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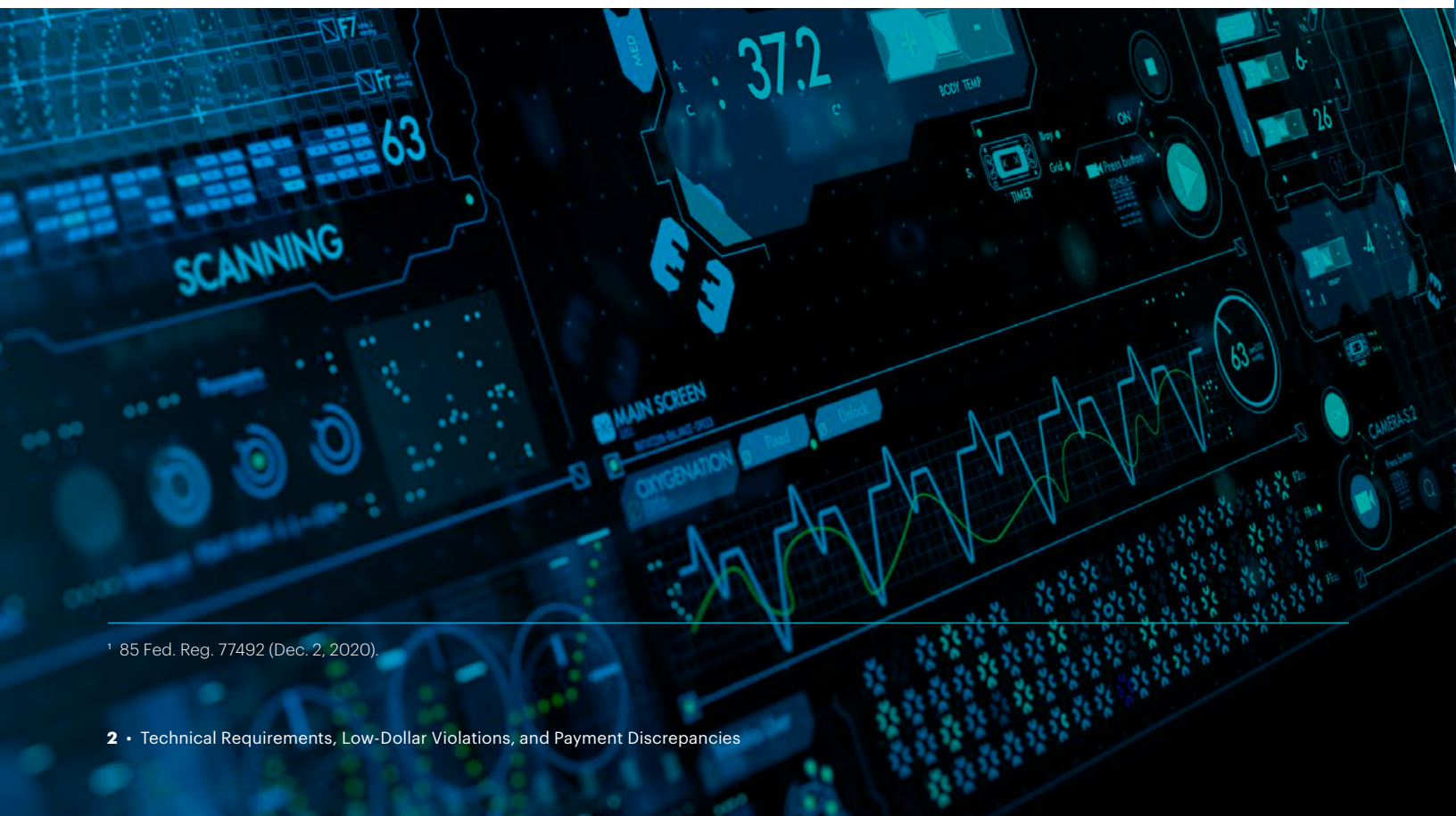
Stark Law Overhaul:
An In-Depth Review on CMS's New Final Rule

White Paper No. 2
Separating the Wheat from the Chaff: Technical Requirements, Low-Dollar Violations, and Payment Discrepancies

Separating the Wheat from the Chaff: **Technical Requirements, Low-Dollar Violations, and Payment Discrepancies**

In December 2020, the Centers for Medicare & Medicaid Services (CMS) finalized its 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 is presenting a series of seven webinars, each with a companion white paper, addressing the principal components of the Final Rule. This is the second of these white papers, covering several important changes CMS made in an effort to reduce the universe of arrangements that, while not implicating any of the Stark Law's principal policy objectives, nevertheless violate its referral and billing prohibitions.



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

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I. Introduction

In certain respects, the Stark Law always has been a public policy disaster waiting to happen. There are many reasons for this. Here are a few.

- Any exchange of "remuneration," no matter how trivial, arguably creates a "financial relationship."
- If a physician and an entity that furnishes "designated health services" (DHS)—a "DHS Entity" for our purposes—have a financial relationship, the physician may not refer Medicare beneficiaries to the DHS Entity for the provision of DHS, and the DHS Entity may not bill for any DHS furnished pursuant to such referrals, unless the parties' arrangement fits into a Stark Law exception. Critically, "substantial compliance" with an exception is not sufficient; each and every requirement of an exception must be satisfied in order to avoid a Stark Law violation.
- Almost every one of the Stark Law's (now 40) exceptions contains one or more highly technical requirements—relating to the timing of signatures, for example—that a party can easily and inadvertently fail to meet in the hustle and bustle of operating a health care organization.
- The Stark Law is a strict liability statute. Thus, whether an arrangement is out of compliance because the physician signed an agreement 91 (rather than the required 90) days after its effective date, or because a hospital compensated a major referral source $100,000 for services that have a fair market value of $20,000, both arrangements are *equally* noncompliant—and the same, potentially staggering, sanctions apply.
- Over the years, CMS has revised and, in some cases, completely overhauled, several critical Stark Law terms and provisions. This, in turn, has prevented the gradual evolution of precedent over time, occasionally resulting in confusing scenarios where the same arrangement appears to violate the Stark Law in one time period but not another.
- Influenced, at least in part, by this undulating regulatory landscape, federal district and appellate courts have been willing to ignore, and at times contradict, CMS with respect to certain key Stark Law elements.[2]

CMS began to recognize this looming public policy disaster almost as soon as the ink was dry on the final installment of the agency's first major Stark Law rulemaking in 2007. The next year, the agency created a "grace period" for meeting the signature requirement, and since then—culminating with the publication of the Final Rule in December 2020—it has gradually tried to soften the law's impact. CMS has principally accomplished this in three ways: (i) by making the Stark Law's technical requirements easier to satisfy, (ii) by effectively eliminating the need to meet any technical requirements in the case of low-dollar compensation arrangements, and (iii) by allowing providers to "cure" certain potential Stark Law violations before they give rise to an out-of-compliance period. It is these three developments that are the subject of this white paper.

[2] *See, e.g., United States ex rel. Bookwalter v. UPMC*, 938 F.3d 397 (3d Cir. 2019); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015).

II. Technical Requirements

The conditions of Stark Law exceptions are sometimes characterized as either "substantive" or "technical." (CMS also uses the terms "procedural" or "form" to refer to the latter set of conditions, but we'll stick with "technical" for purposes of this white paper.) For example, an exception commonly used to protect services arrangements is the regulatory exception for fair market value compensation (FMV Exception).[3] This exception has nine conditions, each of which must be satisfied in order for the parties to rely on this affirmative defense:

1. **Writing Requirement.** The arrangement must be "in writing" and the writing must specify (i) the "services covered under the arrangement," (ii) the "compensation that will be provided under the arrangement" and (iii) the "timeframe for the arrangement."
2. **Signature Requirement.** The arrangement must be "signed by the parties."
3. **Set in Advance Requirement.** The compensation must be "set in advance."
4. **FMV Requirement.** The compensation must be "consistent with fair market value."
5. **Volume or Value Requirement.** The compensation must not be "determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician."
6. **Commercial Reasonableness Requirement.** The arrangement "would be commercially reasonable even if no referrals were made between the parties."
7. **AKS Requirement.** The arrangement does not violate the federal health care program anti-kickback statute.
8. **Legal Compliance Requirement.** The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a federal or state law.
9. **Required Referral Requirement.** If the arrangement is conditioned on the physician's referrals to a particular provider, practitioner or supplier, the arrangement satisfies the special rule on required referrals, at 42 C.F.R. § 411.354(d)(4).

The first three of these requirements—the Writing, Signature and Set in Advance Requirements—often are referred to as technical requirements. The remaining requirements—and particularly the FMV, Volume or Value, and Commercial Reasonableness Requirements—often are referred to as substantive requirements. They are "substantive," of course, because while a physician's late signature on a services agreement with a hospital, for example, tells one (literally) nothing about whether the arrangement will result in overutilization or patient steering, compensation to a physician that goes up or down depending on the volume of Medicare beneficiaries referred by the physician to the hospital tells one a great deal about whether the arrangement may implicate those same policy objectives.

In recent years, it has become increasingly clear that the majority (and likely the vast majority) of arrangements that fail to meet the requirements of the FMV (and similar) Exceptions do so because the parties have failed to meet one or more technical requirements. Recognizing (and largely sharing) the industry's growing frustration with respect to this issue, CMS—through a hodgepodge of amendments, special rules, and interpretations—has gradually softened the impact of non-compliance with the Signature, Writing and Set in Advance Requirements. This softening began in 2008, accelerated in 2015 and continued through CMS's latest rulemaking.

3 42 C.F.R. § 411.357(l).

A. Signature Requirement

We'll start with the Signature Requirement because (generally speaking) it's the most straightforward. Over the years, the Signature Requirement has raised three main issues: (i) What is a "signature"?, (ii) What is the relationship between the Signature and Writing Requirements?, and (iii) When must the required signatures be obtained? Although only the first of these issues is directly addressed in the Final Rule, to provide some context we'll address all three (in reverse order) below.

1. When must the required signatures be obtained?

To answer the question of *when* the required signatures must be obtained, it will be useful to have a hypothetical. Assume the following chronology of events:

- **January 1.** Hospital emails Physician: "Would you be interested in becoming the medical director of Hospital's Cardiology Department? One-year term, 10 hours per week, $250 per hour (as documented in a timesheet). We need someone by 2/1. If you'll do it, attached is our standard medical director agreement (MDA). Apologies for the rush!"
- **January 22.** Physician emails Hospital: "Yes, I will sign the MDA and send it back."
- **February 1.** Physician begins furnishing medical director services to Hospital (and, as such, the parties' "financial relationship" begins).
- **February 25.** Physician signs the MDA (and delivers it to Hospital).
- **April 13.** Hospital signs the MDA.

Historically, this arrangement arguably would have been out-of-compliance under the Stark Law from *February 1* (the day the financial relationship began) through *April 12* (the day before the MDA was fully executed by both parties).

Over the years, however, CMS (and Congress) have gradually liberalized the Signature Requirement through the establishment of a signature "grace period." The first grace period, codified in 2008, gave parties 90 days (from the outset of their financial relationship) to obtain all necessary signatures if the failure to do so in a timely manner was "inadvertent," and 30 days to do so in all other cases.[4] Since nobody (including CMS) knew how to apply this inadvertent/not inadvertent distinction in practice, it was abandoned by CMS effective January 1, 2016[5] and, today, the rule is that the Signature Requirement will be met as long as (i) the compensation arrangement otherwise "fully complies with an applicable exception," and (ii) the parties "obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception" (i.e., the date on which the signature(s) "were required under the applicable exception but the parties had not yet obtained them").[6] In most cases, then, the rule, reduced to its essentials, is this: Parties need to obtain the required signatures within 90 days of the start of their financial relationship.

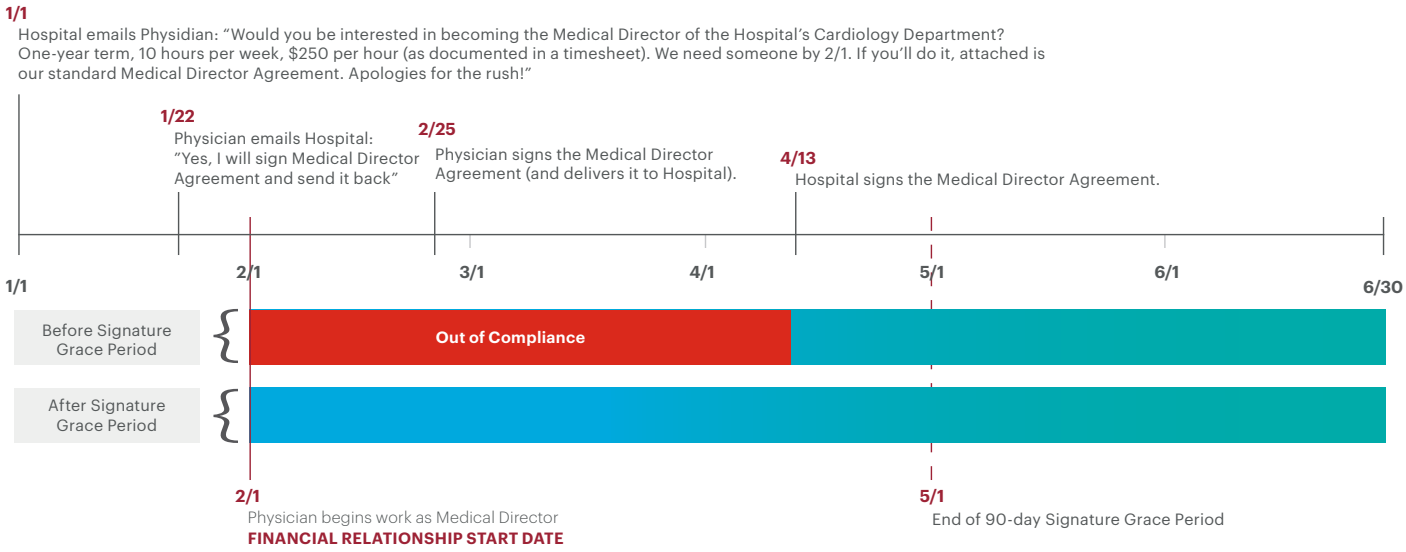
4 42 C.F.R. § 411.353(g) (2008) as set forth at 73 Fed. Reg. 48434, 48751 (Aug. 19, 2008).

5 42 C.F.R. § 411.353(g)(1)(ii) (2016) as set forth at 80 Fed. Reg. 70886, 71374 (Nov. 16, 2015).

6 In 2008, a DHS Entity could avail itself of the signature grace period only once every three years with respect to the same physician. 73 Fed. Reg. at 48751. In 2018, when Congress amended certain statutory provisions of the Stark Law—codifying, among other things, the 90-day signature grace period—this "once every three years" limitation was omitted. Bipartisan Budget Act of 2018, Pub. L. 115–123, § 50404(a)(2), 132 Stat. 64, 218-19 (codified at 42 U.S.C. § 1395nn(h)(1)(E)). That same year, CMS followed suit, abandoning the limitation as well. 83 Fed. Reg. 59452, 60074 (Nov. 23, 2018).

In our hypothetical, then, assuming all other requirements of the FMV Exception were met as of February 1 (when the parties' compensation arrangement began), the arrangement would not have had any out-of-compliance period because all of the necessary signatures were obtained by April 13, which is within 90 consecutive calendar days of February 1. See *Diagram* 1 below.

Diagram 1



The Final Rule did not modify the Signature Requirement's grace period.

2. What is the relationship between the Signature and Writing Requirements?

As noted above, the Writing Requirement provides that the "arrangement" at issue must be "in writing" and that this writing must "specify" (i) the "services covered under the arrangement," (ii) the "compensation that will be provided under the arrangement," and (iii) the "timeframe for the arrangement." Assuming the signatures covered by the Signature Requirement must somehow relate to one or more of these conditions, *how* must they relate, and *when*? In 2015, CMS took a first stab at answering this question, but only in the preamble to its rulemaking:

> For the same reason that parties do not need a single formal written contract to comply with the writing requirement, parties also do not need to sign a single formal written contract to comply with the signature requirement of an applicable exception. Nor do we expect every document in a collection of documents to bear the signature of one or both parties. To satisfy the signature requirement, a signature is required on a contemporaneous writing documenting the arrangement. The contemporaneous signed writing, when considered in the context of the collection of documents and the underlying arrangement, must clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect.[7]

7 80 Fed. Reg. at 71316 (emphasis in original).

Reduced to its essentials, then, the test appears to be this: A signature will satisfy the Signature Requirement if (i) it is "on a contemporaneous writing documenting the arrangement" and (ii) that document—"when considered in the context of the collection of documents and the underlying arrangement"—"clearly relate[s] to the other documents in the collection and the arrangement that the party is seeking to protect." Once again, let's unpack this a bit using a hypothetical. Assume the following:

- **January 1.** Hospital sends Physician an Emergency Department call coverage agreement signed by Hospital on that date. The agreement specifies the services to be furnished by Physician, the term (one year) and the start date (February 1). Although the parties earlier had verbally agreed to a payment rate of $150 per hour, Hospital neglects to fill in the space in the agreement covering compensation, so the agreement simply states that Physician will be paid "___ per hour."
- **January 15.** Physician (who does not notice the above omission) signs the agreement and returns it to Hospital.
- **February 1.** Physician furnishes four hours of Emergency Department call coverage (and, as such, the parties' "financial relationship" begins).
- **February 14.** Physician emails Hospital: "I was about to invoice for my call coverage and looked at our agreement. The hourly amount is blank. Can you send a revised version and a check for my February 1 shift? Thanks."
- **February 15.** Hospital emails Physician: "Sorry about that! Per our discussion, we'll pay $150 per hour. The revised agreement (and check!) are on the way."
- **April 15.** Physician receives letter from Hospital. "This got buried in Jane's inbox. Really apologize. Enclosed is a revised agreement with the compensation ($150 per hour) and a check for $600 (4 hours x $150) for your services on February 1. Please sign the agreement and send it back when you get a chance." Both the check and agreement were signed by Hospital on April 10.
- **May 10.** Physician signs the agreement and returns it to Hospital. Physician also endorses and deposits the check in her bank account.

In this hypothetical, Hospital has signed three documents: one on *January 1* (the original agreement without the rate of hourly compensation), and two on *April 10* (the revised agreement with the rate of hourly compensation and the Hospital's check for $600). Similarly, Physician has signed the same three documents, but on different dates: Physician signed the first document (the original agreement without the rate of hourly compensation) on *January 15* and the other two documents (the revised agreement and Hospital's check) on *May 10*.

Because the financial relationship began on February 1 (when Physician furnished four hours of Emergency Department call coverage), the parties must have all necessary signatures in place by May 1 in order to rely on the 90-day grace period. All of Hospital's signatures occurred before May 1 and, as such, one of the two parties has met the Signature Requirement. But only one of Physician's signatures—the January 15 signature on the original agreement (which was silent on the rate of compensation)—occurred before May 1. So the question becomes: *Does Physician's January 15 signature satisfy the Signature Requirement?*

On the one hand, there were no writings existing as of January 15 that specified the compensation to be provided under the arrangement (i.e., $150 per hour). In our hypothetical, that writing didn't exist for another month, when Hospital emailed Physician (on February 15) the rate it would be paying. Thus, as of January 15, Physician had not signed one or more writings that, when taken together, satisfied the Writing Requirement. This could be problematic because the Signature Requirement grace period applies only where all other requirements of the applicable exception (here, the FMV Exception) are satisfied.[8]

On the other hand, it is not clear that all of the conditions of the Writing Requirement must, in fact, be satisfied *before* the Signature Requirement may be met. As noted above, the test developed by CMS appears to be that a signature will satisfy the Signature Requirement if (i) it is "on a contemporaneous writing documenting the arrangement" and (ii) that

8 42 U.S.C. § 1395nn(h)(1)(E)(ii) ("[T]he compensation arrangement otherwise complies with all criteria of the applicable exception.").

document—"when considered in the context of the collection of documents and the underlying arrangement"—"clearly relate[s] to the other documents in the collection and the arrangement that the party is seeking to protect." Moreover, the statutory provision that requires that the compensation arrangement comply with all criteria of the applicable exception, does not specify *when* "all other criteria" must be satisfied—e.g., as of the date of each signature, or at *any* point during the formation of the compensation arrangement. In our hypothetical, Physician signed the original agreement on January 15. That agreement is a "contemporaneous writing" and it **cl**early "relates" to (i) the other documents in the collection (i.e., the emails, letter and updated agreement), and (ii) the "arrangement" the parties are seeking to protect.

To be clear, it is a best practice to obtain the signatures of both parties only after all of the components of the Writing Requirement have been met. But, again, the test laid out by CMS in late 2015 does not, at least arguably, require that particular chronology of events. Unfortunately, CMS did not confirm this in the Final Rule.

3. What is a "Signature"?

A final question is this: what exactly qualifies as a "signature"? Clearly a "wet" signature by each of the parties to the arrangement at issue qualifies, but does anything else? Generally speaking, of course, a signature signals the signee's assent to, or agreement with, some particular, identifiable proposition or set of facts. Assume, for example, that on January 1, Hospital delivers to Physician a formal, written personal services agreement (PSA) that includes Hospital's (wet) signature and otherwise satisfies all of the requirements of the FMV Exception save one: Physician, herself, has not yet signed the PSA. The next day, January 2, Physician sends an email to Hospital: "I am in receipt of the PSA and in complete agreement with its terms and conditions. Can't wait to get started!" Assuming there is no dispute that the email is authentic (i.e., that it was authored and sent by Physician, etc.), has the Signature Requirement been met?

To date, CMS has not been willing to go quite that far. It has, however, dipped its toes into the "electronic signature" waters. In the 2019 proposed rulemaking (Proposed Rule), for example, the agency stated that its "longstanding policy" has been that an "electronic signature" that is "legally valid under Federal or State law" is sufficient for purposes of meeting the Signature Requirement.[9] In the Final Rule, CMS codifies this policy in the regulations themselves.[10] Specifically, a new special rule states that "[i]n the case of any signature requirement . . . such requirement may be satisfied by an electronic or other signature that is valid under applicable Federal or State law."[11]

The circumstances under which dozens of different jurisdictions deem "action X" or "action Y" to constitute a "valid" "electronic or other signature" is beyond the scope of this white paper. Suffice it so say, however, that where meeting this particular component of the Signature Requirement is the only potential obstacle standing in way of a violation of the Stark Law's referral and billing prohibitions, delving into these authorities may be time well spent.

B. Writing Requirement

Turning now to the Writing Requirement, many Stark Law exceptions require that the compensation arrangement at issue be set forth in "writing." The FMV Exception, for example, provides that the "arrangement" at issue must be "in writing" and that the writing must "specify" (i) the "services covered under the arrangement," (ii) the "compensation that will be provided under the arrangement," and (iii) the "timeframe for the arrangement." Two questions that repeatedly have arisen over the years are these:

- How formal (and unified/singular) must the writing (or writings) be in order to satisfy the Writing Requirement?
- Must the Writing Requirement be met on or before the start date of the parties' financial relationship (or can it be satisfied at some later point in time)?

Although the Final Rule addresses only the second question, we discuss them both to provide context.

9 84 Fed. Reg. 55766, 55815 (Oct. 17, 2019).

10 85 Fed. Reg. 77492, 77592 (Dec. 2, 2020).

11 42 C.F.R. § 411.354(e)(3) as set forth at 85 Fed. Reg. at 77667.

1. Substance of Writing

Historically, there was some confusion as to whether the Writing Requirement could be met only through a single written agreement that incorporated in one place all of the material terms and conditions of the parties' arrangement or, alternatively, could be met through some amalgam of writings/documents. This confusion should not have come as a surprise, as some Stark Law exceptions used the (specific) term "agreement" while others used the (more malleable) term "arrangement." In all events, this confusion persisted for 25 years, until CMS finally took up the issue in earnest in 2015.

In a rulemaking that year, CMS acknowledged that while "a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with an applicable exception," there "is no requirement . . . that an arrangement be documented in a single formal contract."[12] Rather, depending on the facts and circumstances, "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties," could suffice.[13] According to CMS, examples of what might constitute "contemporaneous documents" include:

> Board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services, or rent.[14]

As noted above, CMS did not modify this component of the Writing Requirement in the Final Rule.

2. Timing of Writing

CMS did, however, make a major change in the Final Rule regarding *when* the parties' writing (or writings) must be in place in order to satisfy the Writing Requirement. As discussed above, there has been, since 2008, a "grace period" in place for the Signature Requirement. However, for years CMS declined to establish a similar grace period for the Writing Requirement. In the Proposed Rule CMS broke down, proposing to extend the 90-day grace period to the Writing Requirement as well.[15] Based on its experience overseeing the Voluntary Self-Referral Disclosure Protocol (SRDP), the agency observed that it was common for parties facing operational constraints to begin performance of an otherwise legitimate compensation arrangement before reducing all of the arrangement's key terms and conditions to writing.[16] According to CMS, these instances of "procedural or form" non-compliance tended to last for relatively short periods and, more importantly, did not pose a material risk of program abuse.[17]

Consistent with this rationale, the Final Rule provides that the Writing Requirement (like the Signature Requirement) will be met as long as (i) the compensation arrangement otherwise "fully complies with an applicable exception," and (ii) the parties "obtain the required writings(s) . . . within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception" (i.e., the date on which the writings(s) "were required under the applicable exception but the parties had not yet obtained them").

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12 80 Fed. Reg. at 71314-15.

13 *Id.* at 71315.

14 *Id.* at 71316. A little over two years later, in February 2018, Congress amended the text of the Stark Law statute to incorporate the agency's expansive position regarding the manner in which parties may satisfy the writing requirement. Specifically, the new legislation inserted a new subparagraph (D) to Section (h)(1), called "Written Requirement Clarified." Bipartisan Budget Act of 2018, Pub. L. 115–123, § 50404(a)(1), 132 Stat. 64, 218 (codified at 42 U.S.C. § 1395nn(h)(1)(D)). The new subparagraph provides that "any requirement . . . for a compensation arrangement to be in writing . . . shall be satisfied by such means as determined by the Secretary, including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved." 42 U.S.C. § 1395nn(h)(1)(D). Later that year, CMS, in the course of promulgating the Medicare Physician Fee Schedule final rule for calendar year 2019, codified in the Stark Law regulations this same provision almost verbatim. 42 C.F.R. § 411.354(e)(2) as set forth at 83 Fed. Reg. 59452, 60074 (Nov. 23, 2018).

15 84 Fed. Reg. 55766, 55813-15 (Oct. 17, 2019).

16 *Id.* at 55814.

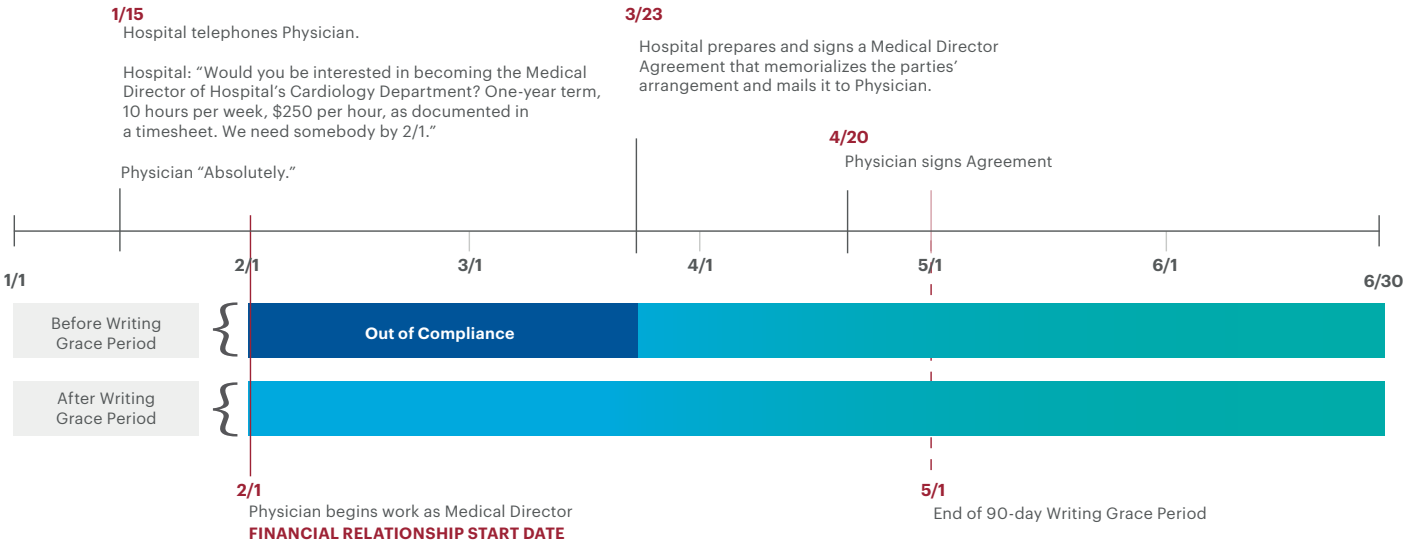
17 *Id.* at 55813-14 (internal quotation marks omitted).

Assume, for example, the following chronology of events:

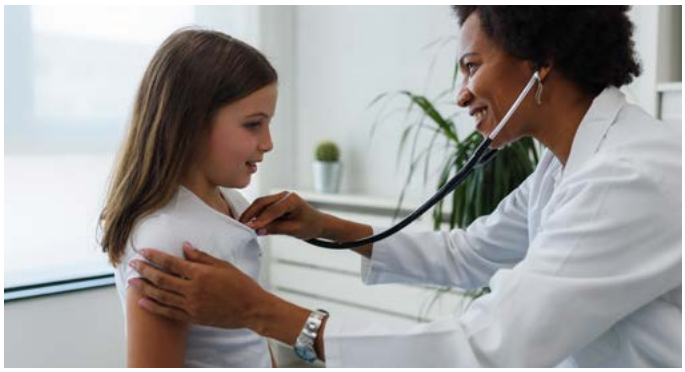
- **January 15.** Hospital telephones Physician. Hospital says, "Would you be interested in becoming the medical director of Hospital's Cardiology Department? One-year term, 10 hours per week, $250 per hour, as documented in a timesheet. We need someone by 2/1." Physician says, "Absolutely."
- **February 1.** Physician begins furnishing medical director services to Hospital.
- **March 23.** Hospital prepares and signs a medical director agreement (MDA) that memorializes the parties' arrangement and mails it to Physician.
- **April 20.** Physician signs the MDA.

Prior to the Final Rule, this arrangement would have met the Signature Requirement. Although both signatures were not obtained until April 20—over 10 weeks after the parties' financial relationship began (on February 1)—the 90-day grace period covering the Signature Requirement did not end until May 1. Assuming the parties had no "writings" other than the MDA itself, however, the arrangement would *not* have met the Writing Requirement, and, as a result—and assuming the parties were relying on the FMV Exception—the arrangement would have been out of compliance for 50 days, from February 1, when the parties financial relationship began, through March 22, the day before the Writing Requirement was satisfied. Pursuant to the Final Rule, however, because the Writing Requirement was met prior to May 1, there is no out-of-compliance period. See *Diagram* 2 below.

Diagram 2



It is worth noting that the flexibility afforded by the Writing Requirement's new 90-day grace period has its limits. CMS takes the position, for example, that if an arrangement terminates or expires within 90 days of its onset, the special rule does not apply. For example, if parties have an arrangement with a 60-day term that is not reduced to writing until day 75, the special rule would not protect that arrangement.[18] (As discussed in Section III below, however, it might be possible to protect the arrangement under the new regulatory exception for limited remuneration to a physician.)



C. Set In Advance Requirement

1. Background

A number of Stark Law exceptions, including the FMV Exception, require that the compensation to be paid for the items or services at issue be "set in advance."[19] This requirement principally is intended to prevent parties from periodically adjusting the amount of compensation paid by a DHS Entity to a physician over the course of an arrangement to reflect the volume or value of the physician's referrals to or other business generated for the DHS Entity or its affiliates.

One issue that arose early on was whether the Set in Advance Requirement could be met only if, at the outset of the arrangement, the parties had agreed on the total *aggregate* amount of compensation that would be paid under the arrangement. For example, assume Hospital hires Physician under a PSA that has a term of one year, and Hospital agrees to pay Physician $200 per hour for "up to and not to exceed" 10 hours per month. Over the term of the arrangement, Physician might be paid anywhere from $0 (if Physician works 0 hours during the term) to $24,000 (if Physician works 120 hours during the term). Does that arrangement meet the Set in Advance Requirement?

In 2001, CMS made it clear that the answer is "yes," creating a special rule on compensation at 42 C.F.R. § 411.354(d)(1)—the "Set in Advance Special Rule"—providing that unit-based compensation methodologies (such as "time-based" or "per unit of service-based" compensation methodologies) will meet the Set in Advance Requirement.[20] Three years later, CMS expanded the Set in Advance Special Rule, providing that subject to certain conditions (discussed below), compensation also would be considered "set in advance" if it was calculated pursuant to a predetermined "formula" (e.g., 10 percent of collections).[21]

To summarize, then: Prior to the Final Rule, where a physician and DHS Entity entered into an arrangement pursuant to which the physician would furnish items or services and the DHS Entity would compensate the physician therefor, the compensation under the arrangement would be considered "set in advance" under any of the following four circumstances:

1. The "*aggregate*" compensation to be paid by the DHS Entity to the physician—e.g., $50,000 per year—was set out in writing before the furnishing of any items or services under the arrangement.

18 85 Fed. Reg. 77492, 77591 (Dec. 2, 2020).

19 *See, e.g.*, 42 C.F.R. §§ 411.355(e) (academic medical centers), 411.357(a) (rental of office space), 411.357(b) (rental of equipment), 411.357(d) (personal services), 411.357(l) (fair market value compensation), and 411.357(y) (timeshare arrangements). In the ordinary course, the statutory and regulatory exceptions for bona fide employment relationships do not include a Set in Advance Requirement. *See* 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c). This changes, however, where the employer directs the referrals of the physician-employee. *See* 42 C.F.R. § 411.357(c)(5) ("If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier," the arrangement must satisfy the conditions of 42 C.F.R. § 411.354(d)(4), which requires, among other conditions, that the compensation be set in advance). The regulatory exception for indirect compensation arrangements also does not contain a Set in Advance Requirement. *See* 42 C.F.R. § 411.357(p).

20 66 Fed. Reg. 856, 959 (Jan. 4, 2001).

21 69 Fed. Reg. 16054, 16125 (Mar. 26, 2004).

2. A "*time-based*" amount of compensation to be paid by the DHS Entity to the physician—e.g., $150 per hour—was set out in writing before the furnishing of any items or services under the arrangement.
3. A "*per-use*" or "*per-service*" amount of compensation to be paid by the DHS Entity to the physician—e.g., $200 for each unit of service X furnished by physician—was set out in writing before the furnishing of any items or services under the arrangement.
4. A specific *formula* for calculating the compensation to be paid by the DHS Entity to the physician—e.g., 10 percent of the DHS entity's collections for service X—was set out in writing before the furnishing of any items or services under the arrangement, but only if the formula (i) was set forth in sufficient detail so that it could be objectively verified, and (ii) was not modified during the course of the arrangement in any manner that took into account the volume or value of referrals or other business generated by the referring physician.

A second issue that arose over time was whether parties could periodically *modify* the compensation provided for under their arrangement without running afoul of the Set in Advance Requirement and, if so, under what circumstances such modifications would be permitted. For example, assume Hospital and Physician enter into a PSA that (i) is effective January 1, 2017, (ii) has a three-year term (i.e., from January 1, 2017, through December 31, 2019), and (iii) provides for Hospital to compensate Physician at $150 per hour. If the parties wish to amend the agreement to increase or decrease Physician's compensation at some point during the three-year term, can this be done without violating the Set in Advance Requirement?

In 2008, CMS confirmed—albeit only in preamble—that the answer is "yes." According to the agency, parties to an otherwise compliant arrangement may amend its compensation terms without running afoul of the Set in Advance Requirement, provided the new compensation amount or formula (i) is determined before it is implemented, (ii) is sufficiently detailed such that it can be objectively verified, (iii) does not take into account the volume or value of the physician's referrals or other business generated, and (iv) at least with respect to Stark Law exceptions requiring the arrangement at issue to have a term of at least one year,[22] remains in place (without further changes to the compensation amount or formula) for a period of at least one year from the date of the amendment.[23]

Thus, going back to our three-year (January 1, 2017 through December 31, 2019) PSA between Hospital and Physician, the parties could change the compensation rate from $150 per hour to $175 per hour, effective March 1, 2018, provided the new rate was determined prior to March 1, 2018; did not take into account the volume or value of Physician's referrals to or other business generated for Hospital; and remained in place through (at least) February 28, 2019.

2. Final Rule

In the Proposed Rule, CMS did not propose any substantive changes to the Set in Advance Requirement or the Set in Advance Special Rule.

22 73 Fed. Reg. 48434, 48697 (Aug. 19, 2008) ("We are taking the opportunity here to clarify that the rule regarding the amendment of arrangements between DHS entities and physicians (or physician organizations) applies to all of the exceptions for compensation arrangements in 42 CFR, Subpart J that include a 1-year term requirement for satisfying the exception.").

23 *Id.*

The agency did emphasize, however, that the Set in Advance Special Rule is simply a "deeming provision" and, as such, does not establish a mandatory set of requirements.[24] In other words, CMS clarified that if a payment methodology satisfies the Set in Advance Special Rule, then it is "deemed" to meet the Set in Advance Requirement. However, the fact that a payment methodology does *not* satisfy the Set in Advance Special Rule does *not* mean that the methodology *necessarily* violates the Set in Advance Requirement. It might or it might not, depending on the particular facts and circumstances.

Like the Proposed Rule, the Final Rule makes it clear that the Set in Advance Special Rule is solely a deeming provision. In addition, however, the Final Rule reorganizes and makes some significant changes to the Set in Advance Special Rule, essentially dividing it into two distinct parts, each of which is discussed below.

a. Part 1: Before the Arrangement Begins

The first part of the Set in Advance Special Rule—memorialized in 42 C.F.R. § 411.354(d)(i) ("Part 1")—largely tracks the Special Rule as it existed before the Final Rule. For example, Part 1 covers the four circumstances (discussed above) under which compensation will be deemed to be set in advance (i.e., aggregate, time-based, per-use/service-based, formula). Consistent with the Proposed Rule, Part 1 also emphasizes the *"deeming"* nature of the Special Rule by replacing the phrase "is *considered* 'set in advance'" with the phrase "is *deemed* to be 'set in advance.'"[25]

Three points should be highlighted here. First, remember that the Set in Advance Special Rule applies only if the compensation/formula at issue is set out in writing before the furnishing of any items or services under the arrangement. In the preamble to the Final Rule, CMS emphasizes that, as with the Writing Requirement, "there are many ways in which the amount of or a formula for calculating the compensation under an arrangement may be documented before the furnishing of items or services" for purposes of the Set in Advance Special Rule.[26] For example, the writing component of the Set in Advance Special Rule can be met prior to the onset of the parties' financial relationship through a collection of documents including, but not limited to, "informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from other similarly situated physicians for similar items or services."[27]

Second, it is important to remember that because the Set in Advance Special Rule is a deeming provision, while compensation must be set forth in writing before the parties' arrangement begins in order for it to be "deemed" set in advance, compensation that is *not* set forth in writing before the start of an arrangement *still* may satisfy the Set in Advance Requirement (even though it cannot satisfy the Set in Advance Special Rule). Indeed, CMS makes this clear in the preamble of the Final Rule: "[C]ompensation may be set in advance even if it is not set out in writing before the furnishing of items or services as long as the compensation is not modified at any time during the period the parties seek to show the compensation was set in advance."[28]

Let's repurpose (with some changes) the hypothetical we used to explain the Writing Requirement's new 90-day grace period:

- **January 15.** Hospital telephones Physician. Hospital says, "Would you be interested In becoming the medical director of Hospital's Cardiology Department? One-year term, 10 hours per week, $250 per hour, as documented in a timesheet. We need someone by 2/1." Physician says, "Absolutely."
- **February 1.** Physician begins furnishing medical director services to Hospital.
- **May 10.** Hospital prepares and signs a medical director agreement (MDA) that memorializes the parties' arrangement and mails it to Physician.
- **May 11.** Physician signs the MDA.

24 84 Fed. Reg. 55766, 55782 (Oct. 19, 2019).

25 85 Fed. Reg. 77492, 75591 (Dec. 2, 2020) (emphasis added).

26 *Id.* at 77592.

27 *Id.; see also id.* at 77596 (noting that this list is "illustrative only and is not exhaustive").

28 *Id.* at 77591.

As of February 1, when the parties' financial relationship began, the compensation ($250 per hour) was not set forth in any writing and, as such, could not be "deemed" set in advance under the Set in Advance Special Rule. Based on the facts and circumstances, however—i.e., the compensation that was discussed in the January 15 telephone call was in fact incorporated into the May 10 MDA—there would be a strong argument that the compensation at issue ($250 per hour) was in fact "set in advance" as of the start date of the financial relationship at issue (February 1) and, as such, satisfies the Set in Advance Requirement.

This brings us to our third cautionary point: Even if the Set in Advance Requirement can be met prior to the compensation terms being set forth in a writing, the lack of a writing may create a problem with respect to *other* requirements of an applicable exception. Recall, for example, that the FMV Exception has a Writing Requirement pursuant to which there must be a "writing" that, among other things, "specifies" the "compensation that will be provided under the arrangement." In the above hypothetical, then, although it may be the case that the Set in Advance Requirement is met by dint of the parties' January 15 telephone call, in order to satisfy the Writing Requirement, within 90 days of February 1 (i.e., by May 1), the "compensation that will be provided under the arrangement" (i.e., $250 per hour) must be reduced to writing. Under our hypothetical, that is not the case. The Writing Requirement is not met until May 10.

b. Part 2 - After the Arrangement Begins

The second part of the Set in Advance Special Rule—memorialized at 42 C.F.R. § 411.354(d)(ii) ("Part 2")—is new. Part 2 essentially codifies in a regulation what CMS discussed in preamble in 2008—i.e., the circumstances under which compensation may be modified after the onset of an arrangement without running afoul of the Set in Advance Requirement. Specifically, Part 2 provides that "compensation (or a formula for determining the compensation)

may be modified at any time during the course of a compensation arrangement," and still satisfy the Set in Advance Requirement, if three requirements are met:

- First, all requirements of an applicable exception must be satisfied as of the effective date of the modified compensation or formula.
- Second, the modified compensation or formula must be determined "before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid."
- Third, in the case of a compensation formula, before the furnishing of the items, services, office space or equipment for which the modified compensation is to be paid, "the formula for the modified compensation" must be "set forth in writing in sufficient detail so that it can be objectively verified."

  The regulation further notes that, for purposes of meeting this requirement, the new 90-day grace period with respect to the Writing Requirement is not available.[29]

Recall that when CMS addressed this issue in preamble in 2008, a requirement was that the modified compensation be in place for at least one year. Significantly, this "one-bite-at-the-apple" restriction is not included in the Final Rule; and in the preamble to the Final Rule CMS makes it clear that the Set in Advance Special Rule "does not require that the modified compensation remain in place for at least [one] year from the date of amendment and there is no prohibition on the number of times the parties may modify the compensation," provided that the Special Rule's conditions "are met each time the compensation is modified."[30]

29 In other words, although the Final Rule affords parties a 90-day grace period in which to memorialize their compensation terms in a writing, it does not extend that flexibility to amendments to the terms of compensation. When it comes to changes in compensation, the amended terms will meet the Set in Advance Requirement only if and when the new terms are set forth in writing.

30 85 Fed. Reg. at 77595.

III. Limited Remuneration Exception

Notwithstanding the significantly increased flexibility CMS has introduced with respect to the Signature, Writing and Set in Advance Requirements, there still are many arrangements that implicate the Stark Law by virtue of not meeting one or more these technical requirements, but that do not necessarily pose a material risk of program or patient abuse. CMS provides an example of one such arrangement in the preamble to the Final Rule. The arrangement, which was disclosed to the agency under the SRDP, involved the provision of medical director services by a physician to a hospital on a short-term basis. As explained by CMS:

> Despite the hospital's need for the services and compensation that was fair market value and not determined in any manner that took into account the volume or value of the referrals or other business generated by the physician, the arrangement could not satisfy all the requirements of any applicable exception because the compensation was not set in advance of the provision of the services and was not reduced to writing and signed by the parties.[31]

Recognizing that arrangements such as this are "unlikely to cause overutilization or similar harms to the Medicare program,"[32] CMS has created a new regulatory exception for arrangements that involve the furnishing of limited amounts of remuneration to a physician (Limited Remuneration Exception).[33] According to the agency, the new exception is designed to "allow entities to compensate physicians for short-term or infrequent arrangements, many of which commence under exigent circumstances, with little time to reduce the arrangement to writing or set the compensation in advance."[34]

Reduced to its essentials, the Limited Remuneration Exception protects the exchange of (i) remuneration "from an entity to a physician" (ii) "for the provision of items or services" by "the physician to the entity" (iii) "in an amount that does not exceed an aggregate of $5,000 per calendar year,"[35] provided the following four conditions are met:

1. the compensation is not "determined in any manner that takes into account the volume or value of referrals or other business generated by the physician";
2. the "compensation does not exceed the fair market value of the items or services";
3. the arrangement "would be commercially reasonable even if no referrals were made between the parties"; and
4. if the "remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier," the arrangement must satisfy the directed referral requirements set forth in Section 411.354(d)(4).

If the arrangement involves the "lease" or "use" of space or equipment, the exception also prohibits the use of certain percentage- and unit-based compensation formulas.

The Limited Remuneration Exception essentially serves as a Stark Law compliance Swiss army knife, allowing parties to avoid out-of-compliance periods under a wide range of circumstances provided the exception's annual dollar cap is not exceeded (and the other aforementioned conditions are satisfied).

31 *Id.* at 77623.

32 *Id.*

33 42 C.F.R. § 411.357(z).

34 85 Fed. Reg. at 77625.

35 Similar to the dollar caps found in other Stark Law exceptions, the $5,000 cap in the Limited Remuneration Exception will be adjusted on an annual basis to account for inflation.

As a threshold matter, the exception can be used by itself to protect a compensation arrangement from beginning to end. Assume for example, that Hospital and Physician enter into a six-month arrangement pursuant to which Physician provides Emergency Department call coverage services at Hospital between January 1 and June 30. During this six-month period, Physician works 10 eight-hour shifts and is paid $400 per shift (so a total of $4,000). Hospital and Physician agree upon the terms of the arrangement orally, but neglect to put the arrangement in writing. Due to the lack of a signed writing, the arrangement does not qualify for protection under the FMV Exception (or any other exception with Writing and/or Signature Requirements). Notwithstanding, as long as the arrangement meets the four conditions set forth above—i.e., $4,000 does not exceed fair market value for the services at issue, the arrangement is commercially reasonable, etc.—the entire six-month arrangement will be protected under the Limited Remuneration Exception.

The Limited Remuneration Exception also can be used in conjunction with other Stark Law exceptions to avoid out-of-compliance periods that might otherwise result. Assume, for example, the following:

- **January 1.** Hospital and Physician enter into a PSA that complies with all of the requirements of the FMV Exception. The written PSA memorializing their arrangement has a one year term and provides for Physician to furnish service A to Hospital for $100 per hour.
- **January 1-March 31.** Physician furnishes 10 hours of service A.
- **April 1.** Hospital pays Physician $1,000 for performing 10 hours of service A in the first calendar quarter (i.e., January 1 through March 31). On that same day, Hospital asks Physician during a telephone conversation if Physician also would be willing to furnish services B and C under their arrangement for $125 per hour for each service. Physician agrees.
- **April 1-June 30.** Physician furnishes 10 hours of service A, 10 hours of service B and 20 hours of service C.
- **July 1.** The parties prepare and execute an amendment to the PSA. The amendment adds service B at $125 per hour to the PSA's terms and conditions, but does not address service C. Hospital pays Physician $1,000 for the 10 hours of service A rendered in the prior three months. Hospital does not pay for service B ($1,250) or service C ($2,500) because those services were not covered by a signed writing when they were furnished.
- **July 1-September 30.** Physician (once again) furnishes 10 hours of service A, 10 hours of service B and 20 hours of service C.
- **October 1.** The parties prepare and execute a second amendment to the PSA. The second amendment adds service C at $125 per hour to the PSA's terms and conditions. With respect to the services furnished during the third quarter, Hospital pays Physician $1,000 for service A and $1,250 for service B. Hospital does not pay for service C ($2,500) because those services were not covered by a signed writing when they were furnished.
- **October 1-December 31.** Physician (once again) furnishes 10 hours of service A, 10 hours of service B, and 20 hours of service C.

- **December 31.** The one-year PSA, as twice amended, expires by its terms.
- **January 5** of the new calendar year. Hospital pays Physician for services performed in the last quarter of the prior calendar year: $1,000 for service A, $1,250 for service B and $2,500 for service C. Physician asks Hospital to pay her $1,250 for her performance of 10 hours of Service B in the second quarter of the prior calendar year (April 1 through June 30) and $5,000 for her performance of 40 hours of service C in the second and third quarters of the prior calendar year (April 1 through September 30).

We will tackle this example on a service-by-service basis.

Service A. The direct compensation arrangement between Physician and Hospital relating to service A, and the associated payments for that service, arguably was protected by the FMV Exception for the entire one-year term; that is, the terms and conditions of the service A arrangement were covered by a signed writing (the PSA) from the first day service A was furnished (January 1) through the last day of the PSA's term (December 31). In sum: From January 1 through December 31, Physician furnished 40 hours of service A for which she was paid $4,000; and all of this remuneration appears to be protected under the FMV Exception.

Service B. The direct compensation arrangement relating to service B began on April 1 and ran through December 31. Although these services were furnished in the second calendar quarter (i.e., April 1 through June 30) in the absence of a signed writing, the terms and conditions were (i) agreed to orally on April 1 (and, as such, arguably set in advance as of that date), and (ii) memorialized in a signed writing (i.e., the first amendment) within 90 days of the commencement of the service B arrangement. Arguably, then, this arrangement was protected under the FMV Exception from April 1 through December 31 and, as such, Hospital may (and should) pay Physician $1,250 for performing 10 hours of service B in the second quarter. In sum: From April 1 through December 31, Physician furnished 30 hours of service B for which she was (and/or will be) paid $3,750; and all of this remuneration appears to be protected under the FMV Exception.

Service C. The direct compensation arrangement relating to service C began on April 1 and ran through December 31. The parties cannot rely on the FMV Exception to protect the period from April 1 through September 30, because the Writing and Signature Requirements with respect to service C were not met until October 1 (i.e., more than 90 days after the service C compensation arrangement began). The parties can, however, rely on the FMV Exception from October 1 through December 31. So that takes care of the 20 hours of service C furnished in the fourth quarter and the $2,500 relating to those services. But what about the 40 hours of service C furnished in the second and third quarters and the $5,000 relating to those services? This portion of the Service C arrangement can be protected under the Limited Remuneration Exception provided its various conditions are satisfied (i.e., the $125 per hour is fair market value for service C, etc.).[36]

36 Note that had the parties been forced to rely on the Limited Remuneration Exception to protect the $1,250 in payments for service B furnished in the second calendar quarter, Hospital would have hit the exception's $5,000 cap at some point in the third quarter, resulting (at least potentially) in some out-of-compliance period between July 1 and September 30, with the precise date being that on which Physician furnished her 11th hour of service C.

See *Table* 1 below for as summary of the above.

Table 1

Service/ Payments	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
A	FMV Exception	FMV Exception	FMV Exception	FMV Exception
B	N/A	FMV Exception	FMV Exception	FMV Exception
C	N/A	Limited Remuneration Exception	Limited Remuneration Exception	FMV Exception

A few final points relating to the new Limited Remuneration Exception are worth highlighting:

One-Way/Physicians Only. The Limited Remuneration Exception is circumscribed in two important respects. First, it is a "one-way" exception, applying only to remuneration "from an entity to a physician" and not vice versa. Second, the exception covers arrangements with physicians but not immediate family members (IFMs). This latter carve-out was due, in part, to a concern that "if each [IFM] had a separate annual aggregate remuneration limit under the exception, the sum total of remuneration to a physician and [their IFMs] could be substantial, depending on the number of [IFMs]."[37]

Not All or Nothing. CMS makes it clear in the Final Rule's preamble that the Limited Remuneration Exception may be used to protect just a portion of a compensation arrangement. That is, a DHS Entity may rely on the exception "up to the point in a calendar year immediately prior to when the annual aggregate remuneration limit is exceeded."[38] After that point, the Stark Law's referral and billing prohibitions apply. "For example, if the aggregate payments from an entity to a physician exceed the annual aggregate remuneration limit on April 1 of a given year, the exception is available to protect referrals from January 1 to March 31, but not for referrals from April 1 to December 31."[39]

Protecting Different Types of Arrangements. As CMS notes in the Final Rule's preamble, during any given calendar year, the Limited Remuneration Exception "may be applied to the provision of different types of items or services, including office space and equipment."[40] For example, if, in single calendar year, "a physician is paid $500 for one service, $350 for a separate service, $150 for certain items, and $400 for a short-term lease of equipment," the amount allocated to the annual limit for that year is $1,400.[41]

Standing in the Shoes. If a DHS Entity has a direct compensation arrangement with a physician organization that has two physician-owners, then—through the operation of the "stand in the shoes" rule—each physician will be deemed to have a direct compensation arrangement with the DHS Entity. The parties may use the Limited Remuneration Exception under these circumstances and, if they do, the remuneration at issue will be allocated as follows: "if an entity pays a physician organization $1,000 under [the Limited Remuneration Exception] for lease of the physician organization's equipment, and the physician organization consists of two owners (Drs. A and B) who stand in the shoes of the organization, then $1,000 is counted towards the annual aggregate remuneration limit of both Drs. A and B."[42]

37 85 Fed. Reg. at 77625.

38 *Id.* at 77627.

39 *Id.*

40 *Id.*

41 *Id.*

42 *Id.* at 77626.

Physician Employees. Finally, the Limited Remuneration Exception, by its terms, provides that a "physician may provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice)." As CMS explains in preamble, what this means is that "any payments for items, office space, equipment, or services provided through a physician's employee, wholly owned entity, or locum tenens physician would be counted towards the annual aggregate remuneration limit applicable to the physician." That is, "there are not separate limits for a physician and his or her employees." For example, "if an entity pays a physician $1,000 for personally performed services, $400 for services provided through the physician's employee, and $150 for items provided through the physician's employee, assuming no other previous payments for the calendar year, the sum of $1,550 is counted towards the annual aggregate remuneration limit applicable to the physician."[43]

43 *Id.* at 77625.

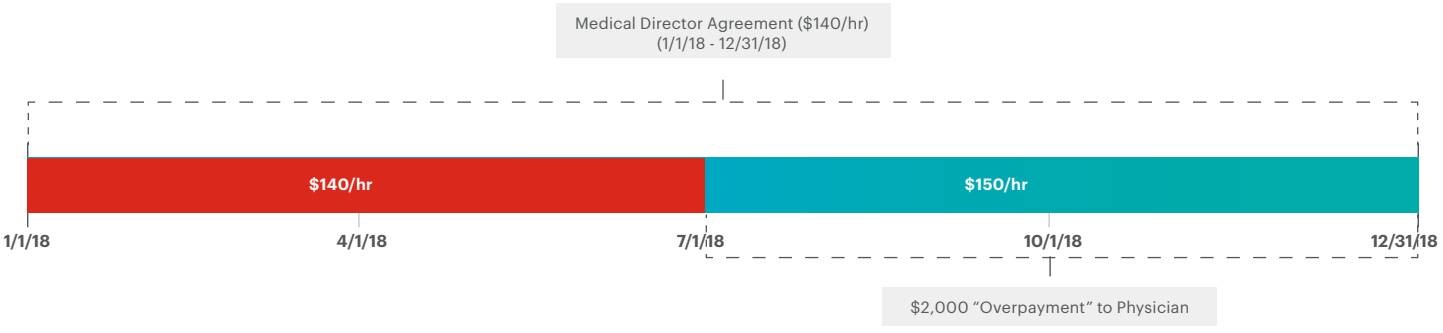
IV. Payment Discrepancies

Finally, and significantly, in addition to (i) making the Signature, Writing, and Set in Advance Requirements more flexible, and (ii) creating the Limited Remuneration Exception as an additional backstop, the Final Rule addresses the closely related issue of whether and how administrative or operational errors may be "cured" so as to avoid out-of-compliance periods. Once again, a hypothetical will be of some assistance. Assume the following:

- Hospital needs a part-time medical director for its Internal Medicine Department. Physician is qualified and interested in the position.
- In December 2017, the parties enter into negotiations, which culminate in a written medical director agreement (MDA) that (i) is signed by both parties on December 31, 2017, (ii) has a start date of January 1, 2018, (iii) has a term of one year, (iv) provides for Hospital to pay Physician $140 per hour for her services, and (v) by its terms, meets all of the conditions of the FMV Exception.
- During the first six months of the MDA (January through June), Physician provides 200 hours of medical director services, and Hospital pays Physician $140 per hour for those services (i.e., the amount provided for in the MDA).
- During the next six months of the MDA (July through December), Physician again provides 200 hours of medical director services. However, Hospital inadvertently pays Physician $150 per hour (i.e., $10 per hour more than is provided for in the MDA). Neither Hospital nor Physician notice the payment discrepancy at the time.
- Because Physician worked and was paid for a total of 200 hours for the July-December period, the total amount of the "overpayment" from Hospital to Physician is $2,000 (i.e., 200 hours x $10 per hour).
- The overpayment is discovered in early January 2019, after the arrangement has expired.

See *Diagram* 3 below.

Diagram 3



Historically, hypotheticals such as this—which are extremely common—have raised a number of thorny issues. For example:

- The parties' "financial relationship" began on January 1, 2018, but when did it end? The term of the MDA ended on December 31, 2018, but is that when the parties' *financial relationship* ended? Does the answer to this question depend on whether and/or when the $2,000 overpayment to Physician is recovered by Hospital?
- Separate and apart from when the parties' financial relationship began and ended, during what portion of this period, if any, was the arrangement *out of compliance* for Stark Law purposes? For example, was the arrangement out of compliance (i) for the last six months of the MDA (i.e., the period for which the Physician was overpaid), (ii) the entire term for of the MDA, (iii) until the $2,000 is repaid, or (iv) for some other period?
- Next, if repayment of the $2,000 may serve to shorten the duration of the parties' financial relationship and/or out-of-compliance period, does the extent of this shortening turn on *when* the overpayment is returned to Hospital?
- Finally, is it *enough* simply to repay the $2,000, or do the answers to any of the above questions turn on whether Physician pays that amount plus interest? Put differently, does the mistaken payment of $2,000 constitute a "loan," such that a full refund would need to include the "time value" of that mistaken payment?

We explore each of these questions below.

A. Payment Discrepancy Special Rule

As a threshold matter, CMS takes the position that, as a general rule (and subject to all applicable grace periods, special rules, etc.), if a physician and DHS Entity have a financial relationship in the form of a direct compensation arrangement, and the only available exceptions have a Writing Requirement, then any period during which the parties' actual *conduct* is not consistent with the terms and conditions of their *writing* is an out-of-compliance period on the ground that during that period, the parties actual arrangement did not meet the Writing Requirement. (Were the case otherwise, CMS observes, the Writing Requirement would be rendered essentially meaningless.)

In our above hypothetical, then, the general rule would point to the following conclusion: The parties' direct compensation arrangement was out of compliance during the second six months of the MDA on the ground that the payments made by Hospital to Physician (i.e., $150 per hour) for services rendered during that period were not consistent with the terms of the MDA (which provided for $140 per hour in compensation) and, as such, the arrangement did not meet the Writing Requirement of the FMV Exception.[44]

Although this represents what historically had been considered the general rule, and although CMS continues to take the position that parties cannot simply "turn back the clock" in order to avoid violations of the Stark Law's referral and billing prohibitions, the agency also states in the Final Rule that it never intended to suggest that "administrative or other operational failures during the course of an arrangement, such as the erroneous payment of excess

44 Note that if Hospital did not actually pay Physician for Physician's July services until August 15, 2018, any inconsistency between the parties writing ($140 per hour) and their actual arrangement ($150 per hour) arguably did not occur until August 15, 2018, possibly shortening the out-of-compliance period by 45 days.

compensation or the erroneous failure to pay the full amount of compensation due during the timeframes established under the terms of an arrangement, would necessarily result in noncompliance" with the Stark Law.[45] Rather, CMS posits, it is the failure to "remedy" such "payment discrepancies" that creates potential Stark Law issues.[46]

More specifically, the agency states that "it is a normal business practice, and a key element of an effective compliance program, to actively monitor ongoing financial relationships, and to correct problems that such monitoring uncovers."[47] As such, an entity that "detects a problem in an ongoing financial relationship" and "corrects the problem while the financial relationship is still ongoing" is addressing a current problem and is not "turning back the clock" to fix past noncompliance.[48] "On the other hand," CMS continues, "once a financial relationship has ended, parties cannot retroactively 'cure' the previous noncompliance by recovering or repaying problematic compensation."[49]

CMS has clarified and memorialized its position in a new "special rule for reconciling compensation," which we'll call the "Payment Discrepancy Special Rule." By its terms, the new Special Rule provides as follows:

> An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—
>
> 1. No later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and
> 2. Except for [such] discrepancies in payments..., the compensation arrangement fully complies with an applicable exception in this subpart.[50]

In the preamble to the Final Rule, CMS discusses the Special Rule's two key terms/phrases: "discrepancies in payments" and "a compensation arrangement." Generally speaking, to constitute a "discrepancy," the overpayment or underpayment at issue must have been the result of "an administrative or other operational error."[51] In other words, the overpayment/underpayment must have been "unintended."[52] (We'll call this the "Unintended Error Condition.") Second, the payment discrepancy must have been identified and any amounts due and owing repaid either (i) during the compensation arrangement to which the payment discrepancy relates or (ii) within 90 days following the expiration or termination of that compensation arrangement. (We'll call this the "90-Day Condition.")

In our above hypothetical, then, as long as (i) Hospital did not "intend" to overpay Physician during the second six months of the MDA, and (ii) the $2,000 at issue is repaid by Physician within 90 days of the expiration of the MDA, the conditions of the Payment Discrepancy Special Rule will be satisfied. As a result, the parties will have successfully "cured" what otherwise might have been a failure to comply with the Writing Requirement of the FMV Exception from July 1 through December 31, 2018.

Not surprisingly, perhaps, there are a number of open questions relating to the Payment Discrepancy Special Rule. We discuss several of these below.

1. Unintended Error Condition

With respect to the Unintended Error Condition, what does it mean exactly for a payment discrepancy to be "unintended"? In the Final Rule's preamble, CMS suggests that one way in which a payment discrepancy would meet the Unintended Error Condition is if it

45 85 Fed. Reg. at 77581.

46 *Id.*

47 *Id.*

48 *Id.*

49 *Id.*

50 42 C.F.R. § 411.353(h).

51 85 Fed. Reg. at 77582.

52 *Id.* at 77582-83.

was "due to a typographical error entered into an accounting system."[53] In our hypothetical, for example, if someone at Hospital inadvertently typed "$150" instead of "$140" into the facility's accounting system, and it was this keystroke error that caused Physician to be paid $150 per hour for services furnished as of July 1, 2018, this would satisfy the Unintended Error Condition.

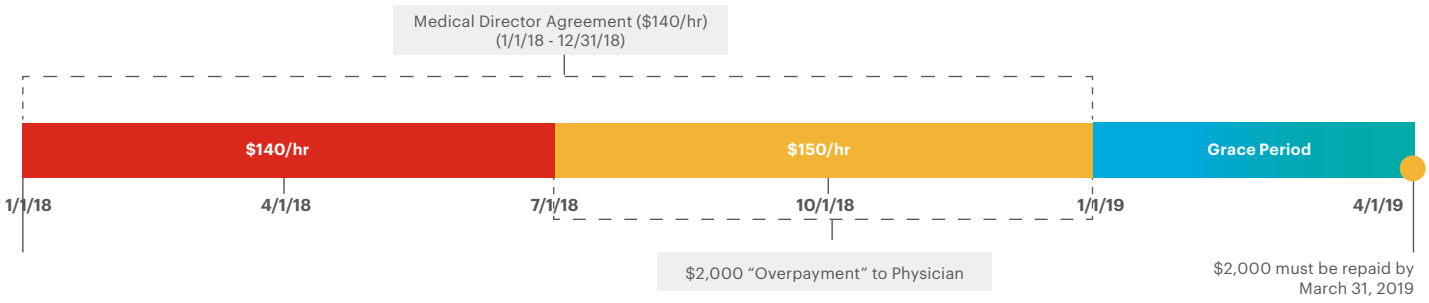
While presumably this is not the *only* type of error that qualifies for protection, CMS does not, unfortunately, provide any additional examples in either the Proposed or Final Rules. In the context of our hypothetical, however, a reasonable interpretation of the agency's position would be this: If a Hospital employee or contractor knew (i.e., had actual knowledge) that the MDA provided for Physician to be paid $140 per hour and—notwithstanding such knowledge—made the affirmative decision to pay Physician $150 per hour anyway, the Unintended Error Condition would not be satisfied. If, on the other hand, the payment discrepancy was, to use CMS's words, the result of an "administrative or operational error" or otherwise "unintended," then the Unintended Error Condition would be satisfied.

CMS's failure to unpack the Unintended Error Condition further—and/or confirm an interpretation along the lines of that offered above—is frustrating for several reasons, not least of which is the fact that we've been down this road before. As discussed above, for a time, whether parties had 30 or 90 days to meet the Signature Requirement turned on whether their failure to obtain signatures in a timely manner was "inadvertent." If so, the parties had a 90-day grace period; if not, they had a 30-day grace period. This standard proved virtually impossible to apply in practice and was ultimately abandoned by CMS. The Unintended Error Condition, with its focus on whether or not an "error" was "intended"—phraseology that itself has an Alice in Wonderland-ish quality to it—threatens to be equally difficult to administer.

2. 90-Day Condition

Assuming the overpayment or underpayment meets the Unintended Error Condition, what does it mean for a payment discrepancy to be resolved within 90 days of the expiration or termination of "a compensation arrangement"? In our hypothetical, the MDA has a one-year term, expiring on December 31, 2018. Thus, in order to satisfy the 90-Day Condition, the $2,000 at issue would have to be repaid to Hospital on or before March 31, 2019. See *Diagram* 4.[54]

Diagram 4



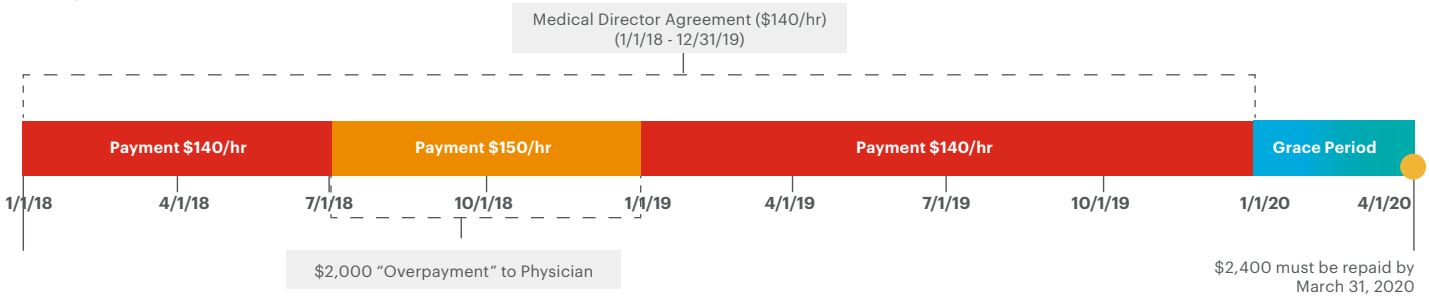
53 *Id.* at 77581.

54 One head-scratcher CMS does not address is this: What if Hospital pays Physician for the services furnished from July 1, 2018 through December 31, 2018—which payment includes $2,000 more that it should due to the $150 v. $140 payment discrepancy—on April 15, 2019 (i.e., well after end of the one-year "term" of the MDA)? Did the 90-day period end on March 31, 2019 meaning that even if Physician repays hospital the same day they receive the overpayment (April 15, 2019), that's too late? Or does the 90-day clock only *begin* to run on April 15, when the last payment for services covered by the arrangement is made, in which case Physician would have until mid-July to repay Hospital.

a. Multi-Year Arrangements

Suppose that the MDA had a two-year term instead of a one-year term. That shouldn't change the analysis: We still have "an" arrangement; it just ends on December 31, 2019 instead of December 31, 2018. Thus, instead of the $2,000 repayment being due on or before March 31, 2019, it's due on or before March 30, 2020 (because 2020 was a leap year). See *Diagram* 5.

Diagram 5



Nor, presumably, is there any particular magic to the length of the arrangement more generally. That is, whether the MDA has a one-, two-, five- or ten-year term should not alter the analysis. And, with one possible exception (discussed in Section IV.B. below), CMS says as much in the Final Rule.[55]

55 85 Fed. Reg. at 77583-84.

b. Auto-Renewal

Next, what if our MDA doesn't have a two-year term but instead has an original term of one year and provides for the agreement to automatically renew for one additional 12-month period unless either party objects on or before October 1, 2018? Once again, this should not change the result. That is, assuming the MDA does in fact auto-renew for an additional year, CMS presumably would not take the position that this renewal resulted in the creation of two "arrangements"—one covering 2018 and one covering 2019 and, as such, that the $2,000 overpayment must be returned within 90 days of the first arrangement (i.e., by March 31, 2019) and not within 90 days of the second arrangement (i.e., by March 30, 2020). And, once again, the logic of this rule also would apply to arrangements that auto-renew for multiple one-year (or other) periods.

c. Other Renewal

Next, what about an agreement that does not, by its terms, provide for auto-renewal but, nevertheless, is in fact renewed or extended by the parties? In our hypothetical, for example, assume that Hospital and Physician decide mid-way through the term of the MDA to extend it for a second year (and execute an amendment to that effect). Once again, logic suggests that this should not change the analysis. That is, *how* the term of the MDA is extended—i.e., pursuant to an auto-renewal provision in the agreement at the time of execution or pursuant to the subsequent negotiations of the parties—should not alter the fact that there still is only one "arrangement" (covering both 2018 and 2019) and not two "arrangements" (one covering 2018 and a second covering 2019).

d. Holdover Arrangements

Similarly, what about a personal services arrangement that, by its terms, expires at the end of a one-year term, but is extended through the parties' conduct pursuant to (and in compliance with) the holdover arrangement provisions set forth at 42 C.F.R. § 411.357(d)(vii)? Here, too, it appears that the analysis should hold. In other words, if an arrangement that was originally intended to last 12 months continues through month 15 in compliance with the applicable holdover provisions, logic suggests that even absent an amendment memorializing the extension of the term of the arrangement, months 13 through 15 would be treated as part of the same arrangement that existed in months 1 through 12.

e. Other Amendments

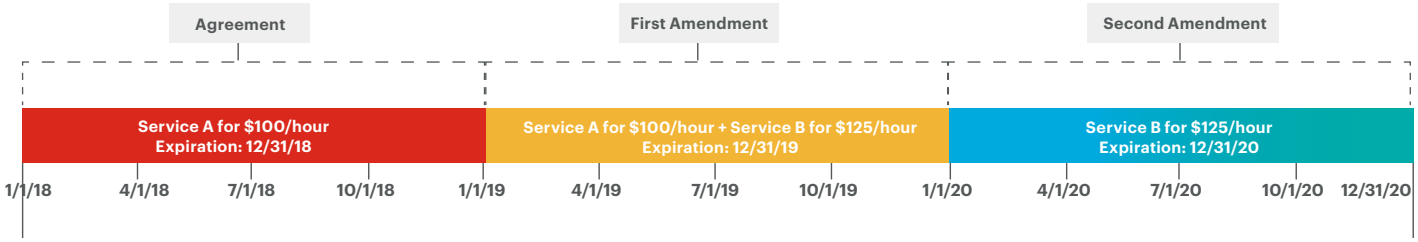
A final question is this: Is there any point in time at which what otherwise would be considered one continuous arrangement for purposes of the 90-Day Condition will become two (or more) distinct arrangements due to a changes in the parties' arrangement that are unrelated to the length of its term? Assume for example, the following:

- **January 1 through December 31, 2018 (Year One).** Hospital and Physician enter into an agreement (PSA) with a term of one year. Pursuant to the PSA, which is effective on January 1, 2018, Physician agrees to furnish service A for $100 per hour.
- **January 1 through December 31, 2019 (Year Two).** In October 2018, the parties amend the PSA (First Amendment). Pursuant to the First Amendment, which is effective January 1, 2019, the term of the PSA is extended by one year. None of the other terms of the PSA are changed with one exception: In addition to furnishing service A for $100 per hour, Physician also agrees to furnish service B for $125 per hour.

- **January 1 through December 31, 2020 (Year Three).** In October 2019, the parties amend the agreement a second time (Second Amendment). Pursuant to the Second Amendment, which is effective January 1, 2020, the term of the PSA again is extended by one year. None of the other terms of the PSA are changed with one exception: Physician will no longer furnish service A under the PSA. Physician will, however, continue to furnish service B for $125 per hour.

See *Diagram* 6.

Diagram 6



Do the services and compensation exchanged between Hospital and Physician between January 2018 through December 31, 2020 constitute one, two or three "arrangements" for purposes of the 90-Day Condition? This matters, of course, because whether the 90-day grace period for payment discrepancies expires on March 31, 2019, March 31, 2020, or March 31, 2021 turns on the answer to this question.

Unfortunately, CMS does not specifically address this issue in either the Proposed or Final Rules. The agency focuses on the broad term "arrangement," however, and that generally consists of the exchange of *any* type of items or services. Further, it is extremely common for parties to modify their arrangement over time to add or remove items and services to be furnished thereunder or to change the compensation amounts for those items and services. Indeed, to ensure that an arrangement provides for compensation that is consistent with fair market value, parties often *must* modify the payment terms of their arrangement in order to qualify for continued protection under a Stark Law exception.

Under these circumstances, the better argument appears to be this: As long as the parties have a continuous (i.e., unbroken) arrangement, that arrangement will be considered a *single* arrangement for purposes of triggering the grace period under the 90-Day Condition—and this is true irrespective of whether the parties modify (i) the term of the arrangement, (ii) the items and/or services to be furnished under the arrangement, or (iii) the compensation to be exchanged therefore.

Assuming this is correct, if, in our above hypothetical with the three-year term, Hospital overpaid Physician with respect to service A during Year 1, and this overpayment satisfies the Unintended Error Condition, then Hospital would have until March 31, 2021 (i.e., 90 days following the end of Year 3) to recover this overpayment, and this is true notwithstanding the fact that in Year 3, when the Year 1 error was discovered, Physician no longer was furnishing service A under the PSA.

B. The "Loan" Issue

Another question that historically has arisen is this: Are there circumstances under which *one* financial relationship (involving a "payment discrepancy") becomes *two* financial relationships (involving both a payment discrepancy and a "loan")? For example, assume Hospital and Physician have a compensation arrangement that lasts for 15 years. In the second year of the arrangement the parties discover that Hospital overpaid Physician in the amount of $10,000. Although the discrepancy was identified in the second year of the arrangement, it is not repaid until 10 years later (when the arrangement is in its 12th year). It is undisputed that the payment discrepancy itself was unintended and the overpayment was collected during the term of the

parties' arrangement. In other words, it is undisputed that the Payment Discrepancy Special Rule applies to the $10,000 overpayment. So, with the repayment of the $10,000, haven't the parties extinguished all potential Stark Law liability emanating from the overpayment? The short answer is "not necessarily," but, unfortunately, that's about all we know.

In the preamble to the Final Rule, CMS notes that some commenters complained that the Payment Discrepancy Exception favors parties to long-term arrangements, because the parties may "discover an error in the first few months" but "not have to correct it until the end of the arrangement," years later.[56] Parties to short-term arrangements, on the other hand, must act much more quickly "in order to maintain compliance with the physician self-referral law."[57] In response, CMS stated that the assumption that parties may "discover an error in the first few months of a long-term arrangement and suffer no consequences" if "they wait until the end of the arrangement to reconcile the discrepancies is incorrect."[58]

> Although the [Payment Discrepancy Special Rule]... allows an entity to avoid violating the billing prohibition of the [Stark Law] if the parties reconcile all payment discrepancies under their arrangement within 90 consecutive calendar days following the expiration or termination of the arrangement, parties that fail to reconcile known payment discrepancies risk establishing a second financial relationship (for example, through the forgiveness of debt or the provision of an interest-free loan) that must satisfy the requirements of an applicable exception in order to avoid the prohibitions of the physician self-referral law.[59]

Under what circumstances will such "risk" arise? The agency is vague, simply stating that if the payment discrepancy is "significant enough" it may "give rise to a separate financial relationship," which "must satisfy the requirements of an applicable exception once it exists."[60] Assuming the "significant enough" test is met, the "commencement date of the second financial relationship" will depend on the "facts and circumstances," such as "the amount of excess compensation or unpaid compensation and how long the known overpayment or underpayment of the compensation has continued."[61] For example, "a large amount of excess compensation that is not recovered may give rise to a financial relationship in a shorter amount of time than a very small amount of unrecovered excess compensation or unpaid compensation."[62]

> Thus, even if the entity is deemed not to have violated the [Stark Law's] billing prohibition once the original compensation arrangement is ultimately reconciled, the entity would be prohibited from submitting a claim or bill for a designated health service referred by the physician beginning at the point where the second financial relationship exists.[63]

Given these statements by CMS, in our above hypothetical, there is a "risk" that, depending on the "facts and circumstances," the $10,000 overpayment to Physician may, at some point in time, have triggered the beginning of a new financial relationship—in the form of a loan by Hospital to Physician. Whether such a second financial relationship will be created and, if so, when it will begin are unclear. What is clear, however, is that if such a financial relationship is created, CMS takes the position that it will not be protected by the parties' satisfaction of the conditions of the Payment Discrepancy Special Rule. Thus, unless and until CMS provides some clearer guidance, best practices are to resolve payment discrepancies as quickly as possible, whether they arise in connection with a short- or long-term arrangement.

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56 *Id.* at 77584.

57 *Id.*

58 *Id.*

59 *Id.*

60 *Id.* at 77584-85. The agency's vague reference to an amount that is "significant enough" is particularly unhelpful given that in every other respect, the Stark Law does not provide for a *de minimis* amount exception or carve-out. To the contrary, the Stark Law statute defines a compensation arrangement in terms of an arrangement between a physician and an entity "involving *any remuneration*." 42 U.S.C. § 1395nn(h)(1)(A) (emphasis added).

61 85 Fed. Reg. at 77585.

62 *Id.*

63 *Id.*

V. Conclusion

The changes in the Final Rule supplement CMS's efforts over the years to soften the impact of the Stark Law by addressing technical requirements, low-dollar violations, and payment discrepancies. Like its previous efforts, however, the agency has left many open questions, particularly surrounding the new Payment Discrepancy Special Rule. Remaining white papers and webinars in our series, *Stark Law Overhaul: An In-Depth Review of CMS's New Final Rule*, will delve into 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.

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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: Technical Requirements, Low-Dollar Violations, and Payment Discrepancies
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

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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*.

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