

Publications

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Don't Let The Stark Law Catch You Off Guard: Risk Remains Despite the Lull

Key Takeaways

- **CMS and DOJ activity related to the Stark Law has been notably quiet in recent years, with no material rule updates since 2023 and limited enforcement actions.** This slowdown has left many providers wondering whether Stark compliance remains a government priority.
- **Despite the lull, the Stark Law remains a strict liability statute with a six-year lookback period, and core risk areas such as FMV assessments, unsigned contracts and prohibited financial relationships still present exposure.** Even technical missteps can trigger penalties, making documentation and exception management critical.
- **Health care providers should take advantage of this quiet period to review their compliance practices,** particularly around physician arrangements and designated health services.

The Stark Law may have gone quiet, but it hasn't gone away. One of the significant laws in the government's anti-fraud and abuse arsenal, the so-called Stark Law has regulated hospital, laboratory and other provider's operations for decades — but it has not received much government attention in recent years.

The Centers for Medicare and Medicaid Services (CMS) did not substantially tweak the Stark Law regulations at all in the 2023, 2024, 2025 and 2026 Hospital Outpatient Prospective Payment System rulemaking.¹ That's four straight years! Similarly, CMS has not updated its Stark Law FAQ since 2021² — four years again! CMS has not issued an advisory opinion (other than for grandfathered physician-owned hospitals) since June 2021. This dearth of activity does not appear to be limited to CMS. The press room for the U.S. Department of Justice Civil Division lists only one settlement in 2025 that discusses alleged violations of the Stark Law.³

A Rare Window to Reassess Stark Compliance

What should providers make of this relative quiet? Has the government forgotten about this rigid, strict liability law? In a word: no. The Stark Law is too foundational and the

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penalties are too large for enforcement related to this law to be quiet for long. The statute of limitations is also six long years — meaning mistakes do not go away quickly. The current lull in changes to the Stark Law regulations and a downturn in enforcement activity presents a window of opportunity for health care providers to perform maintenance on their related compliance practices. Smart providers will take this time of relative calm to assess and update their compliance processes.

What the Stark Law Covers

The proper name for the Stark Law is the physician self-referral law and it prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she has a financial relationship, unless the arrangement complies with an applicable exception. If there is a prohibited referral, then the entity is prohibited from billing Medicare for the service.

While the Stark Law is limited to a finite set of services, the list of designated health services is quite broad and includes:

- Clinical laboratory services;
- Physical therapy services;
- Occupational therapy services;
- Outpatient speech-language pathology services;
- Radiology and certain other imaging services;
- Radiation therapy services and supplies;
- Durable medical equipment and supplies;
- Parenteral and enteral nutrients, equipment and supplies;
- Prosthetics, orthotics and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs; and
- Inpatient and outpatient hospital services.

Since ordinary interactions between physicians and hospitals, labs and other health care entities often can create financial relationships, compliance with the Stark Law often hinges on satisfying one of its many exceptions. The applicable regulations have over 40 exceptions and most are complicated and impose significant technical documentation and administrative requirements.

Common Stark Compliance Pitfalls

Before the current quiet period, there had been decades of enforcement of alleged noncompliance with the Stark Law. Historically, the largest risks facing providers fell into a handful of categories:

- **Fair Market Value.** Many exceptions limit otherwise permissible payments to a physician to an amount that is fair market value. The aggressive enforcement often alleges that facilities paid referring physicians more than fair market value.
- **Technical Contracting.** Many exceptions require written and signed contracts. For larger facilities, managing the contracting process can present operational challenges. While CMS has given some grace to truly technical documentation issues, the law's payment prohibitions and penalties can convert small administrative errors into significant liabilities.
- **Consideration of referrals.** In numerous places, the implementing regulations expressly disallow consideration of the "volume or value" of a physician's referrals.
- **Ownership prohibitions.** In certain situations, the law prohibits physician ownership or investment with no exception.
- **Inadvertent financial relationships.** The Stark Law casts a broad net as to what can

create a “financial relationship” such that what may appear to be a typical relationship between a provider and a physician may not be compliant.

Proactive Steps for Providers to Reduce Risk

The Stark Law is too central to federal health care regulation to be quiet for long. Accordingly, health care providers should proactively review their Stark Law compliance practices. That starts with assessing whether they furnish designated health services and/or have financial arrangements (even indirectly) with physicians. From there, providers should then outline the types of risks that the Stark Law presents to their organization and institute measures to reduce those risks. That might mean auditing the contracting process to ensure that all payments to physicians are supported by a signed contract, or refreshing fair market value assessments to ensure that current payments remain within an acceptable range. Over time, these types of compliance efforts will pay dividends in reduced risk and enhanced regulatory compliance.

Please contact your Polsinelli attorney or a member of the Health Care team for questions and assistance regarding Stark Law compliance practices.

[1] <https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/significant-regulatory-history>

[2] <https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/frequently-asked-questions>

[3] <https://www.justice.gov/usao-edca/pr/fresno-based-community-health-system-agree-pay-315-million-resolve-allegations-false>