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Expensive Mistakes: Preventing Technical Violations of the Stark Law

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The Stark law generally prohibits physician referrals of designated health services (DHS)¹ for Medicare and Medicaid patients if the physician (or an immediate family member)² has a financial relationship with the entity the patient is referred to and to prohibit billing for such services, unless an exception applies.³

The Stark law is referred to as a “strict liability” law because violations may occur without any improper intention. Stark law compliance is mandatory, and if a physician makes a prohibited referral and no exception applies, penalties can be imposed. Examples of penalties include: denial of payment or refund of monies received, civil penalties of up to \$15,000 per service,⁴ and exclusion from Medicare and/or state healthcare programs

including Medicaid.⁵ The False Claims Act also imposes treble damages up to \$11,500 in fines for each claim submitted or retained in violation of the law.⁶

While not formally delineated as such in the Stark law statute or regulations, violations may be characterized as either “substantive” or “technical” in nature. “Substantive” violations target core issues the law was designed to prevent, such as a hospital’s payment for physician services above fair market value. Examples of substantive violations by DHS entities may include: failure to have certain financial relationships with physicians memorialized pursuant to a written agreement, calculating a physician’s salary or bonus based on referral volume, or leasing office space to a physician below fair market value. *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.* is a recent example of such alleged substantive Stark law violations. The court ordered Tuomey Healthcare System to pay approximately \$237,000,000 in fines after finding that the system had agreements in which physicians’ compensation fluctuated based upon Tuomey’s net collections for physicians’ procedures.⁷

¹ The following services are considered “designated health services” under Stark law: 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. 42 C.F.R. § 411.351.

² “Immediate family member” is defined under the Stark law as including spouse, birth, or adoptive family members, stepfamily members, in-laws, grandparents, grandchildren, and even spouse of a grandparent or grandchild. 42 C.F.R. § 411.351.

³ See 42 C.F.R. §§ 411.355–411.357 for list of exceptions.

⁴ 42 U.S.C. §1395nn(g)(3).

⁵ See Office of Inspector General, *A Roadmap for New Physicians: Fraud & Abuse Laws*. Available at <http://oig.hhs.gov/compliance/physician-education/01laws.asp>.

⁶ 42 C.F.R. § 1003.100(b)(viii).

⁷ Scott Becker and Molly Gamble, “An Overview of the Tuomey Healthcare Case,” *Becker’s Hospital Review*, October 4, 2013. Available at www.beckershospitalreview.com/legal-regulatory-issues/5-things-to-know-about-the-tuomey-healthcare-case.html.

“Technical” violations tend to be unintentional acts, like forgetting to sign a contract, allowing a contract to expire without renewal, or unintentionally omitting an element of an exception from the agreement. Because these violations are typically unintentional, they occur more frequently, and it is estimated that roughly 95 percent of DHS entities (i.e., healthcare providers that render DHS, like hospitals, labs, imaging centers, etc.) have arrangements with physicians that are technically in violation of the Stark law.⁸ Nonetheless, even “technical” violations can result in large penalties for providers.

Discovery of Violations

Technical violations generally are inadvertent and are harder to discover but often surface during: 1) internal compliance reviews, 2) diligence pursuant to a merger or acquisition, or 3) a government investigation. However, the Stark law does not distinguish between “substantive” and “technical”—all violations are subject to the same penalties.

A DHS entity may proactively conduct an internal compliance review to identify any areas of noncompliance. Technical violations uncovered during internal reviews are sometimes reported to the government pursuant to the Medicare self-referral disclosure protocol. For example, in 2013, Intermountain Healthcare settled alleged Stark law violations involving payments to more than 200 doctors with the Department of Justice (DOJ) for \$25,500,000.⁹ Intermountain voluntarily disclosed potential violations after uncovering the potential issues through a regular internal review of its arrangements with physicians, most of which were “technical” in nature.¹⁰

Violations are also identified during diligence reviews pursuant to a merger or acquisition. In 2010, the DOJ announced that Detroit Medical Center (DMC) had agreed to pay \$30,000,000 to settle allegations that it violated the Stark law and other laws by “engaging in improper financial

⁸ See Jean Wright Veilleux, “Catching Flies with Vinegar: A Critique of the Centers for Medicare and Medicaid Self-Disclosure Program,” *Health Matrix*, Vol. 22, No. 1, January 2012.

⁹ See Joe Carlson, “Intermountain to Pay \$25.5 Million to Settle Stark Case,” *Modern Healthcare*, April 3, 2013. Available at www.modernhealthcare.com/article/20130403/NEWS/304039948.

¹⁰ *Ibid.*

relationships with referring physicians.”¹¹ The violations were discovered during a due diligence review in connection with DMC’s sale to Vanguard Health Systems, Inc. (VHS). Most violations involved “office lease agreements and independent contractor relationships that were either inconsistent with fair market value or not memorialized in writing.”¹² Alleged violations also included improper perks for doctors, including special compensation, entertainment, and unreasonable lease deals.¹³ As is typical, VHS’s ultimate acquisition of DMC was contingent on DMC’s resolution of any liability in connection with the alleged violations.

Government investigations can also uncover “technical” Stark law violations. Westerly Hospital in Rhode Island recently settled allegations of improper payments to and arrangements with physicians following an investigation by the federal government into allegations including failing to maintain accurate records of compensation arrangements with physician leaders and failing to document and update lease arrangements with physicians. Westerly settled nine potentially improper agreements for \$500,000 and stated that many violations resulted from “sloppy paperwork.”¹⁴

Exceptions for “Technical” Violations

Phase II and III of the Stark law regulations provide some limited relief for “technical” violations. Although this relief does not fundamentally alter the Stark law’s basic scope of prohibited referrals, the regulations nonetheless reflect flexibility to minimize the Stark law’s effect on common business arrangements through some limited exceptions.

In Phase II, CMS added an exception for certain arrangements involving temporary noncompliance with a Stark law exception, which allows DHS

¹¹ David Burda, “Detroit Medical Center to Pay \$30 Million Settlement,” *Modern Healthcare*, January 3, 2011. Available at www.modernhealthcare.com/article/20110103/MAGAZINE/301039988.

¹² Department of Justice, Office of Public Affairs, “Detroit Medical Center Pays U.S. \$30 Million to Settle False Claims Act Allegations, Allegedly Engaged in Improper Financial Relationship with Referring Physicians,” December 30, 2010. Available at www.justice.gov/opa/pr/2010/December/10-civ-1484.html.

¹³ Burda, 2011.

¹⁴ Dale P. Faulkner, “Settlement Outlines Investigation,” *The Westerly Sun*, June 22, 2013.

entities and physicians to submit claims for DHS provided during a period when an arrangement was noncompliant, if certain requirements are met. In Phase III, CMS extended this temporary noncompliance provision to address temporary noncompliance with *signature* requirements applicable to many Stark law exceptions.¹⁵

Although this exception provides some relief to noncompliant parties, DHS entities and physicians should not rely on these provisions for every oversight, as each provision can be used only once every three years with respect to the same referring physician.¹⁶ Moreover, these provisions are not applicable in many cases of noncompliance. For example, the Phase II exception for temporary noncompliance is limited to instances where noncompliance is due to “reasons beyond the control” of the DHS entity, which CMS has not really defined beyond stating that this determination is made on a case-by-case basis.¹⁷ The provision also protects DHS services provided only “during the period of time it takes the entity to rectify the noncompliance,” which must not exceed 90 days after the date the agreement became noncompliant. Likewise, the exception for temporary noncompliance with a signature requirement is limited to 90 or 30 days after the compensation arrangement became noncompliant, depending on whether the noncompliance was inadvertent.

This short-term exception provides little relief when a noncompliant agreement remains undetected for years—Intermountain Healthcare’s alleged violations spanned from 2000 to 2009.¹⁸ Critics argue that the temporary noncompliance provisions do little to relieve the burden of “technical” mistakes and have urged CMS to toll the exceptions until the date the noncompliance was discovered. CMS, however, has defended the current regulations by stating that a “discovery-based” rule is difficult for the government to monitor and enforce, and that it is the responsibility of DHS entities and physicians to regularly monitor compliance with the Stark law to ensure detection of noncompliance is made in a timely fashion.¹⁹

¹⁵ 42 C.F.R. § 411.353(g).

¹⁶ See, e.g., 42 C.F.R. § 411.353(f), (g).

¹⁷ CMS suggests that removal of a Health Professional Shortage Area designation is “beyond the control” of the DHS entity. 72 Fed. Reg. 51012, 51025–51026 (September 5, 2007).

¹⁸ Carlson, 2013.

¹⁹ 72 Fed. Reg. 51012, 51025 (September 5, 2007).

Contract Holdovers

The Stark regulations also provide some flexibility for temporarily noncompliant space or equipment rental and personal services agreements by incorporating holdover provisions. Under the holdover provisions, the arrangement continues for up to six months after the expiration of the term of the written agreement if the arrangement between the parties during the holdover period continues *on the same terms and conditions as the expired written agreement*. The holdover provision protects arrangements in which the agreement does not automatically renew and provides the parties with time to negotiate the terms of a new written agreement.

Unlike with the temporary noncompliance provisions, there is no limit on how often the holdover provision can be used for one referring physician; however, the terms from the previously valid agreement must not change during the holdover period (e.g., no rent increases unless the expired lease included a holdover rent premium). Furthermore, the six-month cutoff period cannot be extended. If the violation extends beyond six months for any reason, such as a long eviction process, the technical violation will not be excused by the holdover provision and constitutes a violation of the Stark law.²⁰

Recommendations to Avoid “Technical” Violations

To avoid “technical” violations of the Stark law, DHS entities and physicians need to be proactive in evaluating financial relationships with physicians. Although technical violations will occur, DHS entities and physicians can decrease the chance of violating the Stark law by following the recommendations listed below.

Financial Relationship Sign-Off

The broad definition of “financial relationship,” which includes direct and indirect relationships, under the Stark law may cause DHS entities and physicians to easily miss an improper financial relationship.²¹ In addition, arrangements with physicians whose family members are also physicians practicing in the community or whose family members otherwise have financial relationships with the DHS entity may lead to violations of the Stark law. To help prevent these

²⁰ 72 Fed. Reg. 51045.

²¹ 42 C.F.R. § 411.354(a).

violations, the DHS entity should make a specific person or department responsible for reviewing and signing off on each direct and indirect financial arrangement the DHS entity maintains with a referring physician. The DHS entity should require physicians with whom it maintains financial relationships to annually provide conflict-of-interest information on their and their immediate family members' direct or indirect employment arrangements, investments, and other financial activities to allow the DHS entity to evaluate whether problematic relationships exist.

Drafting Checklist

To ensure an arrangement is compliant with the Stark law, a DHS entity should consider using a drafting checklist to determine, for example, whether the agreement:

- Contains an evergreen clause to prevent termination while the parties continue to perform under the agreement.
- Satisfies each element of an applicable Stark law exception.
- Was cross-referenced against and added to the DHS entity's master list of agreements.

Also, parties should regularly review and update agreements to ensure they remain compliant as laws evolve.

Drafting Techniques

Certain drafting techniques may also help reduce the likelihood of a Stark law violation. For example, an evergreen clause allows an agreement to automatically renew unless otherwise terminated.

Arrangements that are unlikely to change over time could benefit from the addition of an evergreen clause. However, such clauses should not be used when fair market value determinations should be reviewed periodically. In addition, while not strictly necessary, a DHS entity may desire to include certain provisions that proactively anticipate a potential holdover of the contract. If a holdover rental premium is included in the contract, for example, the premium must still be consistent with fair market value at the time the agreement is initially executed.

Contract Management

DHS entities should consider adopting contract management software to assist the DHS entity in monitoring all its physician agreements. Such software provides monitoring capabilities by: 1) notifying parties of approaching agreement expiration dates, 2) aggregating all contracts in a searchable repository, and 3) customizing workflows, which incorporate checklists and verify whether required elements are included in the contract, alerting the drafter when deviations from the workflow occur.

Seek Advice from Legal Counsel

If any potential violation has occurred, before self-disclosing such violation, DHS entities and physicians should discuss the specific facts with legal counsel experienced in Stark law compliance to determine whether another exception may be applicable or whether the arrangement is even subject to the Stark law.

The Governance Institute thanks Holly Carnell, associate, and Anna Timmerman, associate, McGuireWoods, LLP, for contributing this article. The discussion and recommendations outlined in this article are intended to assist DHS entities and physicians in complying with the Stark law. If you have any questions about Stark law compliance or would like advice regarding a potential violation, please contact one of the authors. They can be reached at hcarnell@mcguirewoods.com and atimmerman@mcguirewoods.com.