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Valuation of Care Coordination Services: Regulatory Environment

Healthcare providers face 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 organizations. As the final installment of the five-part series on the valuation of care coordination services, this Health Capital Topics article discusses these fraud and abuse laws, as well as recent enforcement actions.

Fraud & Abuse Laws

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.[1] While violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[2]

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] if only one purpose of the arrangement in question 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 of the AKS for the government to prove a kickback violation;[5] the person only needs to have 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, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties plus treble damages (or three times the illegal remuneration).[8] In addition to the civil monetary penalties paid under the AKS, if the AKS violation triggers liability under the FCA, defendants can incur additional civil monetary penalties of $13,508 to $27,018 per violation, 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 the U.S. Department of Health and Human Services (HHS) to protect certain business arrangements by means of promulgating several *safe harbors*.[11] 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.[12] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[13] 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.[14]

Of note, in December 2020, the HHS Office of Inspector General (OIG) released new revisions to the AKS in a final rule, many of which are similar to those revisions to the Stark Law proposed by the Centers for Medicare & Medicaid Services (CMS), discussed further below.[15] The changes contained in the final rule were part of the larger effort by HHS to modernize and clarify fraud and abuse laws as part of the *Regulatory Sprint to Coordinated Care* initiative, which aimed to reduce regulatory barriers and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination.[16] In the revisions, the OIG established new rules, and rule changes, that are more consistent with emerging value-based healthcare delivery and payment models, and which may allow for better coordination of care. Among the more notable revisions included new safe harbors for value-based arrangements (the safe harbor requirements for which arrangements lessen as the participants take on more financial risk).[17]

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).[18] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[19] DHS include, but are not limited to, the following:

(1) Certain therapy services, such as physical therapy;
(2) Radiology and certain other imaging services;

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(3) Radiation therapy services and supplies;
(4) Durable medical equipment;
(5) Outpatient prescription drugs; and,
(6) Inpatient and outpatient hospital services.[20]

Under the Stark Law, financial relationships include ownership interests – through equity, debt, or other means – and ownership interests in entities that have ownership interests in DHS providers.[21] 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.[22]

Civil penalties under the Stark Law include overpayment or refund obligations, potential civil monetary penalties of $15,000 for each service, plus treble damages, and exclusion from Medicare and Medicaid programs.[23] Similar to the AKS, violation of the Stark Law can also trigger a violation of the FCA.[24]

Notably, the Stark Law contains many exceptions which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[25] Similar to the AKS safe harbors, without these exceptions, the Stark Law may prohibit legitimate business arrangements. It must be noted that 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.[26]

Unlike the AKS safe harbors, an arrangement must *fully* fall within one of the exceptions to be shielded from enforcement of the Stark Law.[27]

As noted above, in response to the *Regulatory Sprint to Coordinated Care* initiative, CMS also released several revisions to the Stark Law in a December 2020 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.[28]

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.[29]

Recent Enforcement Actions Related to Care Coordination Services

While the December 2020 regulatory revisions expanded protections for value-based arrangements, federal enforcement agencies have simultaneously increased scrutiny of billing practices related to care coordination services. Recent enforcement actions indicate that improper billing for chronic care management (CCM) and remote patient monitoring (RPM) services remains a significant compliance risk.

In June 2024, the U.S. Department of Justice (DOJ) announced a settlement with Bluestone Physician Services, a primary care and chronic disease management provider operating in Florida, Minnesota, and Wisconsin.[30] The company agreed to pay over $14.9 million to resolve allegations that it knowingly submitted false claims for CCM services and domiciliary rest home visits that did not support the level of service provided.[31] In connection with the settlement, Bluestone entered into a five-year Corporate Integrity Agreement (CIA) with the OIG.[32] The Bluestone settlement is one of the first major FCA settlements involving CCM billing codes, signaling increased federal scrutiny of these services.

Remote patient monitoring (RPM) services have also attracted significant regulatory attention. In November 2023, the OIG issued a Consumer Alert warning Medicare beneficiaries about fraudulent RPM enrollment schemes involving aggressive marketing, enrollment without clinical justification, and billing for services not actually provided.[33] In September 2024, the OIG published a report recommending additional oversight of RPM services, noting that the number of Medicare enrollees receiving RPM increased more than tenfold between 2019 and 2022, with Medicare and Medicare Advantage payments exceeding $300 million in 2022.[34] The report identified concerns that Medicare lacks key information for oversight, including who ordered the monitoring for enrollees, and found that approximately 43% of enrollees who received RPM did not receive all three components of the service, raising questions about whether monitoring was being used as intended.[35]

In August 2025, OIG released a Data Snapshot analyzing 2024 Medicare billing for RPM services, revealing that Medicare payments had reached $536 million (a 31 percent increase from 2023) and that nearly one million Medicare beneficiaries received RPM services during the year.[36] The Data Snapshot identified five billing patterns warranting heightened scrutiny: abrupt spikes in patient enrollment, billing for high proportions of patients with no prior relationship to the practice, billing by multiple practices for RPM services furnished to the same patient, high billing for claims with no prior ordering visit, and billing for multiple monitoring devices per month for the same enrollee.[37] These enforcement trends underscore the importance of robust compliance programs for organizations engaging in care coordination arrangements, particularly those involving CCM or RPM services.

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Conclusion

The regulatory framework governing care coordination arrangements requires careful attention. While the AKS and Stark Law address similar concerns, they operate through distinct mechanisms and carry different penalty structures. The December 2020 revisions to both statutes create new pathways for legitimate value-based care coordination arrangements while maintaining protections against fraud and abuse.

For healthcare providers and executives structuring care coordination arrangements, the core requirements remain consistent across both regulatory frameworks: compensation must reflect Fair Market Value, arrangements must be commercially reasonable, and remuneration must not take into account the volume or value of referrals. As recent enforcement actions make clear, adherence to these Big Three requirements remains the foundation of any defensible care coordination arrangement.

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19 "Limitation on certain physician referrals" 42 U.S.C. §1395nn(a)(1)(A).
20 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1)(B); "Definitions" 42 C.F.R. § 411.351. 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)."
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