大成 DENTONS

Stark Law Overhaul

An In-Depth Review of CMS's Final Rule

White Paper No. 1
Rolling Up Our Sleeves:
A Stark Law Refresher

Rolling Up Our Sleeves
A Stark Law Refresher

To learn more about the event series, please **click here**.

In December 2020, the Centers for Medicare & Medicaid Services (CMS) finalized long-awaited changes to the agency's regulations governing the federal physician self-referral law, commonly known as the Stark Law (Final Rule).[1] The Final Rule represents the most significant Stark Law rulemaking in more than a decade. The Health Care Group at Dentons US LLP is presenting a series of seven webinars, each with a companion white paper, addressing the principal components of the Final Rule. This is the first of these white papers. It sets the stage for the balance of the series, providing a high-level refresher on the Stark Law's architecture and addressing a handful of changes—some minor, some more significant—that the Final Rule makes to the Stark Law's most basic building blocks, including the definitions of "physician," "referral" and "designated health services."

1 85 Fed. Reg. 77492 (Dec. 2, 2020).

Contents

I. Stark Law Overview 5

A. Physician, IFM, Entity & Financial Relationship 5
B. Referral, Furnishing & DHS 7
C. Exceptions 8
D. Sanctions and Collateral Consequences 9

II. Final Rule 10

A. Physician 10
B. Remuneration 10
C. Ownership Interests –"Titular" Ownership 11
D. Ownership Interests – Employee Stock Ownership Programs 12
E. Designated Health Services 16
F. Referral 17

III. Conclusion 18

Appendix A 20

I. Stark Law Overview

Congress enacted the Stark Law in 1989 due to concerns that physicians with a financial stake in determining whether or where to refer patients for medical care might order "items and services for patients that, absent a profit motive, they would not have ordered" otherwise.[2] Congress also noted that 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."[3] Finally, Congress observed, 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."[4]

Consistent with these objectives, the Stark Law has two basic prohibitions: a referral prohibition and a billing 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" (IFM)—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 pwrogram.[5] Pursuant to the billing prohibition, in the absence of an applicable exception, a healthcare 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 a secondary insurer or the patient.[6]

A. Physician, IFM, Entity & Financial Relationship

In most cases, determining whether an arrangement implicates the Stark Law begins with determining whether there is a "financial relationship" between (i) a "physician" (or one of their "immediate family members") and (ii) an "entity." If there is a financial relationship, then the physician's referrals to the entity may implicate the Stark Law (if its other elements are met). If there is no financial relationship, then the physician's referrals to the DHS entity will not implicate the Stark Law (and the inquiry ends). Before turning to the definition of a "financial relationship," let's quickly touch on the other three elements of a *prima facie* Stark Law cause of action:

- **Physician**. In general, a "physician" is a doctor of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine or optometry, or is a chiropractor.[7]
- **Immediate Family Member**. An "immediate family member" (IFM) is a "husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in- law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild."[8]

---

2 63 Fed. Reg. 1659, 1662 (Jan. 9, 1998).

3 *Id.*

4 *Id.*

5 42 U.S.C. § 1395nn(a)(1)(A).

6 *Id.* §1395nn(a)(1)(B).

7 42 C.F.R. § 411.351; *see also* 57 Fed. Reg. 8588, 8593 (Mar. 11, 1992) (defining "physician").

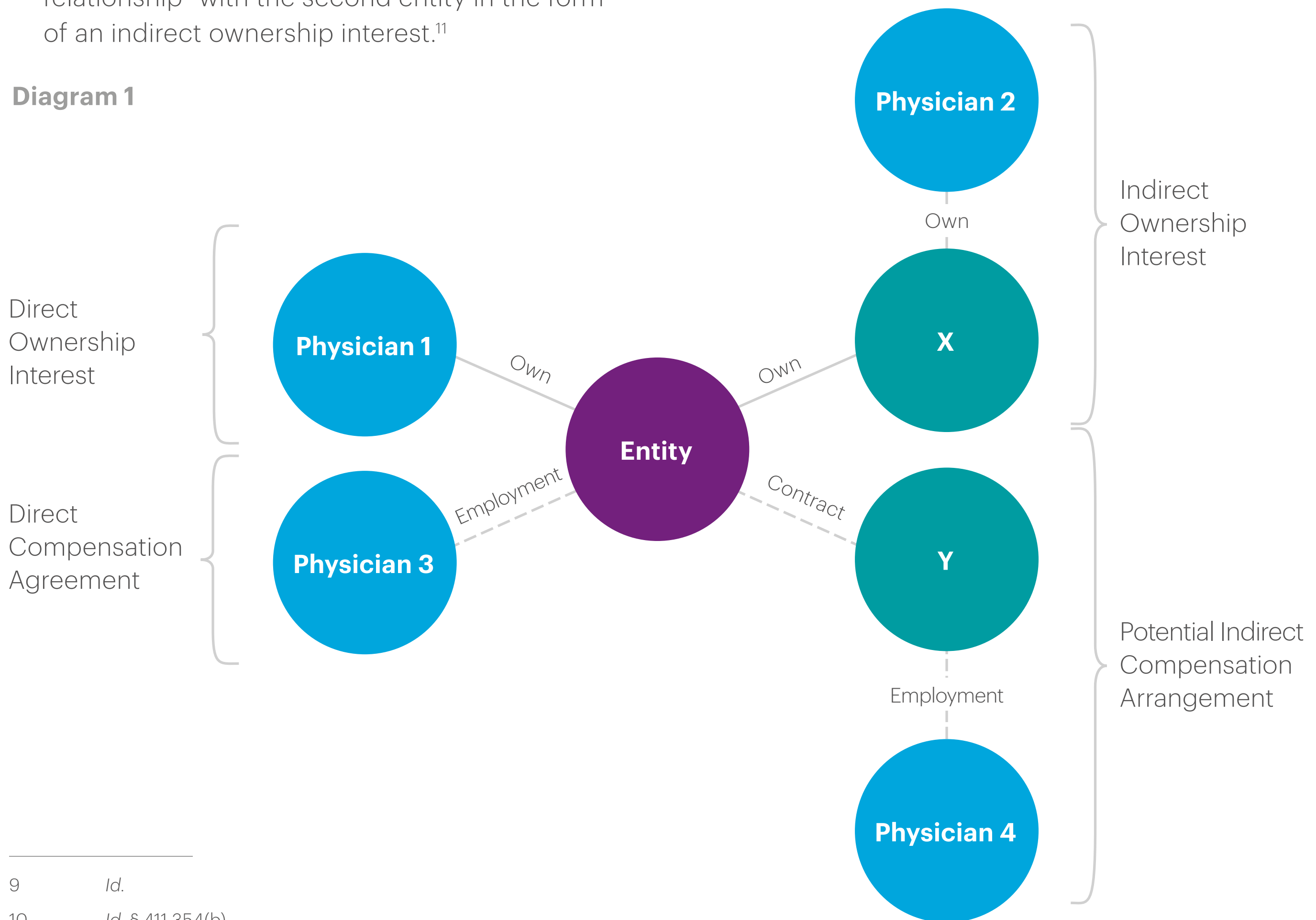
8 *Id.*

- **Entity**. Generally speaking, an "entity" includes (i) any "corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association," or any "other person, sole proprietorship, public or private agency or trust," and (ii) a "physician's solo practice or a practice of multiple physicians."[9]

For Stark Law purposes, there are four types of "financial relationships" that a "physician" (or IFM) could have with an "entity." See *Diagram 1* below.

- **Direct Ownership Interest**. If a physician/IFM has an ownership or investment interest in an entity, then the physician has a "financial relationship" with the entity in the form of a direct ownership interest. [10]
- **Indirect Ownership Interest.** If a physician/IFM has an ownership or investment interest in one entity that, in turn, has an ownership or investment interest in a second entity, then the physician has a "financial relationship" with the second entity in the form of an indirect ownership interest.[11]
- **Direct Compensation Arrangement**. If a physician/IFM receives remuneration directly from (or gives remuneration directly to) an entity, the physician has a "financial relationship" with the entity in the form of a direct compensation arrangement.[12]
- **Indirect Compensation Arrangement**. Finally, if a physician/IFM receives remuneration indirectly from an entity (i.e., through one or more intervening individuals or entities), the physician/IFM *may* have a "financial relationship" with the entity in the form of an indirect compensation arrangement.[13] (We use the term "may" because of the four types of financial relationships that a physician/IFM can have with an entity, determining whether a relationship constitutes an indirect compensation arrangement is the most involved. We will explore the definition of an "indirect compensation arrangement," both before and after the Final Rule, in a subsequent white paper.)

Diagram 1



9 *Id.*

10 *Id.* § 411.354(b).

11 *Id.* § 411.354(b)(5).

12 *Id.* § 411.354(c)(1).

13 *Id.* § 411.354(c)(2).

B. Referral, Furnishing & DHS

If a "physician" (or IFM) has a "financial relationship" with an "entity," then—in the absence of an applicable exception—the physician may not make a "referral" to that entity for the "furnishing" of "designated health services" covered by Medicare. Let's unpack these terms, at least at a high level, in reverse order.

- **Designated Health Services**. Since 1995, DHS have included the following 10 categories of items and services: (i) clinical diagnostic laboratory services (including pathology services); (ii) physical therapy, occupational therapy, and outpatient speech-language pathology services; (iii) radiology and certain other imaging services; (iv) radiation therapy services and supplies; (v) durable medical equipment and supplies; (vi) parenteral and enteral nutrients, equipment, and supplies; (vii) prosthetics, orthotics, and prosthetic devices and supplies; (viii) home health services; (ix) outpatient prescription drugs; and (x) inpatient and outpatient hospital services (other than lithotripsy).[14]
- **Furnishing**. An entity is deemed to be "furnishing" DHS if the entity either(i) "perform[s]" the services or (ii) "present[s] a claim to Medicare" for the services.[15] (In most cases, these are one and the same entity.)
- **Referral**. Subject to certain exceptions, a "referral" includes either (i) "the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any [DHS] for which payment may be made under Medicare Part B," or (ii) the "request by a physician" [e.g., a physician order] for "the provision of any [DHS] for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such [DHS], or the certifying or recertifying of the need for such [DHS]."[16] As a practical matter, if a physician orders DHS that is paid for by Medicare, the physician has made a "referral."[17]

14 *Id.* § 411.351.

15 *Id.*

16 *Id.*

17 A physician order for the provision of DHS that is not paid for by Medicare constitutes, in Stark Law parlance, "other business generated." CMS uses the terminology "volume or value of referrals or other business generated" throughout the Stark Law regulations, but does not define the phrase "other business generated" in the regulations themselves. *See, e.g.*, 42 C.F.R. § 411.354(c)(2)(ii)(A). Given that the definition of the term "referral" makes it clear that a referral involves (i) designated health services (ii) that may be paid for by Medicare, it follows that "other business generated" applies to services, including, without limitation, designated health services, paid for by other payors. CMS confirmed this interpretation in 2001 preamble guidance. *See* 66 Fed. Reg. 856, 877 (Jan. 4, 2001) ("[A]ffected payments cannot be based or adjusted in any way on referrals of DHS or on any other business referred by the physician, including other Federal and private pay business.").

C. Exceptions

If (i) a physician has a financial relationship with an entity and (ii) the physician makes a referral to the entity for the furnishing of DHS, the referral will (i) violate the Stark Law's referral prohibition and (ii) any claim seeking reimbursement for the DHS will violate the Stark Law's billing prohibition, unless an exception applies. The exceptions—which may be statutory and/or regulatory—fall into two categories: ones that apply to certain types of services,[18] and ones that apply to certain types of financial relationships.[19] A complete list of all Stark Law exceptions can be found in Appendix A.

An example of a "services" exception is the exception for services covered by a prepaid plan.[20] Pursuant to this this exception, if a physician refers a Medicare beneficiary to an entity for the furnishing of DHS (e.g., to a hospital for an inpatient procedure), the referral will not violate the Stark Law's referral prohibition, and the hospital may seek reimbursement for the procedure without violating the Stark Law's billing prohibition, if the beneficiary is enrolled in a Medicare Part C (i.e., Medicare Advantage) or a similar plan.[21] This is true irrespective of the type of financial relationship that the physician has with the hospital.

An example of a "financial relationship" exception is the exception for bona fide employment arrangements.[22] Pursuant to this exception, if a physician is employed by an entity, the physician may refer Medicare beneficiaries to the entity for the furnishing of DHS, and the entity may bill for that DHS, provided certain conditions are met. For example, the employment must be for "identifiable services" and the "amount of the remuneration under the employment" must be "[c]onsistent with the fair market value of the services" provided by the physician.[23]

18 *Id.* § 411.355.

19 *Id.* §§ 411.356 (ownership interests) and 411.357 (compensation arrangements).

20 *Id.* § 411.355(c).

21 *Id.*

22 *Id.* § 411.357(c).

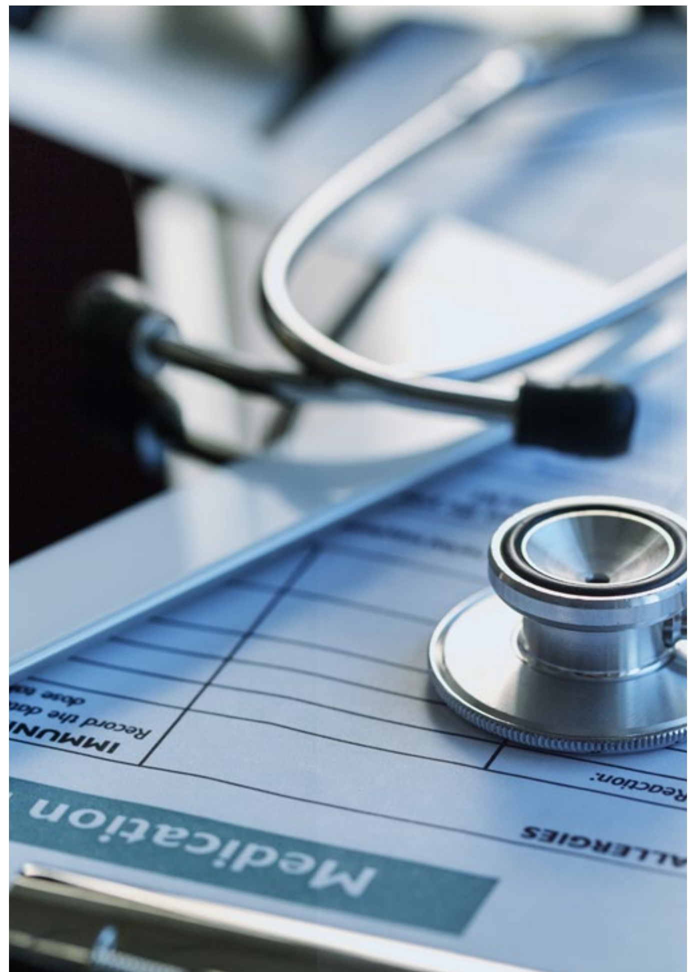
23 *Id.*

D. Sanctions and Collateral Consequences

Where a physician has violated the referral prohibition and an entity has violated the billing prohibition, a variety of sanctions may be imposed. The Stark Law itself provides for several types of sanctions.

- **Denial.** As an initial matter, the Stark Law provides that a claim for Medicare payment for DHS performed pursuant to a prohibited referral must be denied.[24]
- **Refund.** Second, the Stark Law provides that an entity that collects payment for DHS performed pursuant to a prohibited referral must refund all collected amounts on a timely basis.[25]
- **CMP/Assessment/Exclusion.** Next, 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 (i) a civil monetary penalty (CMP) of up to $25,820 per service; (ii) an assessment (in lieu of damages) of up to three times the amount claimed; and (iii) exclusion from participation in any federal healthcare program.[26]
- **Circumvention.** Finally, 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 $172,137 and may be excluded from participation in federal healthcare programs.[27]

In addition to the sanctions provided for in the Stark Law itself, a violation of the Stark Law's billing prohibition may result in liability under the so-called federal "overpayment statute," which generally requires that if a health care provider receives a payment from a federal healthcare program to which the provider is not entitled, that "overpayment" must be reported and returned within 60 days.[28] Thus, if a hospital, for example, receives a payment from Medicare for a service furnished to a beneficiary who was referred to the hospital in violation of the Stark Law's referral prohibition, that payment constitutes an "overpayment," which must be returned to the government within 60 days of being identified. Finally, the federal civil False Claims Act (FCA)—which provides for treble damages and steep fines, and can be enforced by the federal government or private whistleblowers—prohibits both the submission of false claims and, under certain circumstances, the failure to return amounts due and owing to the federal government.[29] A number of courts have held that a violation of the Stark Law's billing prohibition can give rise to a violation of the FCA.[30]



24 *Id.* § 411.353(c)(1).

25 *Id.* § 411.353(d) (referencing 42 C.F.R. § 1003.101).

26 42 U.S.C. § 1395nn(g)(3); 42 C.F.R. §§ 1003.300(a), (c), 1003.310(a)(1), (b)(1); 45 C.F.R. § 102.3. The CMP amounts are adjusted annually.

27 42 U.S.C. § 1395nn(g)(4); 42 C.F.R. §§ 1003.300(b), 1003.310(a)(2); 45 C.F.R. § 102.3. The CMP amounts are adjusted annually.

28 42 U.S.C. § 1320a-7k(d).

29 31 U.S.C. § 3729 *et seq.*

30 *See e.g., U.S.* ex rel. *Bookwalter v. UPMC*, 946 F.3d 162, 169 (3d Cir. 2019) ("A Medicare claim that violates the Stark Act is a false claim under the False Claims Act.") (citing U.S. *ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir. 2009)).

II. Final Rule

Although the Final Rule touches on many of the elements and exceptions discussed above—and much more—this white paper will focus on the Final Rule's amendments, clarifications and interpretations with respect to the definitions of five pivotal terms: "physician," "remuneration," "ownership interests," "designated health services" and "referral." The remaining white papers in the Dentons *Stark Law Overhaul* series will cover the balance of the Final Rule's amendments, clarifications and interpretations.

A. Physician

Because the Stark Law applies only to referrals by "physicians"—and not to the ordering of items or services by any other type of clinician—having a clear definition of "physician" is critical. In the 2019 proposed rule (Proposed Rule),[31] CMS noted that although it intended the definition of "physician" in the Stark Law regulations to be the same as the definition of "physician" in the Social Security Act (the Act), the "two definitions are not entirely harmonious."[32] Of principal concern was the fact that the Stark Law definition did not explicitly include "all the limitations imposed by the definition of 'physician' at section 1861(r) of the Act."[33] In order to address this, CMS proposed simplifying the definition of "physician" in the Stark Law regulations to make it clear that "[p]hysician has the meaning set forth in section 1861(r) of the Act."[34]

The Final Rule adopts this proposed definition of "physician."[35] As CMS notes, under section 1861(r) of the Act, a "physician" includes "a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor."[36] However, section 1861(r) also provides for certain "limitations" on when such doctors are considered "physicians." A doctor of optometry, for example, is considered a physician but only for certain purposes and only with respect to the provision of certain items and services. CMS emphasized in the Final Rule that it does not believe the referral or billing prohibitions "should apply to any doctor during the period he or she is not considered to be a physician" for purposes of the Social Security Act.[37]

B. Remuneration

As noted above, "financial relationships" include "compensation" arrangements, which are defined broadly to include any arrangement involving an exchange of "remuneration" between a physician (or IFM) and an entity.[38] Subject to certain exceptions, "remuneration" includes "any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind."[39] Prior to the Final Rule, one exception to the definition of "remuneration"—which we'll call the "specimen exception" for ease of reference—covered the "furnishing of items, devices, or supplies

31 84 Fed. Reg. 55766 (Oct. 17, 2019).

32 84 Fed. Reg. 55766, 55805 (Oct. 17, 2019).

33 *Id.*

34 *Id.* at 55840.

35 85 Fed. Reg. 77492, 77660 (Dec. 2, 2020).

36 *Id.* at 77572.

37 *Id.* at 77573

38 42 C.F.R. § 411.354(c).

39 *Id.* § 411.351.

(not including surgical items, devices, or supplies)" "used solely" for (i) collecting, transporting, processing, and/or storing specimens, (ii) ordering tests or procedures, or (iii) communicating the results of tests or procedures (collectively, "permitted purposes").[40]

For a number of years, the industry chafed at CMS's seemingly arbitrary exclusion of "surgical items, devices, or supplies" from the specimen exception. In response to these concerns, CMS stated in the Proposed Rule that the agency was "no longer convinced that the mere fact that an item, device, or supply is routinely used as part of a surgical procedure means that the item, device, or supply is not used solely" for a permitted purpose.[41] The relevant inquiry, the agency agreed, is whether the item, device, or supply *is* or *is not* "used solely for one or more of the [permitted] purposes, regardless of whether the device also is classified as a surgical device."[42]

The Proposed Rule also clarified the "used solely" requirement in the specimen exception, noting that although the "item, device, or supply may not be used for any purpose other than" a permitted purpose, "we recognize that, in many instances, the item, device, or supply could theoretically be used for numerous purposes."[43] For example, in addition to storing specimens (a permitted purpose under the specimen exception), a "specimen lockbox" could be used to "store unused specimen collection supplies" or "as a doorstop" (neither of which are permitted purposes under the exception).[44] To clear up any potential confusion, CMS clarified that if, during the course of the arrangement, the specimen box provided to the physician is not, in fact, used to store supplies or as a doorstop, but instead is used only for one or more permitted purposes, "the furnishing of the specimen box would not be considered remuneration between parties."[45]

CMS finalized these proposed changes in the Final Rule.[46] In sum then, the Final Rule (i) removes the exclusion of "surgical items, devices, or supplies" from the specimen exception and (ii) makes it clear that the specimen collection exception is still available where an item, device, or supply *could* be used for an unpermitted purpose, as long as the item, device, or supply is, *in fact,* used solely for a permitted purpose.

C. Ownership Interests –"Titular" Ownership

Where, for example, a physician owns a clinical laboratory, the concern is that this ownership interest may incentivize the physician to order lab tests that are not medically necessary. Why? Because all other things being equal, the more revenue the lab generates, the greater its profits, and the greater its profits, the greater the returns to the physician. But what if a physician technically has an ownership interest in a DHS entity but is not, in fact, entitled to receive any of the financial benefits associated with such ownership (e.g., distributions of profits or proceeds from the sale of the entity)?

CMS has wrestled with the issue of "titular" ownership on several occasions over the years. For example, since December 2007, the owner of a "physician

40 42 C.F.R. § 411.351 (2016) (amended 2020).

41 84 Fed. Reg. 55766, 55807 (Oct. 17, 2019).

42 *Id.*

43 *Id.*

44 *Id.*

45 *Id.*

46 85 Fed. Reg. 77492, 77574 (Dec. 2, 2020).

organization" is typically considered to "stand in the shoes" of that organization for purposes of determining whether the physician has a direct or indirect compensation arrangement with entities that contract with the physician organization.[47] In 2009, CMS finalized a rule providing that a physician whose ownership interest in a physician organization "is merely titular in nature" is not required to stand in the shoes of the physician organization.[48] By "titular," CMS meant that "the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment."[49]

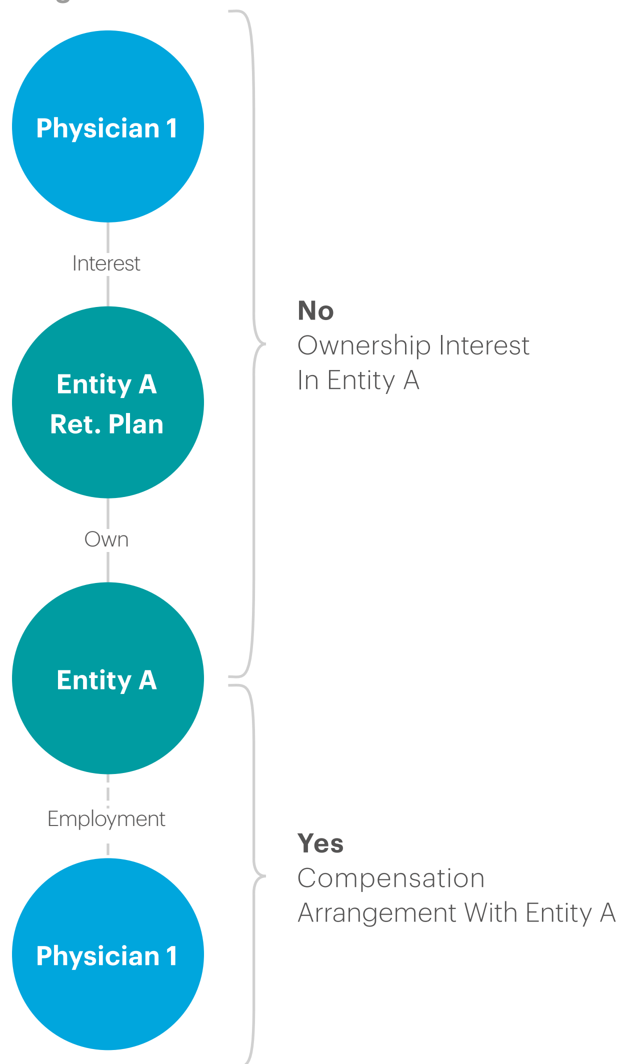
Over time, a question arose as to whether this "titular" ownership doctrine applies outside the stand-in-the-shoes context. For example, if a physician has a "titular" ownership interest (as defined above) in a hospital, clinical laboratory or other DHS entity, does that physician have a "financial relationship" with that DHS entity in the form of a "direct ownership interest"? In the Proposed Rule, CMS proposed clarifying that the answer is "no" and the Final Rule adopts this proposal. The Final Rule, then, "extend[s] the concept of titular ownership or investment interests to [the] rules governing ownership or investment interests" more generally.[50] The agency notes that the new rule should afford providers greater flexibility and certainty, "especially in states where the corporate practice of medicine is prohibited."[51]

The agency cautions, however, that to the extent the titular physician-owner of a DHS entity has a compensation arrangement with the DHS entity —for example, if the physician also furnishes medical director or other services to the DHS entity—that would create a "financial relationship" between the physician and entity (in the form of a direct compensation arrangement), which would need to fit into an exception if the physician will be referring Medicare patients to the entity for the furnishing of DHS.[52]

D. Ownership Interests – Employee Stock Ownership Programs

Historically, CMS took the position that where a DHS entity employs a physician and, pursuant to that arrangement, gives the physician an interest in the entity's retirement fund, that interest is "considered to be part of an employee's overall compensation" and does not create a separate financial relationship in the form of an ownership interest in the entity by the physician.[53] See *Diagram 2* below.

Diagram 2



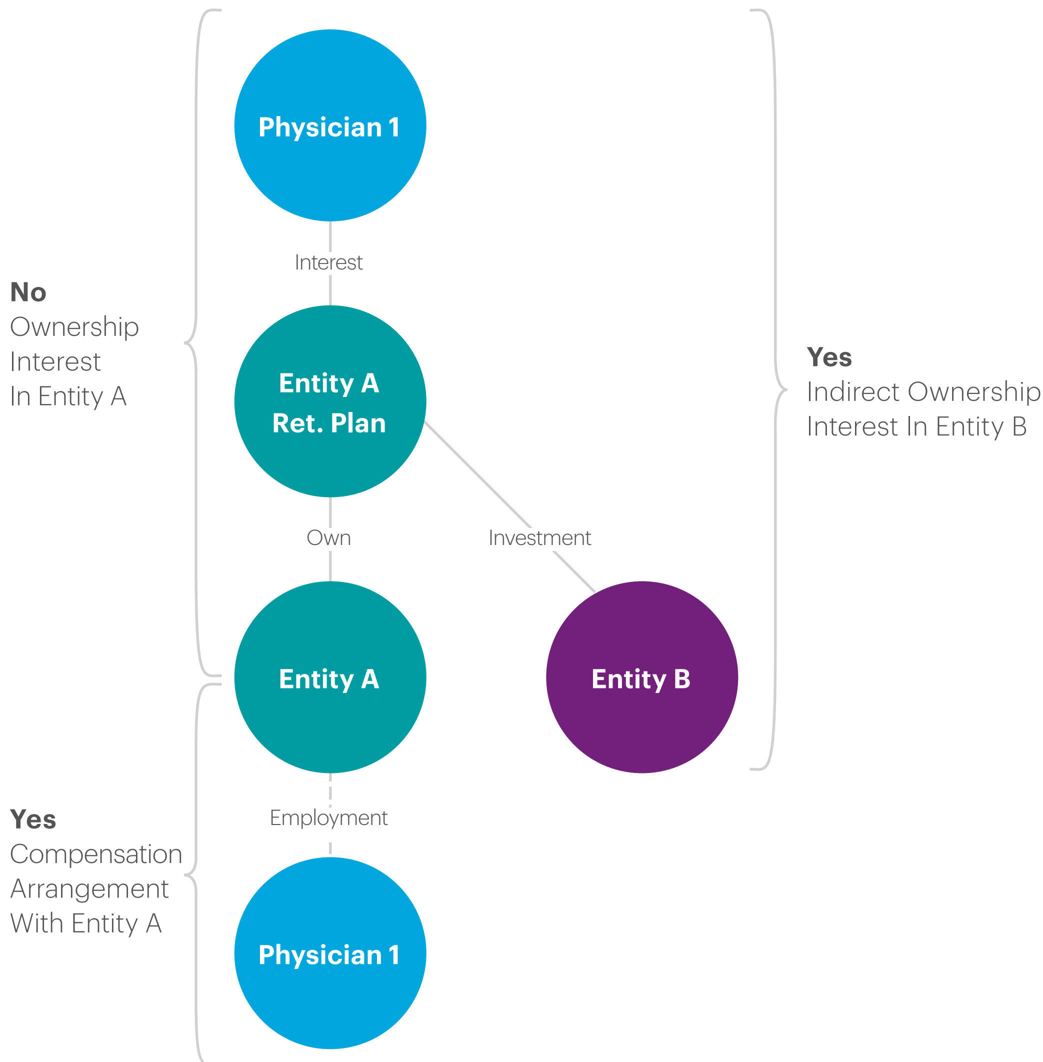
47 42 C.F.R. § 411.354(c)(1)(ii).
48 85 Fed. Reg. at 77587.
49 *Id.*
50 *Id.*
51 *Id.*
52 *Id.* at 77588.
53 *Id.*

In 2008, after learning that some physicians "were using their retirement plans to purchase or invest in other entities (that is, entities other than the entity that sponsored the retirement plan) to which the physicians were making referrals for [DHS]," CMS amended its rule, restricting the retirement interest carve-out to an "interest in an entity that arises from a retirement plan offered by that entity to the physician [or IFM] through the physician's [or IFMS's] employment with that entity."[54] Thus:

> if, through his or her employment by Entity A, a physicianhas an interest in a retirement plan offered by Entity A, any interest the physician may have in Entity A by virtue of his or her interest in the retirement plan would not constitute an ownership or investment interest... On the other hand, if the retirement plan sponsored by Entity A purchased or invested in Entity B, the physician would have an interest in Entity B that would not be excluded from the definition of "ownership or investment interest" for purposes of the physician self-referral law. For the physician to make referrals for designated health services to Entity B, the ownership or investment interest in Entity B would have to satisfy the requirements of an applicable exception.[55]

See *Diagram 3* below.

Diagram 3



54 *Id.*

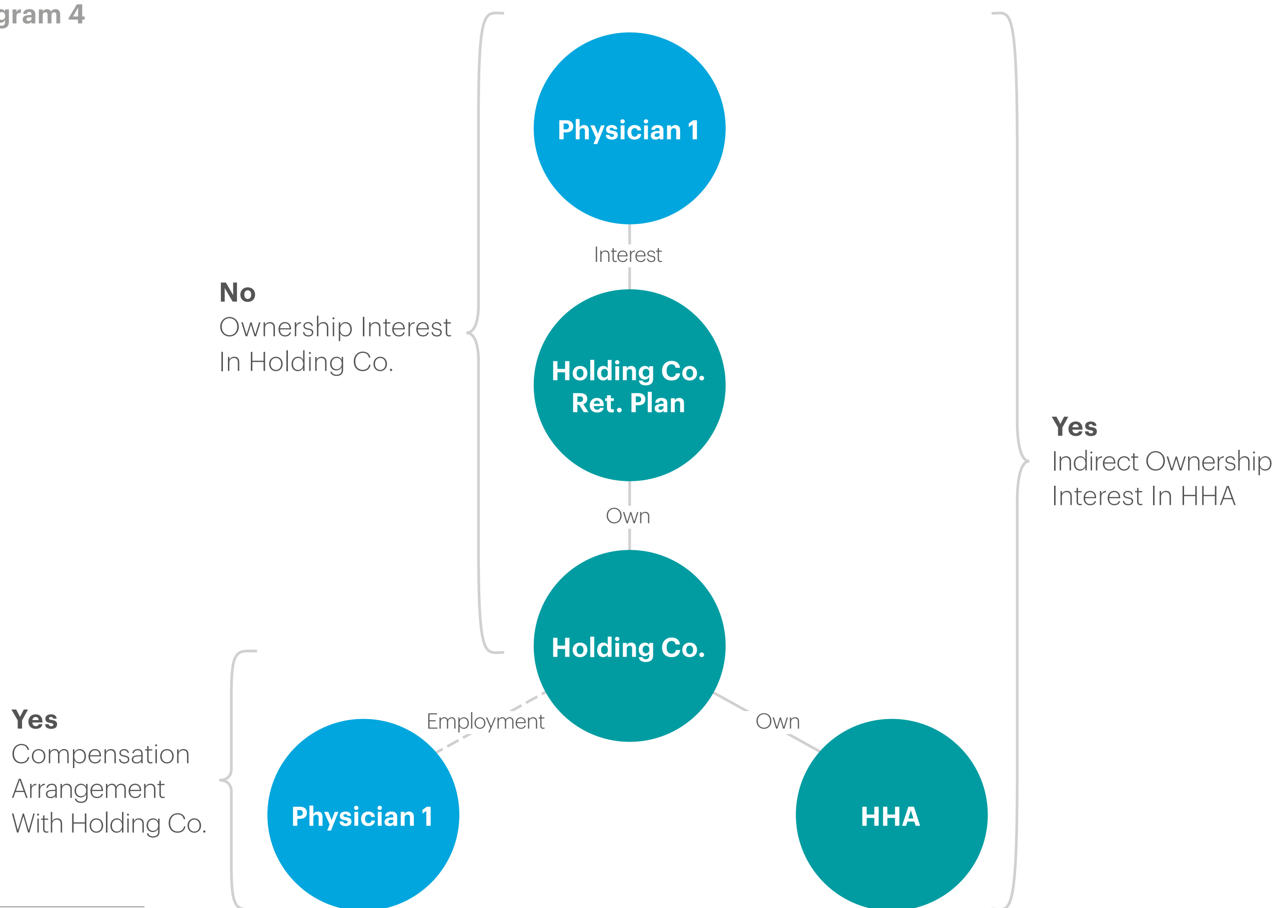
55 *Id.*

Over the past decade, stakeholders have informed CMS that "in certain cases, employers seeking to offer retirement plans to physician employees may find it necessary or practical, for reasons of Federal law, State law, or taxation, to structure a retirement plan using a holding company."[56]

> By way of example, assume a home health agency [HHA] desires to sponsor a retirement plan for its employees and elects to establish such plan using a holding company whose primary asset will be the [HHA]. To effectuate the retirement plan, the [HHA's] assets are transferred to or purchased by the holding company, which then employs the physicians and other staff of the [HHA]. The holding company sponsors the retirement plan for its employees, offering the employees (including physician employees) an interest in the holding company.[57]

Under the current retirement interest carve-out, "the physician's interest in the holding company would not be considered an ownership or investment interest."[58] Why? "[B]ecause the physician is employed by the holding company, the holding company sponsors the retirement plan, and the physician's ownership interest in the holding company arises through the retirement plan sponsored by the holding company."[59] However, "because the physician has an interest in the retirement plan that owns the holding company, and the holding company owns the [HHA], the physician has an indirect ownership or investment interest in the [HHA] that would not be excluded under [the current retirement interest carve-out provision] and may not satisfy the requirements of an applicable exception at § 411.356."[60] See *Diagram 4* below.

Diagram 4

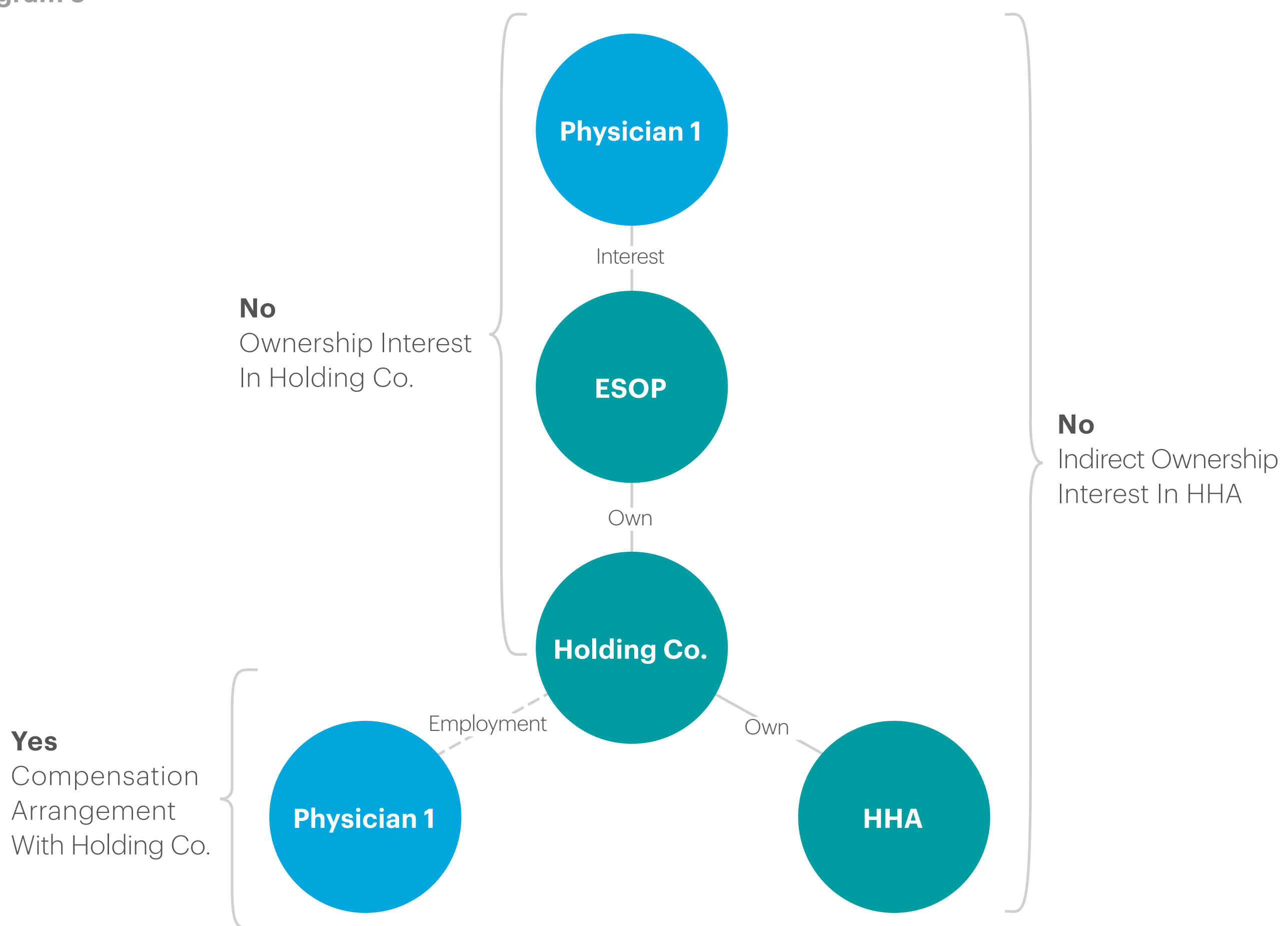


56 *Id.*
57 *Id.*
58 *Id.*
59 *Id.*
60 *Id.*

According to CMS, the above type of retirement plan structure may be necessary (or at least advantageous) in the establishment of certain employee stock ownership plans (ESOPs) governed, in part, by the Internal Revenue Code (IRC) and Employee Retirement Income Security Act of 1974 (ERISA).[61] These authorities, the agency notes, include "certain nondiscrimination rules and vesting rules that, among other things, do not allow an employee to receive the value of his or her employer stocks held through the retirement plan until at least 1 year after separation from the employer."[62]

In light of these safeguards, the Final Rule revises the retirement interest carve-out provision as follows: "an interest in an entity arising through participation in an ESOP merits the same protection from the [Stark Law's] prohibitions as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity."[63] See *Diagram 5* below.

Diagram 5



61 *Id.*

62 *Id.* at 77588-89.

63 *Id.* at 77589.

E. Designated Health Services

As noted above, DHS include 10 categories of items and services. One issue that has arisen over time relates to whether *multiple* "referrals" can be associated with a single inpatient admission and, if so, whether one such referral might "taint" another. Assume, for example, that Physician A (a surgeon) schedules an inpatient procedure at Hospital for Medicare Beneficiary. Under these circumstances, Physician A plainly has made a "referral" to an "entity" for the "furnishing" of a "designated health service" (i.e., an inpatient hospital service). Further assume that during Medicare Beneficiary's inpatient stay, Physician B (a hospitalist) orders a clinical laboratory service, which is a category of DHS separate and apart from inpatient hospital services. Under these circumstance, have there been two referrals of DHS, one by Physician A for inpatient hospital services and one by Physician B for clinical laboratory services?

In the Final Rule, CMS revises the definition of DHS to make it clear that, with respect to "services furnished to inpatients by a hospital," a service will not be considered DHS "if the furnishing of the service does not increase the amount of Medicare's payment to the hospital" under the (i) Acute Care Hospital Inpatient, (ii) Inpatient Rehabilitation Facility, (iii) Inpatient Psychiatric Facility, or (iv) Long-Term Care Hospital prospective payment systems.[64] CMS provides an illustration:

> Suppose that, after an inpatient has been admitted to a hospital under an established Medicare Severity Diagnosis Related Group (MS–DRG), the patient's attending physician requests a consultation with a specialist who was not responsible for the patient's admission, and the specialist orders an X-ray. By the time the specialist orders the X-ray, the rate of Medicare payment under the IPPS has already been established by the MS–DRG (diagnostic imaging is bundled into the payment for the inpatient admission), and, unless the X-ray results in an outlier payment, the hospital will not receive any additional payment for the service over and above the payment rate established by the MS–DRG.[65]

Under these circumstances, CMS concludes that the X-ray is not DHS "even though it falls within a category of services that, when billed separately" would be DHS.[66]

64 *Id.* at 77657.

65 *Id.* at 77570-71.

66 *Id.* at 77571.

> Thus, assuming the specialist had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception to the physician self-referral law at the time the X-ray was ordered, the inpatient hospital services would not be tainted by the unexcepted financial relationship, and the hospital would not be prohibited from billing Medicare for the admission.[67]

As a practical matter, the principal benefit of CMS's clarification of (and amendment to) the definition of DHS is that it reduces the total universe of referrals and claims that might otherwise violate the Stark Law's prohibitions. In a nutshell, as long as the physician who ordered the underlying inpatient admission does not have an unexcepted financial relationship with the hospital, neither that physician's referral of DHS (the inpatient hospital service) nor any other referrals of DHS by any other physicians will violate the Stark Law as long as the services covered by the other referrals do not "increase the amount of Medicare's payment to the hospital."[68]

Notably, CMS declined the industry's invitation to apply the same logic to the agency's Outpatient Prospective Payment System (OPPS), which also provides for Medicare to pay a flat amount for hospital outpatient procedures/ services under the ambulatory payment classification (APC) system.

> As we stated in the [P]roposed [R]ule, we believe that there is typically only one ordering physician for outpatient services, and it would be rare that a physician other than the ordering physician would refer an outpatient for additional outpatient services that would not be paid separately under the OPPS... [and] we believe that extending the rule to [DHS] paid under the OPPS would be burdensome and challenging for stakeholders, CMS, and our law enforcement partners to implement and enforce.[69]

F. Referral

Many Stark Law exceptions require that the compensation provided for under the arrangement at issue be consistent with fair market value (FMV). The exception for personal service arrangements, for example, protects remuneration from an entity to a physician if (among other things) the arrangement between the parties is set out in writing, specifies the services covered by the arrangement, and the compensation to be paid over the term of the arrangement does not exceed FMV.[70] For reasons that are not entirely clear— although presumably falling into the clean-up and/or belts-and-suspenders category—CMS revised the definition of "referral" in the Final Rule to make it clear that a "referral" itself is not an "item or service" for Stark Law purposes.[71] This precludes any argument that paying FMV for "referrals" could conceivably be deemed paying FMV for items or services, a notion CMS emphasizes is "antithetical to the premise of the statute."[72]

---

67 *Id.*

68 *Id.* One open question is this: In CMS's hypothetical, if the ordering of the x-ray by the specialist does cause the amount Medicare pays for the inpatient procedure to increase—say, from $2,000 to $2,100—is this entire amount "tainted" for Stark Law purposes or only that portion ($100) for which the (only) physician with an unexcepted financial relationship with the hospital is responsible?

69 *Id.*

70 42 C.F.R. § 411.357(d).

71 85 Fed. Reg. at 77573.

72 *Id.*

III. Conclusion

This high-level Stark Law overview and discussion of revisions to several of the Stark Law's building blocks serves as the foundation for the remaining white papers and webinars in our series, *Stark Law Overhaul: An In-Depth Review of CMS's New Final Rule*. Forthcoming installments will delve into many of the details of the Final Rule, including the handling of technical and low-dollar violations; the "volume or value," "commercial reasonableness" and "fair market value standards"; the definition of an "indirect compensation arrangement"; the flexibility incorporated into several existing Stark Law exceptions; and the creation of several new exceptions.

Appendix A

Stark Law Exceptions

Exception	Regulatory Cite (42 C.F.R.)	Statutory Cite (if any) (42 U.S.C.)
Service Exceptions		
Physician Services	§ 411.355(a)	§ 1395nn(b)(1)
In-Office Ancillary Services	§ 411.355(b)	§ 1395nn(b)(2)
Prepaid Health Plans	§ 411.355(c)	§ 1395nn(b)(3)
Academic Medical Centers	§ 411.355(e)	
Ambulatory Surgical Center Implants	§ 411.355(f)	
Dialysis-Related Drugs	§ 411.355(g)	
Preventive Screening Tests	§ 411.355(h)	
Eyeglasses After Cataract Surgery	§ 411.355(i)	
Intra-Family Rural Referrals	§ 411.355(j)	
Financial Relationship Exceptions - Ownership		
Publicly-Traded Securities	§ 411.356(a)	§ 1395nn(c)(1)
Mutual Funds	§ 411.356(b)	§ 1395nn(c)(2)
Specific Providers	§ 411.356(c)	§ 1395nn(d)
Financial Relationship Exceptions - Compensation		
Rental of Office Space	§ 411.357(a)	§ 1395nn(e)(1)(A)
Rental of Equipment	§ 411.357(b)	§ 1395nn(e)(1)(B)
Employment	§ 411.357(c)	§ 1395nn(e)(2)
Personal Services	§ 411.357(d)	§ 1395nn(e)(3)
Physician Recruitment	§ 411.357(e)	§ 1395nn(e)(5)
Isolated Transactions	§ 411.357(f)	§ 1395nn(e)(6)
Unrelated to DHS	§ 411.357(g)	§ 1395nn(e)(4)

Exception	Regulatory Cite (42 C.F.R.)	Statutory Cite (if any) (42 U.S.C.)
Hospital-Group Arrangements	§ 411.357(h)	§ 1395nn(e)(7)
Payments by a Physician	§ 411.357(i)	§ 1395nn(e)(8)
Charitable Donations by Physician	§ 411.357(j)	
Non-Monetary Compensation	§ 411.357(k)	
Fair Market Value Compensation	§ 411.357(l)	
Medical Staff Incidental Benefits	§ 411.357(m)	
Risk-Sharing Arrangements	§ 411.357(n)	
Compliance Training	§ 411.357(o)	
Indirect Compensation Arrangements	§ 411.357(p)	
Referral Services	§ 411.357(q)	
Obstetrical Malpractice Insurance Subsidies	§ 411.357(r)	
Professional Courtesy	§ 411.357(s)	
Retention Payments in Underserved Areas	§ 411.357(t)	
Community-Wide Health Information Systems	§ 411.357(u)	
Electronic Prescribing Items/Services	§ 411.357(v)	
Electronic Health Records Items and Services	§ 411.357(w)	
Nonphysician Practitioner Assistance	§ 411.357(x)	
Timeshare Arrangements	§ 411.357(y)	
Limited Remuneration to a Physician	§ 411.357(z)	
Value-Based Arrangements	§ 411.357(aa)	
Cybersecurity Technology	§ 411.357(bb)	

Stark Law Overhaul Series: An In-Depth Review of CMS's Final Rule

REGISTER HERE

On December 2, 2020, the CMS published a final rule incorporating long-awaited changes to the agency's regulations governing the federal physician self-referral law, commonly known as the Stark Law. The final rule represents the most significant Stark Law rulemaking in more than a decade.

Dentons' analysis of this major regulatory overhaul will be presented in a series of seven webinars, each with a companion white paper, addressing all of the principal components of the 2020 rulemaking. Each webinar will provide an in-depth review of a related group of provisions, offer practical examples of the new rule in operation, and highlight questions and issues that remain unresolved.

Join us Thursdays from 12:30-1:45 pm ET for our bi-weekly **Stark Law Overhaul webinar***

Date	Time	Topic*
March 18	12:30-1:45 pm ET	Rolling Up Our Sleeves: A Stark Law Refresher and Clearing the Brush
April 1	12:30-1:45 pm ET	Separating the Wheat From the Chaff: Providing Greater Flexibility for Technical and Low-Dollar Violations
April 15	12:30-1:45 pm ET	Key Standards (Part I): Distinguishing and Defining the 'Volume or Value' Requirement
April 29	12:30-1:45 pm ET	Key Standards (Part II): The 'Fair Market Value' and 'Commercial Reasonableness' Requirements
May 13	12:30-1:45 pm ET	New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions
May 27	12:30-1:45 pm ET	What's Past is Prologue: Technology Subsidies Part Deux
June 10	12:30-1:45 pm ET	The Problem of the Square Peg and the Round Hole: When FFS and Managed Care Collide

** CLE credit is being applied for in Arizona, California, Georgia, Illinois, Missouri, New Jersey, New York, Texas and Virginia. Credit for all other states must be applied for and submitted by individual attendees. Compliance with each state's MCLE requirements is the sole responsibility of the attendee.*

Health Care

Dentons has more than 50 health care lawyers and professionals in the US. Our group closely collaborates with Dentons' corporate, litigation, tax, government enforcement and white collar investigations, public policy and other prominent practice groups, making Dentons the firm of choice among a wide range of health care entities both within the US and worldwide, including health care providers, suppliers, insurers, and network managers.

Key Contacts

The Dentons lawyers presenting this series, including Gadi Weinreich, Chris Janney and Ramy Fayed, are widely recognized as Stark Law thought leaders. They and other members of Dentons' US Health Care practice group have assisted countless clients in navigating this unforgiving law since its enactment in 1989, lectured extensively on its challenges and pitfalls, and authored multiple articles as well as two editions of *The Stark Law: A User's Guide to Achieving Compliance*.

Gadi Weinreich
Partner

Chris Janney
Partner

Ramy Fayed
Partner

Margo Smith
Associate

ABOUT DENTONS

Dentons is the world's largest law firm, connecting talent to the world's challenges and opportunities in more than 75 countries. Dentons' legal and business solutions benefit from deep roots in our communities and award-winning advancements in client service, including Nextlaw, Dentons' innovation and strategic advisory services. Dentons' polycentric and purpose-driven approach, commitment to inclusion and diversity, and world-class talent challenge the status quo to advance client and community interests in the New Dynamic.

dentons.com

© 2021 Dentons. Dentons is a global legal practice providing client services worldwide through its member firms and affiliates.
This publication is not designed to provide legal or other advice and you should not take, or refrain from taking, action based on its content.
Please see dentons.com for Legal Notices.

CSBrand-51862-Stark Law Refresher and Introduction to 2020 Rulemaking-White Paper-08 — 17/03/2021