



## Valuation of Orthopedic Services: Regulatory Environment

As discussed in the third installment of this five-part Health Capital Topics series regarding the valuation of orthopedic services, the reimbursement environment for orthopedic services is undergoing significant transformation, with substantial payment disparities emerging between facility and non-facility settings.<sup>1</sup> This fourth installment examines the regulatory environment for orthopedic services, focusing on the federal fraud and abuse laws that govern financial relationships between orthopedic surgeons and healthcare organizations, and the implications of recent enforcement trends for the valuation of orthopedic services.

Healthcare provider organizations 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. 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 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.

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, even if only one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.<sup>2</sup> 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; the person only needs to have an awareness that the conduct in question is generally unlawful. Further, a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).

Criminal violations of the AKS are punishable by up to 10 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,

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and civil monetary penalties plus treble damages (or three times the illegal remuneration).<sup>3</sup> In addition to the civil monetary penalties paid under the AKS, if the violation triggers liability under the FCA, defendants can incur additional civil monetary penalties up to \$25,595 per violation, plus treble damages.<sup>4</sup>

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited. In response to these concerns, Congress has 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.<sup>5</sup> 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. Failure to meet all the requirements of a safe harbor does not necessarily render an arrangement illegal. It should be noted that, for a payment to meet the requirements of many AKS safe harbors, the compensation must not exceed Fair Market Value.

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).<sup>6</sup> Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral. DHS include, but are not limited to, certain therapy services such as physical therapy, radiology and certain other imaging services, radiation therapy services and supplies, durable medical equipment (DME), outpatient prescription drugs, and inpatient and outpatient hospital services.

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. 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. 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.<sup>7</sup> Similar to the AKS, violation of the Stark Law can also trigger a violation of the FCA.

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The Stark Law contains many exceptions that describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply. Similar to the AKS safe harbors, without these exceptions, the Stark Law may prohibit legitimate business arrangements. To meet the requirements of many exceptions related to compensation between physicians and other entities, compensation be Fair Market Value, not take into account the volume or value of referrals generated by the compensated physician, and be commercially reasonable. Unlike the AKS safe harbors, an arrangement must fully fall within one of the exceptions to be shielded from enforcement of the Stark Law.

The regulatory scrutiny of healthcare entities, especially with regard to fraud and abuse violations, has generally increased over the past decade. The Department of Justice (DOJ) secured over \$6.8 billion in total False Claims Act (FCA) settlements and judgments in fiscal year 2025, the highest single-year recovery in the statute's history.<sup>8</sup> Healthcare-related matters accounted for over \$5.7 billion of that total, or approximately 84%.<sup>9</sup> Whistleblowers filed 1,297 qui tam lawsuits in fiscal year 2025, breaking the prior record of 980 set in fiscal year 2024 and underscoring the continued centrality of relator-driven enforcement in healthcare fraud.<sup>310</sup>

Recent enforcement actions have specifically targeted orthopedic implant manufacturers and their relationships with orthopedic surgeons. In November 2025, Aesculap Implant Systems agreed to pay \$38.5 million to resolve FCA allegations that the company paid illegal kickbacks to an orthopedic surgeon to induce the use of its VEGA knee replacement system.<sup>11</sup> The kickbacks allegedly took the form of consulting fees, international travel, and entertainment.

The Centers for Medicare & Medicaid Services (CMS) settled a record 314 Stark Law self-disclosures in 2024, totaling \$24.7 million, nearly double the prior record of \$12.5 million in 2023.<sup>12</sup> In 2025, CMS settled an additional 244 disclosures for approximately \$20.4

million, bringing cumulative Self-Referral Disclosure Protocol (SRDP) settlements to over \$105 million across 1,234 resolved disclosures since 2011.<sup>13</sup> Separately, the June 2025 National Health Care Fraud Takedown – described by the DOJ as the largest coordinated healthcare fraud enforcement action in U.S. history – charged 324 defendants, including 96 licensed medical professionals, in cases involving over \$14.6 billion in intended loss, with focus areas including DME fraud, illegal kickbacks, and telemedicine schemes.<sup>14</sup>

The severe penalties that may be levied against healthcare providers under the AKS, the Stark Law, or the FCA have significant implications for the valuation of orthopedic services and compensation arrangements. Under current regulations, a hypothetical employer's estimate of the risk related to any arrangement with an orthopedic surgeon must account for potential exposure to these penalties. Compliance considerations for orthopedic practices may include heightened scrutiny of implant manufacturer consulting arrangements, speaker program compensation, clinical support services from health systems, and medical device representative relationships. Notably, DME, prosthetics, orthotics, and supplies (DMEPOS) and medical device entities remain excluded from value-based safe harbors, creating ongoing compliance challenges for orthopedic providers with device relationships. The regulatory environment for orthopedic services is characterized by significant exposure to federal fraud and abuse laws, including the AKS and the Stark Law. Recent enforcement trends demonstrate continued government focus on healthcare fraud, with record whistleblower filings and substantial recoveries.

The next and final installment of this five-part series will examine the technological advancements affecting orthopedic services, including developments in robotic surgery, arthroscopy, diagnostic imaging, and 3D printing.

1 "Valuation of Orthopedic Services: Reimbursement" Health Capital Topics, Vol. 19, Issue 3 (March 2026), [https://www.healthcapital.com/hcc/newsletter/03\\_26/HTML/ORTH/O/val-of-orthopedic-services---reimbursement.php](https://www.healthcapital.com/hcc/newsletter/03_26/HTML/ORTH/O/val-of-orthopedic-services---reimbursement.php) (Accessed 4/23/26).

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

3 *Ibid*; "Civil Monetary Penalties" 42 USC § 1320a-7a(a).

4 "False claims" 31 USC § 3729(a)(1)(G); "Annual Civil Monetary Penalties Inflation Adjustment" Federal Register, Vol. 91, No. 18 (January 28, 2026), p. 3669.

5 "Exceptions" 42 C.F.R. § 1001.952.

6 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn.

7 *Ibid*.

8 "False Claims Act Settlements and Judgments Exceed \$6.8B in Fiscal Year 2025" U.S. Department of Justice, Office of Public Affairs, Press Release, January 16, 2026, <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-68b-fiscal-year-2025> (Accessed 4/23/26).

9 "False Claims Act Insights: Key Takeaways from DOJ's Fiscal Year 2025 Cases & Recoveries" By John P. Bueker, et al., Ropes & Gray LLP, Posted on Ropes & Gray Insights, January 20, 2026, <https://www.ropesgray.com/en/insights/alerts/2026/01/false-claims-act-insights-key-takeaways-from-doj-s-fiscal-year-2025-cases-recoveries> (Accessed 4/23/26).

10 U.S. Department of Justice, Office of Public Affairs, Press Release, January 16, 2026.

11 "Aesculap Implant Systems Agrees to Pay \$38.5M to Resolve False Claims Act Allegations Related to Knee Implant Failures" U.S. Department of Justice, Office of Public Affairs, Press Release, November 2025, <https://www.justice.gov/opa/pr/aesculap-implant-systems-agrees-pay-385m-resolve-false-claims-act-allegations-related-knee> (Accessed 1/15/26).

12 "CMS Nearly Doubles Prior Stark Self-Disclosure Dollar Record in 2024" The FCA Insider, March 2025, <https://www.thefcainsider.com/2025/03/cms-nearly-doubles-prior-stark-self-disclosure-dollar-record-in-2024/> (Accessed 1/15/26).

13 "Self-Referral Disclosure Protocol Settlements" Centers for Medicare & Medicaid Services, Updated March 16, 2026, <https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/self-referral-disclosure-protocol-settlements> (Accessed 4/23/26).

14 "National Health Care Fraud Takedown Results in 324 Defendants Charged in Connection with Over \$14.6 Billion in Alleged Fraud" U.S. Department of Health and Human Services, Office of Inspector General, June 30, 2025, <https://oig.hhs.gov/fraud/enforcement/national-health-care-fraud-takedown-results-in-324-defendants-charged-in-connection-with-over-146-billion-in-alleged-fraud/> (Accessed 4/23/26).



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