



**PCI | HealthDev**<sup>®</sup>  
Medical Real Estate Solutions

# WHITE PAPER



## **ANTI-KICKBACK STATUTE AND STARK LAW COMPLIANCE**

AN OVERVIEW

For physicians and medical business owners, thorough and ongoing legal due diligence is necessary to mitigate financial and reputational risk and ensure a successful, sustainable enterprise. The federal Anti-Kickback Statute, and federal Physician Self-Referral Law, commonly known as the Stark Law, both pose some of the greatest legal risks for physician owners and investors in hospitals, dialysis centers, ambulatory surgical centers, imaging centers, labs, and other medical entities. Physicians seeking to strengthen their financial security by purchasing or investing in medical real estate can be caught off guard by the intensive and time-consuming undertaking of navigating the regulatory environment. This paper provides a brief overview of Anti-Kickback Statute and Stark Law compliance and is not intended to be a comprehensive analysis.



The Anti-Kickback Statute is a criminal statute that prohibits anyone (not only physicians) from knowingly and willfully offering, paying, soliciting, or accepting anything of value to induce or reward patient referrals or generate Medicare or Medicaid business. To avoid violating Anti-Kickback rules when contracting with physicians for services, physicians and providers must ensure there is a legitimate need for those services, the services are provided as described in the contract, compensation is consistent with fair-market value and conducted in an arms-length transaction, and that the arrangement is completely decoupled from the volume or value of Medicare or Medicaid business generated. Violations of Anti-Kickback rules require proof of intent. Penalties can include fines, jail time, and exclusion from federal healthcare programs.

Under the Stark Law, physicians cannot refer patients for Medicare-insured “designated health services”—clinical lab services, home health services, physical therapy, etc.—to an entity in which they have a financial stake. Moreover, the Stark Law definition of “referral” is much broader than the common physician-patient relationship. In addition, the Stark Law prohibits such medical entities from presenting claims to Medicare for these referred services. Adding further complication, Stark also applies to the financial interests of physicians’ immediate family members—not only parents, spouses, and children, but also step-relatives, in-laws, grandparents, and grandchildren. Because the Stark Law is a strict liability statute, violations do not require proof of intent; penalties can be imposed for even inadvertent infringements. Penalties for Stark violations can include fines and exclusion from federal health care programs.

## Compliance Challenges

The significant complexity of the Anti-Kickback Statute and Stark Law make navigating them inherently difficult. Compliance is a moving target: since their enactment, both the Anti-Kickback Statute and Stark Law have been modified to expand their prohibitions and exceptions. As physician investors and healthcare providers evolve their financial holdings and business relationships, they must continuously reevaluate their practices to ensure compliance.

Under both the Anti-Kickback Statute and Stark Law, physician investors and healthcare providers must carefully design business arrangements to avoid scrutiny from regulators. For example, management contracts and physician-services arrangements must be for at least one-year terms to avoid



the impression that contract terms are influenced by inappropriate financial incentives. As such, real estate leases must be long-term with fixed lease rates. Lease and rental rates (both for space and equipment) must be consistent with local fair-market value and transacted for at arms-length – for example, by using independent bank appraisals.

While these fraud-prevention regulations are rife with prohibitions, it is important for physician investors and healthcare providers to also understand the various Anti-Kickback Statute safe harbors and Stark Law exceptions, i.e., specific financial relationships and practices that are safe from prosecution. For example, exceptions and safe harbors that apply to the relationship between dialysis companies and nephrologists have enabled fair market value joint ventures between these parties. Services provided by outpatient dialysis facilities do not fall under Stark’s “designated health services,” and specific drugs administered by dialysis facilities also fall under Stark exceptions.

Clearly, ensuring compliance with the Anti-Kickback Statute and Stark Law requires deep expertise, as their application depends on the particular contours of each situation, including the type of financial arrangement, reimbursement, health service, and setting of care delivery. For practicing physicians who are also business owners, it can seem nearly impossible to dedicate the time and focus required to become experts in the laws’ intricacies. “Complying with these regulations is hugely complicated; it’s like dodging bullets every day,” said PCI | HealthDev Founder and Vice Chairman Pedro Vergne-Marini, MD, FACP, FACC. “Doctors were never taught about this in medical school. They were taught to care for patients and save lives.”

Yet, while the costs of compliance may be heavy, the costs of noncompliance can be even greater. Furthermore, the fallout can go beyond financial and legal penalties to include reputational damage, since even unintentional violations can be interpreted by lay observers (and framed by local media), as nefarious examples of “fraud and abuse.” The potential harm includes undermining a practice’s standing in its local community and its ability to recruit both patients and medical talent.

## Anti-Kickback Statute Safe Harbor

Leases must comply with the following:

1. The lease agreement is set out in writing and signed by the parties;
2. The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease;
3. If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals;
4. The term of the lease is for not less than one year;
5. The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; and
6. The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

## Lease Exception to Stark

Leases must comply with all the following requirements:

- Written agreement, signed by the parties, which specifies the premises it covers;
- Term of at least one year;
- Space is reasonable and necessary for the legitimate business purpose and may include proportional allocation of common area expenses;
- Rent is set in advance and consistent with FMV; Rent not determined in a manner that takes into account the volume or value of referrals;
- The agreement should be commercially viable even if the business receives no referrals;
- Holdover month to month rental for up to six months immediately following an agreement of at least one year that otherwise met all the conditions above, provided the holdover rental is on the same terms and conditions as the immediately preceding agreement.

## The Solution

The risk of contravening the Anti-Kickback Statute and the Stark Law should not deter physician-entrepreneurs from investing in their futures through medical real estate ownership—nor should inadvertent contraventions put at risk the financial and reputational health of well-intentioned providers overwhelmed by the law's complexities. To access the rewards of real estate investment, medical investors need sound advice from trusted, locally knowledgeable experts who can provide high-value added support throughout the lifecycle of a project. Third-party experts can offer guidance to ensure that real estate transactions are at arm's length, lease rates and real estate purchase prices are consistent with local fair-market valuation and owners' business and referral relationships avoid Anti-Kickback Statute and Stark Law violations. Real estate development companies should offer individualized solutions for each client and project, whether helping practices expand, mature practices liquidate, or younger physicians participate in real estate investment through a fractional ownership arrangement.

PCI | HealthDev's team of healthcare industry professionals provide clients with the expertise and support to neutralize Anti-Kickback Statute and Stark Law risk and focus on what really matters to them: caring for patients. The company leverages a wealth of expertise in healthcare services and legal compliance to understand the regulatory vulnerabilities across the medical real estate ecosystem. PCI | HealthDev has an in-house legal and compliance department to ensure that each project adheres to best practices.

While its clients range from small practices to large, leading providers in various fields, PCI | HealthDev has unique expertise across multiple medical modalities, including both the regulatory environment and patient needs.

The professionals at PCI | HealthDev take each project personally, allowing their clients to take solace in knowing that no stone will be left unturned. "We make sure that there is no gray area with regards to Anti-Kickback Statute or Stark Law issues and, in doing so, we provide clients with the confidence that we will keep them out of harm's way," said Vergne-Marini. "Other medical real estate companies are purely builders. We offer something different."

### **PCI | HealthDev Corporate Office**

8117 Preston Road, Suite 400  
Dallas, TX 75225

### **PCI | HealthDev Denver Office**

Seventeenth Street Plaza  
1225 17th Street, Suite 1750  
Denver, CO 80202

Contact: Jeff Kroll  
Phone: 866.936.3089  
Email: jkroll@HealthDev.com

**www.HealthDev.com**

### Sources:

Notes provided by PCI | HealthDev, interviews, and "A Roadmap for New Physicians—Fraud & Abuse Laws," U.S. Department of Health & Human Services (DHHS) Office of Inspector General, DHHS website, <http://oig.hhs.gov/compliance/physician-education/OIlaws.asp>, accessed February 2014;

"Physician Self Referral," Centers for Medicare & Medicaid Services website, last modified November 27, 2013, <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/>, accessed February 2014;

"Frequently Asked Questions—By Topic: Fraud and Abuse," Centers for Medicare & Medicaid Services website, <https://questions.cms.gov/faq.php?id=5005&rtopic=1887>, accessed February 2014;

"Kickback and Physician Self-Referral," U.S. Department of Health & Human Services (DHHS) Office of Inspector General, DHHS website, <https://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp>, accessed February 2014;

"The Federal Anti-Kickback Statute," American Health Care Association website, [http://www.ahcancal.org/facility\\_operations/integrity/Pages/Compliance-Programs.aspx](http://www.ahcancal.org/facility_operations/integrity/Pages/Compliance-Programs.aspx), accessed March 2014;

"Comparison of the Anti-Kickback Statute and Stark Law," Office of Inspector General (OIG) Health Care Fraud Prevention and Enforcement Action Team (HEAT), OIG website, <https://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf>, accessed March 2014;

"Summary of Self-Referral and Anti-Kickback Regulations," American Speech-Language-Hearing Association website, [http://www.asha.org/practice/reimbursement/medicare/regulations\\_sum/#safe](http://www.asha.org/practice/reimbursement/medicare/regulations_sum/#safe), accessed March 2014.

© 2016 Physicians' Capital Investments, LLC. All rights reserved. PCI | HealthDev is a d/b/a of Physicians' Capital Investments, LLC, a Nevada limited liability company. The Physicians' Capital Investments and the PCI | HealthDev name and logo are registered marks of Physicians' Capital Investments, LLC. This communication may contain "forward-looking statements". All statements, other than statements of historical fact, including statements that address activities, events or developments that we or our management intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Forward-looking statements are based on management's assumptions and assessments in light of past experience and trends, current conditions, expected future developments and other relevant factors. They are not guarantees of future performance, and actual results may differ significantly.