in 1972, the AKS was designed to combat fraud and abuse in federal healthcare programs.² Its goals are to preserve independent medical decision-making, prevent overutilization, reduce program costs, protect patients, and prevent unfair competition.³

The Stark Law was enacted in 1989 and also governs patient referrals.⁴ The Stark Law prohibits medical providers from referring patients to entities with which the physician (or any member of the physician’s immediate family) has a financial relationship.⁵ Similar to the AKS, the Stark Law aims to prevent overutilization of services and increased healthcare costs that may result from self-enriching referrals.⁶ The Stark Law only applies to services specifically payable by Medicare or Medicaid.⁷

There are codified regulatory exceptions to these referral prohibitions, often referred to as exceptions or “safe harbors.” The safe harbors under the AKS have long protected investment in

¹ See “Fraud & Abuse Laws.” *Office of Inspector General*. <<https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws>>.

² See “Federal Anti-Kickback Law and Regulatory Safe Harbors Fact Sheet.” *Office of Inspector General* (Nov. 1999). <<https://oig.hhs.gov/documents/compliance/851/safefs.htm>>.

³ See “Fraud & Abuse Laws.” *Office of Inspector General*. <<https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws>>.

⁴ “Physician Self Referral.” *Centers for Medicare & Medicaid Services* (Dec. 1, 2021). <<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index?redirect=/physicianselfreferral>>.

⁵ *Id.*

⁶ See “Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview.” *Congressional Research Service* (July 22, 2016) at 4.

⁷ “Fraud & Abuse Laws.” *Office of Inspector General*. <<https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws>>.

small healthcare joint ventures, space and equipment rental, personal services and management contracts, and investment in physicians' own group practices, for example.⁸ The Stark Law provides for exceptions for in-office ancillary services within the same group practice, bona fide employment arrangements, personal services arrangements, and arrangements involving small non-monetary compensation or fair market value compensation.⁹ There are many specific exceptions, each with its own statutory requirements, and application of an exception or safe harbor varies based on the specific facts and circumstances of the situation at hand.¹⁰

Featured Expert: Professor Louis F. Rossiter

Professor Lou Rossiter was recently retained by a healthcare provider that manages services in medical centers to opine on the regulatory landscape surrounding physician referrals, the evolution of hospital remuneration and incentivization systems, as well as relevant co-management agreements.

Professor Rossiter is a Research Professor in the Public Policy program at the College of William & Mary. He previously served as Senior Policy Advisor to the Administrator of the CMS. In that role, he led the CMS team working with the OIG in its development of the Medicare and State Health Care Programs: Fraud and Abuse: Anti-Kickback Provisions (July 29, 1991)(56 Fed. Reg. 35952), which promulgated the 10 original safe harbor provisions.

For additional inquiries or retaining Professor Rossiter, please contact experts@vegaeconomics.com.

⁸ See "Federal Anti-Kickback Law and Regulatory Safe Harbors Fact Sheet." *Office of Inspector General*(Nov. 1999). <<https://oig.hhs.gov/documents/compliance/851/safefs.htm>>.

⁹ Gosfield, Alice G. "The Stark Truth About the Stark Law: Part II." *Family Practice Management* 11.2 (2004): 41-45 at 41-45.

¹⁰ See 42 U.S.C. § 1395nn (2018); 42 C.F.R. § 1001.952 (2018).