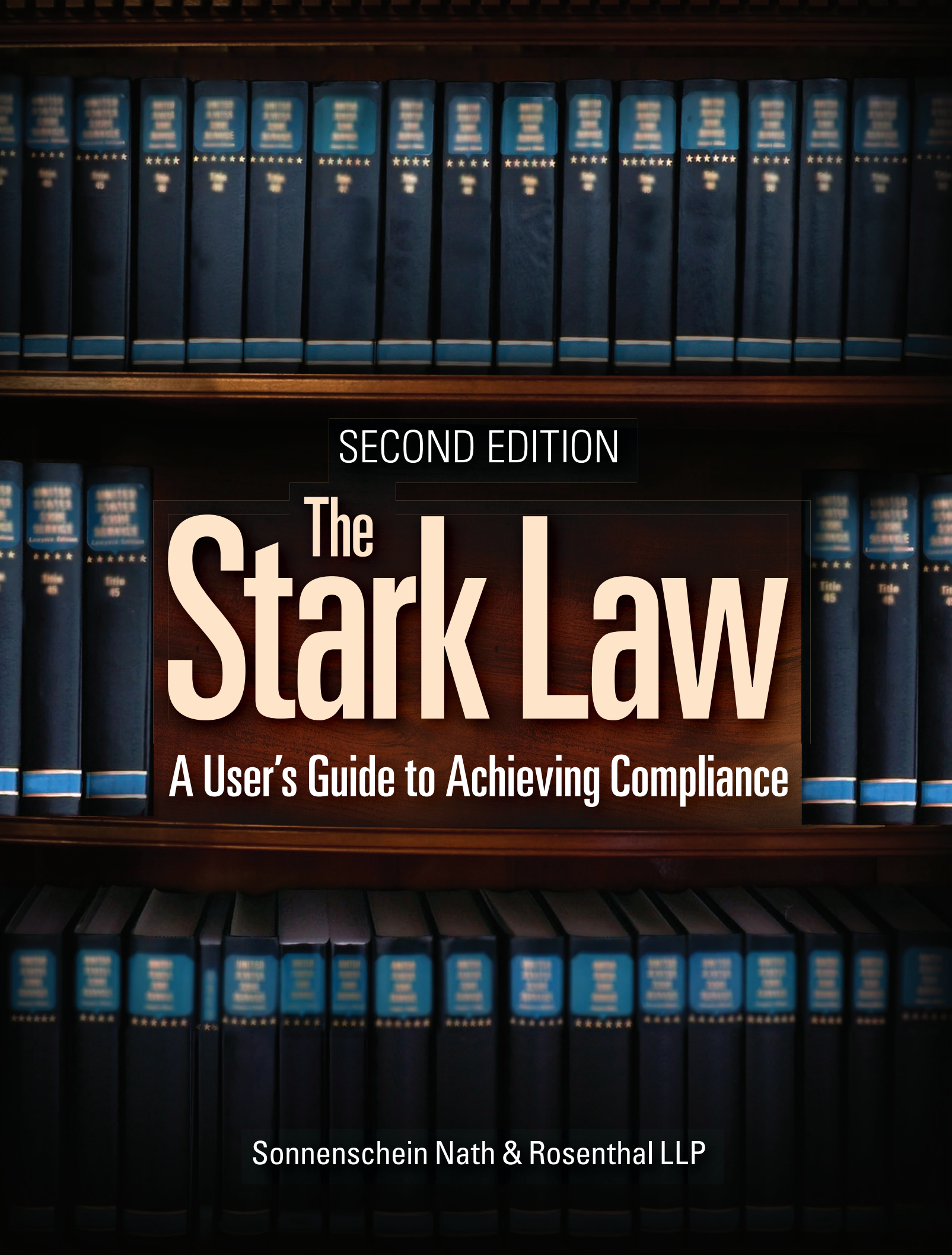

SECOND EDITION

The Stark Law

A User's Guide to Achieving Compliance

Sonnenschein Nath & Rosenthal LLP

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* * *

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Introduction

Midway upon the journey of our life
I found myself within a forest dark,
For the straightforward pathway had been lost.
Ah me! how hard a thing it is to say
What was this forest savage, rough, and stern,
Which in the very thought renews the fear.

—Dante Alighieri, *The Divine Comedy: Inferno,* Canto I

The federal physician self-referral statute and its implementing regulations—commonly and collectively referred to as the "Stark Law"—establishes two basic prohibitions:

- In the absence of an exception, a physician may not refer a patient to a health care entity for the furnishing of certain types of services—referred to as designated health services (DHS)—if the services are paid for by Medicare and the physician (or one of his or her immediate family members) has a financial relationship with the entity.[1] We refer to this as the Stark Law's "referral prohibition."
- A health care entity may not bill any person or entity for DHS provided as the result of an improper referral (i.e., a referral that violated the referral prohibition).[2] We refer to this as the Stark Law's "billing prohibition."

The Stark Law's principal policy objectives are straightforward. According to the Centers for Medicare & Medicaid Services (CMS), the federal agency principally responsible for implementing and enforcing the Stark Law, the Law's referral and billing prohibitions are necessary because:

- Physicians may "overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered."
- A patient's choice "can be affected when physicians steer patients to less convenient, lower quality, or more expensive providers of health care" based on financial considerations.

- "Where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers since new competitors can no longer win business with superior quality, service, or price."[3]

The Stark Law's basic prohibitions and policy objectives can be easily summarized, but almost every other aspect of the Law is quite complex (and occasionally confounding). Moreover, the consequences of violating the Stark Law can be severe. This book is designed to help health care providers, suppliers, and practitioners understand the Stark Law. It does so by untangling and explaining each of the Stark Law's many moving parts, providing a simple and logical system for identifying financial relationships, and (wherever possible) offering suggestions for structuring these relationships to satisfy the requirements of one or more of the Law's exceptions. The book is organized as follows:

Chapter 1: Background and Analytical Framework provides an overview of the Stark Law and sets forth a three-step process for determining whether an arrangement implicates and/or violates the Stark Law.

Chapter 2: Definitions discusses a number of terms and phrases, such as "physician," "immediate family member," "fair market value," and "set in advance" that appear throughout the book and that are critical to understanding and applying the Stark Law.

Chapter 3: Designated Health Services describes the "designated health services" that are covered by the Stark Law.

Chapter 4: Referrals provides the framework for determining whether, under the proposed arrangement at issue, a "physician" will be making a "referral" "to" an "entity" for the "furnishing" of DHS, which is a prerequisite for triggering Stark Law liability.

Chapter 5: Financial Relationships provides the framework for determining whether, under the proposed arrangement at issue, a physician (or a physician's immediate family member) will have a "financial relationship" with an entity that furnishes DHS, also a prerequisite to Stark Law liability.

Chapter 6: All-Purpose Exceptions addresses the Stark Law exceptions that are available regardless of the type of financial relationship that a physician (or his or her immediate family member) has with an entity furnishing DHS.

Chapter 7: Ownership Interest Exceptions addresses the Stark Law exceptions that are available when the financial relationship at issue takes the form of a direct or indirect ownership or investment interest.

Chapter 8: Direct Compensation Arrangement Exceptions addresses the Stark Law exceptions that are available when the financial relationship at issue takes the form of a direct compensation arrangement.

Chapter 9: Indirect Compensation Arrangements Exception addresses the Stark Law exception that is available when the financial relationship at issue takes the form of an indirect compensation arrangement.

Chapter 10: Physician Recruitment and Retention in Underserved Areas addresses the exceptions that are available when the compensation at issue is furnished in connection with a physician recruitment or retention arrangement.

Chapter 11: Period of Disallowance, Temporary Noncompliance, and Technical Noncompliance explains CMS' most recent guidance concerning (1) the so-called "period" of disallowance (i.e., the period, if any, during which referrals are prohibited after a financial relationship has, at least formally, ended), (2) situations involving "temporary noncompliance" with the requirements of a particular Stark Law exception, and (3) situations involving "technical noncompliance with the requirements of a particular Stark Law exception.

Chapter 12: Sanctions, Collateral Consequences, and Reporting Requirements addresses the potential consequences of a Stark Law violation, both under the Stark Law itself and under several other statutes—most notably, the federal civil False Claims Act (FCA). This chapter also discusses the reporting requirements that the Stark Law imposes on entities that furnish DHS to Medicare beneficiaries.

Chapter 13: Advisory Opinions explains the process by which a provider, supplier, or practitioner may seek an advisory opinion from CMS concerning (1) whether a physician has a financial relationship with an entity that furnishes DHS, (2) if he or she does, whether any Stark Law exceptions apply, and (3) certain other issues.

We also have included, in the CD-ROM accompanying this book, copies of the Stark Law, the Stark Regulations, and several of the most important and frequently cited Stark-related *Federal Register (FR)* sections, including those setting forth the preamble to the:

- 1995 Stark I Regulations
- 1998 Proposed Stark II Regulations
- 2001 Stark II, Phase I Regulations
- 2004 Stark II, Phase II Regulations
- 2007 Stark II, Phase III Regulations
- 2008 FY 09 IPPS Final Rule

The Challenges of Analyzing the Stark Law

Before turning to our step-by-step approach to analyzing an arrangement under the Stark Law, the need for such an approach warrants discussion. As noted earlier, it is much easier to articulate the Stark Law's basic prohibitions and principal policy objectives than it is to implement them. Indeed, those who counsel providers, suppliers, and practitioners about how to apply the Stark Law have found the task to be challenging and, at times, quite frustrating, for several reasons.

The Stark Law's breadth

Both as written and as interpreted by CMS, the Stark Law's referral prohibition is quite broad. For example, one could argue that (1) each and every physician in the United States has a "financial relationship" with each and every hospital to which the physician refers patients, and (2) as a result, no physician may refer a Medicare patient to any such hospital without implicating—and, in the absence of an applicable exception, violating—the Stark Law. This is no exaggeration. For Stark Law purposes:

- a physician has a "financial relationship" with any hospital with which the physician has a "compensation arrangement,"[4]
- a compensation arrangement includes "any arrangement" between a physician and hospital that "involves remuneration,"[5] and
- "remuneration" means "any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind."[6]

Thus, if a hospital provides a physician with anything of value, regardless of how small (e.g., a coffee mug),[7] the hospital and physician have a "financial relationship" and, in the absence of an exception, the physician may not refer Medicare patients to the hospital for DHS, and the hospital may not bill anyone for DHS furnished to such patients, without violating the Stark Law.

Proliferation of exceptions

Because its prohibitions are so broad, the Stark Law is overinclusive and implicates thousands of common, everyday provider-physician arrangements—the vast majority of which do not offend any of the Stark Law's underlying policy objectives. For example, no one actually believes that in exchange for a free coffee mug, a physician would refer a Medicare beneficiary to a hospital for a medically unnecessary inpatient or outpatient service.

For this reason, Congress and CMS have created almost three dozen separate exceptions to the Stark Law's prohibitions. The exception for "nonmonetary compensation", for example—which might cover the free coffee mug—protects "compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per year," provided that multiple conditions are met (e.g., the compensation at issue "may not be solicited by the physician or the physician's practice").[8]

The Stark Law's other exceptions cover the following:

- Publicly traded securities
- Mutual funds
- Specific providers
- Rental of office space

- Rental of equipment
- Bona fide employment relationships
- Personal service arrangements
- Physician recruitment
- Isolated transactions
- Remuneration unrelated to DHS
- Certain group practice arrangements with hospitals
- Payments by a physician
- Fair market value compensation
- Medical staff incidental benefits
- Risk-sharing arrangements
- Compliance training
- Indirect compensation arrangements
- Charitable donations by physicians
- Referral services
- Obstetrical malpractice insurance subsidies
- Professional courtesy
- Retention payments in underserved areas
- Communitywide health information systems
- Electronic prescribing items and services
- Electronic health records items and services
- Physician services
- In-office ancillary services
- Prepaid health plan services

- Academic medical center services
- Implants (in ambulatory surgery centers)
- Dialysis-related drugs (end-stage renal disease)
- Preventive screening tests and immunizations
- Postcataract surgery eyeglasses and contact lenses
- Intrafamily rural referrals

Stark's complexity

In addition to the Stark Law's breadth and the many resulting exceptions, the Law can be difficult to navigate for a third reason: Many of the elements of the Stark Law's basic prohibitions and exceptions are complex, counterintuitive, and, in some cases, have been defined, interpreted, redefined, and reinterpreted on multiple occasions by CMS over the past two decades. For example:

- The Stark Law definition of the word "referral" is more than 370 words long.[9]
- A flat fee that does not change may violate the "volume or value" standard,[10] but a per service fee that is tied directly to DHS referrals may not.[11]
- The term "indirect compensation arrangement" was undefined by CMS until 1998,[12] and was redefined by CMS in 2001,[13] 2004,[14] 2007[15] and 2008.[16]

Intermittent guidance

A fourth factor has made compliance with the Stark Law difficult for health care organizations: CMS has provided only sporadic and relatively limited Stark Law guidance. The original Stark Law was enacted in 1989 ("Stark I"),[17] and it was expanded in 1993 ("Stark II"),[18] but CMS did not issue final regulations covering the expanded law until 2001 (Phase I),[19] 2004 (Phase II),[20] and 2007 (Phase III).[21] Congress sought to address this lack of guidance in 1997, when it set up an "advisory opinion" process.[22] Through August 2009, however, CMS had issued only a handful of Stark Law advisory opinions.

Strict liability

To raise the compliance stakes still higher, the Stark Law is (generally speaking) a "strict liability" statute. That is, unlike one of the Stark Law's cousins—the federal health care

program anti-kickback statute,[23] which is violated only if the defendant acts with the requisite state of mind (i.e., "knowingly and willfully")—the Stark Law may be violated even if the parties do not intend to violate the Law and are not aware that they are doing so.

For example, assume that a physician and a hospital have a financial relationship (e.g., because the hospital has given the physician a coffee mug) and that this financial relationship does not fit into an exception (e.g., because the physician "solicited" the mug from the hospital). Under these circumstances, each and every time the physician refers a Medicare patient to the hospital for DHS, the Stark Law's referral prohibition may be violated; and each and every time the hospital bills Medicare (or anyone else) for DHS furnished to such patients, the Stark Law's billing prohibition may be violated—all irrespective of whether the physician or the hospital intended to violate the Stark Law or were even aware that such violations were occurring.

Enforcement

All of the factors that make the Stark Law so challenging from a compliance standpoint would probably be manageable for the health care industry if the federal government had exclusive jurisdiction to enforce the Stark Law. Unfortunately, this is not the case.

Although the jurisprudence in this area is evolving and relatively limited, and although there are no U.S. Supreme Court cases directly on point, several lower federal courts have concluded that when a provider submits a claim for services that were furnished as a result of a referral that violated the Stark Law, this submission may constitute a "false claim" for purposes of the FCA. The FCA, in turn, has a qui tam (or "whistleblower") provision that allows private individuals and organizations to bring FCA actions in the name of (and on behalf of) the federal government.[24] If the whistleblower prevails, he or she is entitled to keep as much as 30 percent of the proceeds of the litigation (which may include treble damages and a fine of up to $11,000 per claim), as well as reasonable expenses and attorneys' fees.[25]

For all of these reasons, providers, suppliers, and practitioners must be extremely careful to comply with the Stark Law and need clear and practical guidance for doing so. This book is intended to provide such guidance.

Endnotes

1. More specifically, in the absence of an applicable exception, a "physician" who has a "financial relationship" with an "entity" (such as a clinical laboratory or a hospital), or who has an "immediate family member" who has such a financial relationship, may not make a "referral" "to" that entity for the "furnishing" of "DHS" for which payment may be made under the Medicare program. 42 United States Code (USC) § 1395nn(a)(1)(A); 42 *Code of Federal Regulations (CFR)* § 411.353(a).
2. More specifically, in the absence of an applicable exception, an entity that furnishes DHS pursuant to a prohibited referral may not "present" or "cause to be presented" a claim or bill for such services to the Medicare program (or to any other individual or entity). 42 USC § 1395nn(a)(1)(B); 42 *CFR* § 411.353(b).
3. Stark II Proposed Regulations (Preamble), 63 *FR* 1659, 1662 (1998).
4. 42 USC § 1395nn(a)(2)(B); 42 *CFR* § 411.354(a)(1)(ii).
5. 42 USC § 1395nn(h)(1)(A); 42 *CFR* § 411.354(c).
6. 42 USC § 1395nn(h)(1)(B); 42 *CFR* § 411.351.
7. Stark II Proposed Regulations (Preamble), 63 *FR* 1659, 1699 (1998).
8. 42 *CFR* § 411.357(k). Pursuant to 42 *CFR* § 411.357(k)(2), the aggregate annual amount is adjusted each year to reflect consumer price index fluctuations.
9. 42 *CFR* § 411.351.
10. Stark II, Phase I Regulations (Preamble), 66 *FR* 856, 878 (2001); 42 *CFR* § 411.354(d)(4).
11. 42 *CFR* § 411.354(d)(2).
12. Stark II Proposed Regulations (Preamble), 63 *FR* 1659, 1705-1706 (1998).
13. Stark II, Phase I Regulations, 66 *FR* 856, 958-959 (2001), setting forth 42 *CFR* § 411.354(c)(2).
14. Stark II, Phase II Regulations, 69 *FR* 16054, 16134 (2004), setting forth a revised 42 *CFR* § 411.354(c)(2).
15. Stark II, Phase III Regulations, 72 *FR* 51012, 51087 (2007), setting forth a revised 42 *CFR* § 411.354(c)(2).
16. FY 09 IPPS Final Regulations, 73 *FR* 48434, 48752 (2008), setting forth a revised 42 *CFR* § 411.354(c)(2).
17. Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Public Law 101–239, enacted on December 19, 1989).
18. Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66, enacted on August 10, 1993).
19. Stark II, Phase I Regulations, 66 *FR* 856 (2001).
20. Stark II, Phase II Regulations, 69 *FR* 16054 (2004).
21. Stark II, Phase III Regulations, 72 *FR* 51012 (2007).
22. 42 USC § 1395nn(g)(6).
23. 42 USC § 1320a-7b(b).
24. 31 USC § 3730.
25. 31 USC § 3730(d).

CHAPTER 1

Background and Analytical Framework

CHAPTER 1

Background and Analytical Framework

This chapter is organized into two sections. Section I summarizes the Stark Law's basic prohibitions, sanctions, policy objectives, and evolution. Section II sets forth a framework for determining whether a particular arrangement implicates and (if so) violates the Stark Law.

I. Background

A. Basic prohibitions

The Stark Law has two basic prohibitions: a referral prohibition and a billing prohibition. These prohibitions are summarized here and discussed in more detail in Chapters 2–10.

1. Referral prohibition

   Pursuant to the referral prohibition, in the absence of an applicable exception, a physician who has a "financial relationship" with an "entity" (personally or through an "immediate family member") may not make a "referral" "to" that entity for the "furnishing" of "designated health services" (DHS) for which payment may be made by the Medicare program.[1]

EXAMPLE 1.1

A physician owns a limited liability company that operates a clinical diagnostic laboratory. The physician draws the blood of a Medicare beneficiary who resides in a metropolitan area and sends the blood to be analyzed by the laboratory. The lab's services are DHS reimbursable by Medicare.

Commentary: In the absence of an exception, this referral violates the Stark Law's referral prohibition.

2. Billing prohibition

Pursuant to the billing prohibition, in the absence of an applicable exception, a health care provider may not bill for improperly referred DHS. More specifically, an entity that furnishes DHS pursuant to a prohibited referral may not "present" or "cause to be presented" a claim or bill for such services to the Medicare program or to any other individual or entity, including secondary insurers and the patient.[2]

EXAMPLE 1.2

This example includes the same facts as Example 1.1. In addition, the laboratory submits a claim for $125 to the relevant Medicare contractor for the services it furnished to the Medicare beneficiary and is reimbursed $100 pursuant to Medicare's clinical laboratory fee schedule.

Commentary: This claim for reimbursement will violate the Stark Law's billing prohibition. Note that the laboratory could not avoid the billing prohibition by foregoing Medicare reimbursement and billing the patient or the patient's secondary insurer.

B. Sanctions

Where a physician has violated the referral prohibition and an entity has violated the billing prohibition, a variety of sanctions may be imposed. These sanctions are highlighted here and discussed in more detail in Chapter 12.

1. Refund

The Stark Law provides that an entity that collects payment for DHS performed pursuant to a prohibited referral must refund "to the individual" all collected amounts on a timely basis.[3] The Stark Regulations eliminate the phrase "to the individual," requiring instead that the entity refund "all collected amounts" on a timely basis.[4]

EXAMPLE 1.3

This example includes the same facts as Example 1.2.

Commentary: By its terms, the Stark Law requires the laboratory to refund to the beneficiary any amounts collected from the beneficiary. Because Medicare beneficiaries have no copayment obligations under the relevant laboratory fee schedule, arguably, the laboratory would have no refund obligations under a literal reading of the Law. Under the Stark Regulations, however, the laboratory would be required to refund $100 to the Medicare program.

2. Civil monetary penalty/assessment/exclusion

Any person "who presents or causes to be presented a bill or claim" for improperly referred DHS and "knows or should know" that the claim is for improperly referred DHS is subject to the following:

- A civil monetary penalty (CMP) of up to $15,000 per service
- An assessment (in lieu of damages) of up to three times the amount claimed
- Exclusion from participation in any federal health care program[5]

EXAMPLE 1.4

This example includes the same facts as Example 1.2.

Commentary: In addition to its refund obligation, the laboratory (and the referring physician) may be subject to a $15,000 CMP, an assessment of three times the amount claimed ($375), and potential exclusion from participation in Medicare and other federal health care program.

3. Circumvention

Any physician or entity that knowingly participates in a "scheme" to circumvent the operation of the Stark Law is subject to a CMP of up to $100,000 and may be excluded from participation in federal health care programs.[6]

C. Policy objectives

According to the Centers for Medicare & Medicaid Services (CMS), the Stark Law reflects Congress' concern that a physician with a financial stake in determining whether or where to refer a patient may be "unduly influenced by a profit motive," thereby undermining efficient utilization, patient choice, and competition among participants in federal health care programs.[7] More specifically, CMS believes that:

- Physicians can "overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered."[8]
- Patient choice "can be affected when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers."[9]
- Where referrals are "controlled by those sharing profits or receiving remuneration, the medical marketplace suffers since new competitors can no longer win business with superior quality, service, or price."[10]

EXAMPLE 1.5

An orthopedic surgeon has a 50 percent ownership interest in a physical therapy (PT) company, PT Company A, that is located 25 miles from the surgeon's office. A representative from a second company, PT Company B, meets with the surgeon and states that PT Company B charges less than PT Company A and is located in the same building as the surgeon. After this meeting, the surgeon continues to refer all of her patients to PT Company A.

Commentary: CMS might be concerned that the surgeon is steering patients to PT Company A—a more expensive and potentially less convenient provider—not because PT Company A provides better quality medical care than PT Company B, but because the surgeon shares in the profits of PT Company A.

D. Medicare vs. Medicaid

Many federal fraud and abuse laws—including one of the Stark Law's older "cousins," the federal health care program anti-kickback statute[11]—apply to Medicare, Medicaid, and a host of other federally funded health care programs. The Stark Law, however, only prohibits referrals for DHS that are covered by Medicare. Although there is a common misconception that the Stark Law has been "extended" (in its entirety) to cover Medicaid referrals and billing, the relevant statutory provision does not do so.[12] Rather, the Stark Law generally prohibits the use of federal funds to pay for services furnished to a Medicaid patient that would be considered improperly referred services under the Medicare program.[13] That is, the Law's prohibitions and sanctions do not attach to Medicaid referrals, but arrangements that would be improper under the Stark Law may prevent the relevant state from receiving federal matching funds for those services.

EXAMPLE 1.6

A physician who has a financial relationship with a hospital (to which no exception applies) refers a Medicare patient to the hospital for outpatient hospital services. The hospital furnishes the services and, notwithstanding its knowledge of the physician's financial relationship, submits a claim to Medicare, which results in a payment of $1,000 under the applicable ambulatory payment classification code.

Commentary: The physician and hospital have violated the Stark Law's referral and billing prohibitions and may be subject to sanctions.

EXAMPLE 1.7

This example includes the same facts as Example 1.6, except the patient is neither entitled to nor eligible for Medicare. Instead, the patient is a Medicaid recipient residing in Pennsylvania.

Commentary: Neither the physician nor the hospital has violated the Stark Law. The federal government, however, might refuse to pay Pennsylvania the federal government's share of the state's payment to the hospital (or, if this share already has been paid, the federal government might seek to recoup it).

E. Evolution of Stark Law and Stark Regulations

The original Stark Law was enacted in 1989, and CMS issued its first set of implementing regulations (the "Stark Regulations") in 1991. Since then, the Law has been amended, and CMS has issued additional regulations, on several occasions. The timeline below summarizes major developments relating to the Stark Law and Stark Regulations. The specific provisions of these authorities (e.g., the definition of "immediate family member" and the requirements of the exception for bona fide employment relationships) are discussed, analyzed, and applied throughout this book in the sections to which they relate.

Timeline

- **1989:** Congress enacts the first Stark Law, commonly referred to as "Stark I."[14] Stark I's referral and billing prohibitions apply only to referrals for clinical laboratory services.
- **1990:** Congress amends Stark I, clarifying certain definitions and reporting requirements.[15]
- **1991:** CMS issues interim final regulations that relate to one component of Stark I (concerning reporting requirements).[16]
- **1992:** CMS issues proposed regulations implementing Stark I (the "Stark I Proposed Regulations").[17]
- **1993:** Congress extensively revises the Stark Law.[18] Most notably, these amendments—commonly referred to as "Stark II"—expand the referral and billing prohibitions beyond clinical laboratory services to cover 10 additional types of DHS.

- **1994:** Congress amends the Stark Law's reporting requirements and changes some of Stark II's effective dates.[19]
- **1995:** Stark II takes effect on January 1, 1995. CMS issues final regulations implementing Stark I (the "Stark I Regulations").[20]
- **1998:** CMS issues proposed regulations implementing Stark II (the "Stark II Proposed Regulations").[21]
- **2001:** CMS issues final regulations implementing a portion of Stark II. These are commonly referred to as the "Stark II, Phase I Regulations." With a few exceptions, these Regulations take effect on January 4, 2002.[22]
- **2004:** CMS issues interim final regulations implementing the remainder of Stark II. These are commonly referred to as the "Stark II, Phase II Regulations." These regulations take effect on July 26, 2004.[23]
- **2007:** CMS issues final regulations implementing Stark II. These are commonly referred to as the "Stark II, Phase III Regulations." With a few exceptions, these Regulations take effect on December 4, 2007.[24]
- **2008:** As part of the fiscal year 2009 final rule relating to hospital inpatient prospective payments, CMS promulgates additional Stark regulations. For purposes of this book, we will refer to these as the "FY 09 IPPS Final Regulations."[25]

II. Analyzing Arrangements Under the Stark Law

Determining whether an arrangement violates the Stark Law is a three-step process. The first two steps address whether the arrangement at issue "implicates" the Stark Law. In general, an arrangement implicates the Stark Law if—in the absence of an applicable exception—DHS referrals made pursuant to the arrangement would violate the Law's referral prohibition and the submission of any claims relating to such referrals would violate the Law's billing prohibition. The third step addresses whether the arrangement at issue "violates" the Stark Law. An arrangement violates the Stark Law if the arrangement both implicates the Law and does not qualify for protection under any Stark Law exception.

A. Step one: Referrals

Step one requires answering the following question: Does the arrangement involve a "physician" making a "referral" "to" an "entity" for the "furnishing" of "DHS" covered by Medicare? If the answer is "no," then the arrangement does not implicate—and, therefore, cannot violate—the Stark Law. If the answer is "yes," then the arrangement may implicate the Stark Law, and one must proceed to step two. The various components of the step one inquiry are discussed in detail in Chapters 2–4.

B. Step two: Financial relationships

Step two requires answering the following question: Does the physician (or one of his or her immediate family members) have a "financial relationship" with the entity furnishing DHS? As discussed more fully in Chapter 5, the Stark Law and Regulations recognize the following four basic categories of financial relationships.

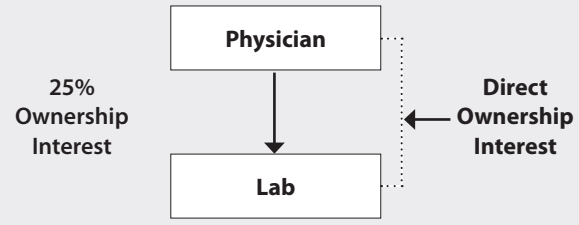
1. Direct ownership interests

   If a physician—himself or herself—has an ownership or investment interest in an entity that furnishes DHS, then the physician has a financial relationship with the entity in the form of a "direct ownership/investment interest."

EXAMPLE 1.8

A physician has a 25 percent ownership interest in a clinical laboratory.

Commentary: The physician has a "financial relationship" with the laboratory in the form of a direct ownership interest.



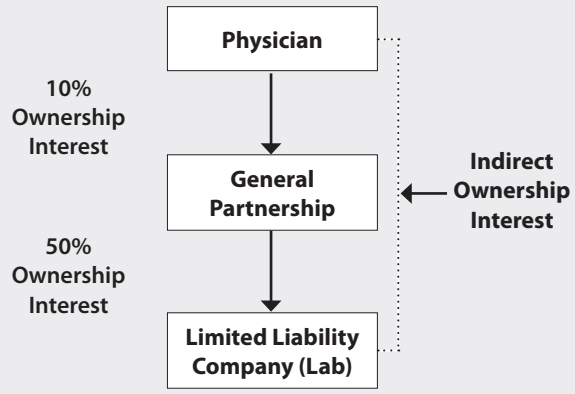
2. Indirect ownership interests

   If a physician has an ownership or investment interest in an entity that, in turn, has an ownership or investment interest in an entity that furnishes DHS, the physician has a financial relationship with the DHS entity in the form of an "indirect ownership/investment interest."

EXAMPLE 1.9

A physician has a 10 percent partnership stake in a general partnership, which, in turn, is a 50 percent member of a limited liability company that operates a clinical laboratory.

Commentary: The physician has a "financial relationship" with the laboratory in the form of an "indirect ownership interest."



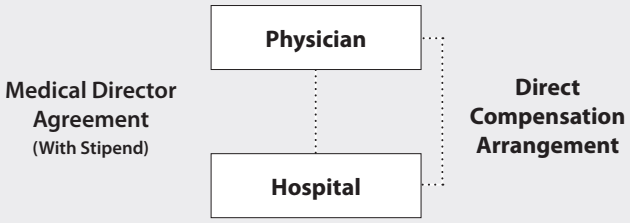
3. Direct compensation arrangement

If a physician receives remuneration directly from (or gives remuneration directly to) an entity that furnishes DHS, the physician has a financial relationship with the entity in the form of a "direct compensation arrangement."

EXAMPLE 1.10

A physician has a contract with a hospital to serve as the medical director of its radiology department pursuant to which she receives a monthly stipend.

Commentary: The physician has a "financial relationship" with the hospital in the form of a "direct compensation arrangement."

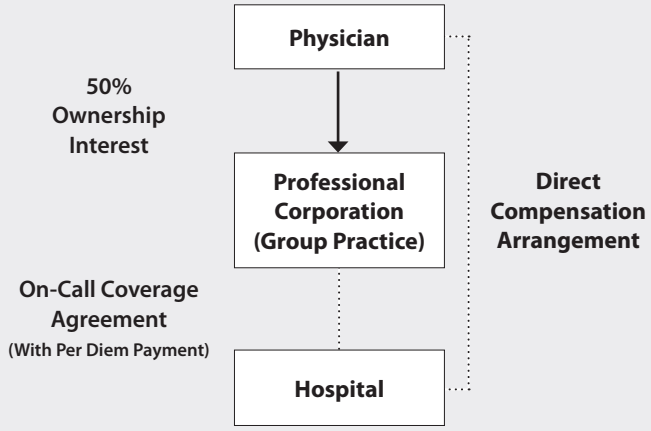


In addition, under certain circumstances, even where remuneration does not pass directly between a physician and a DHS entity, the physician and the entity nevertheless will be deemed to have a "direct compensation arrangement." This occurs if (1) the referring physician has an ownership or investment interest in a "physician organization" (e.g., a physician group practice) that is not "titular" in nature, and (2) remuneration passes directly between the physician organization and the DHS entity at issue. Under these circumstances, the referring physician is deemed to "stand in the shoes" of his or her physician organization and, as such, is considered to have a "direct compensation arrangement" with the DHS entity. (The scope and application of the "stand in the shoes" rule is discussed in further detail in Chapters 5 and 9.)

EXAMPLE 1.11

A physician owns 50 percent of the outstanding shares in her group practice, which is organized as a professional corporation. The group, in turn, has a contract with a hospital to provide on-call coverage, for which the group is compensated by the hospital on a per diem basis.

Commentary: Through the application of the "stand in the shoes" rule, the physician "stands in the shoes" of her group practice and, as such, has a "financial relationship" with the hospital in the form of a "direct compensation arrangement."



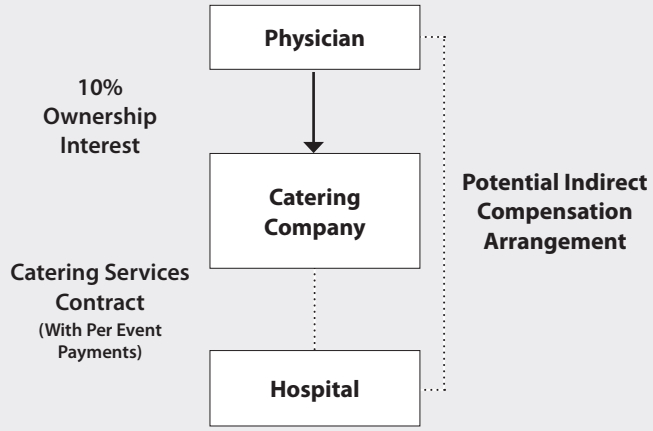
4. Indirect compensation arrangement

Subject to the "stand in the shoes" rule discussed above, if a physician receives remuneration indirectly from an entity that furnishes DHS (i.e., through one or more intervening individuals or entities), the physician may have a financial relationship with the DHS entity in the form of an "indirect compensation arrangement." We use the term "may" because of the four types of financial relationships that a physician may have with an entity for purposes of the Stark Law, determining whether a relationship takes the form of an indirect compensation arrangement is the most complicated.

EXAMPLE 1.12

A physician has a 10 percent ownership interest in a catering company. The catering company, in turn, has a contract with a hospital to provide catering services for special events, for which the catering company is compensated by the hospital on a per event basis.

Commentary: The physician may have a "financial relationship" with the hospital in the form of an indirect compensation arrangement. (Note that the physician does not "stand in the shoes" of the catering company because it is not a "physician organization.")



If neither the referring physician nor any of his or her immediate family members has a financial relationship with the entity furnishing DHS, then the arrangement does not implicate (and, therefore, cannot violate) the Stark Law, and the physician is free to refer Medicare patients to the entity for DHS—and the entity is free to bill for such DHS—without violating the Stark Law. If such a financial relationship does exist, however, then the arrangement does implicate the Law, and one must proceed to step three.

C. Step three: Exceptions

Step three requires answering the following question: Does the arrangement qualify for protection under one or more of the Stark Law's exceptions? These exceptions generally fall into four categories:

1. All-purpose exceptions (Chapter 6). These exceptions are available for all four types of financial relationships: (1) direct ownership interests, (2) indirect ownership interests, (3) direct compensation arrangements, and (4) indirect compensation arrangements.
2. Ownership/investment exceptions (Chapter 7). These exceptions are available for two types of financial relationships: direct ownership interests and indirect ownership interests.
3. Direct compensation arrangement exceptions (Chapters 8 and 10). These exceptions are available for one type of financial relationship: direct compensation arrangements.
4. Indirect compensation arrangements exception (Chapter 9). This exception is available for only one type of financial relationship: indirect compensation arrangements.

If the arrangement at issue satisfies the requirements of one or more exceptions, then the Stark Law will not be violated. If the arrangement does not meet at least one exception, the Stark Law will be violated if a prohibited DHS referral is made or claims for such DHS are presented for payment.

Endnotes

1. 42 United States Code (USC) § 1395nn(a)(1)(A).
2. 42 USC § 1395nn(a)(1)(B).
3. 42 USC § 1395nn(g)(2).
4. 42 *Code of Federal Regulations (CFR)* § 411.353(d), referencing 42 *CFR* § 1003.101.
5. 42 USC § 1395nn(g)(3); 42 *CFR* §§ 1003.102(a)(5), 1003.102(b)(9), 1003.105.
6. 42 *CFR* § 1395nn(g)(4); 42 *CFR* § 1003.102(b)(10).
7. Stark II Proposed Regulations (Preamble), 63 *Federal Register (FR)* 1659, 1662 (1998).
8. Stark II Proposed Regulations (Preamble), 63 *FR* 1659, 1662 (1998).

9. Stark II Proposed Regulations (Preamble), 63 *FR* 1659, 1662 (1998).
10. Stark II Proposed Regulations (Preamble), 63 *FR* 1659, 1662 (1998).
11. 42 USC § 1320a-7b(b).
12. 42 USC § 1396b(s).
13. Specifically, the Social Security Act denies any Federal financial participation payment to a State under its Medicaid program for services that would have been prohibited by Medicare under the Stark Law if Medicare covers the services to the same extent as the State's Medicaid plan. 42 USC § 1396b(s). See also Stark II Proposed Regulations (Preamble), 63 *FR* 1659, 1704 (1998).
14. Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Public Law 101–239, enacted on December 19, 1989).
15. Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508, enacted on November 5, 1990).
16. 56 *FR* 61374 (1991).
17. 57 *FR* 8588 (1992).
18. Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66, enacted on August 10, 1993).
19. Section 152 of the Social Security Act Amendments of 1994 (Public Law 103–432, enacted on October 31, 1994).
20. 60 *FR* 41914 (1995).
21. 63 *FR* 1659 (1998).
22. 66 *FR* 856 (2001).
23. 69 *FR* 16053 (2004).
24. 72 *FR* 51012 (2007).
25. 73 *FR* 48434, 48688 (2008).

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