大成 DENTONS

# Stark Law Overhaul

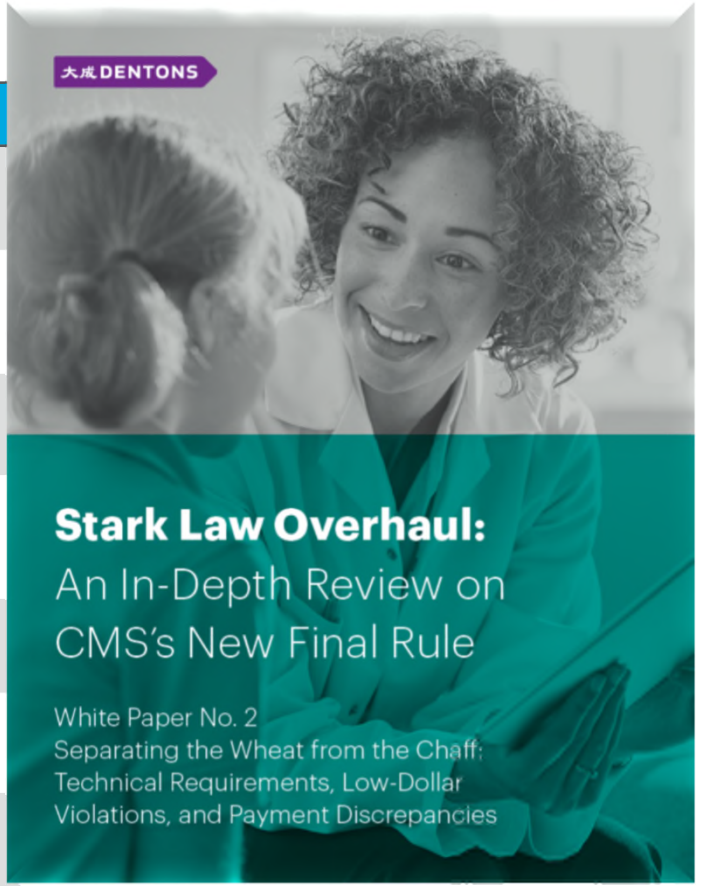
## An In-Depth Series on CMS's New Final Rule

# Webinar 2

# Separating the Wheat From the Chaff: Technical Requirements, Low-Dollar Violations, and Payment Discrepancies

# Stark Law Overhaul Series

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



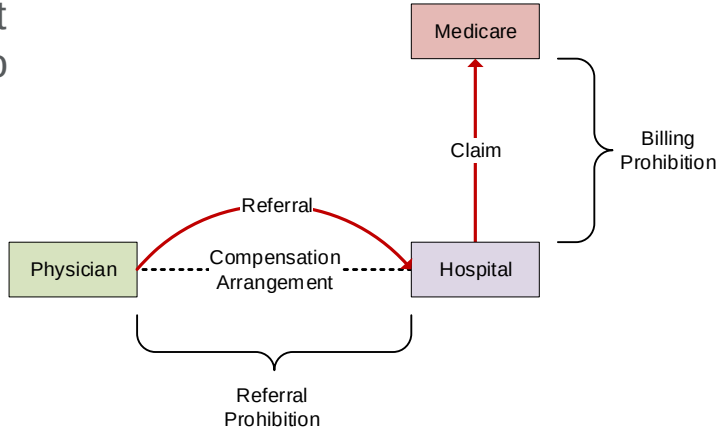
# Agenda

- Background
- Technical Requirements
  - Signature Requirement
  - Writing Requirement
  - Set in Advance Requirement
- Limited Remuneration to a Physician Exception
- Payment Discrepancy Special Rule
- Q&A

# Background

# The Problem of Over-inclusiveness

- The Stark Law is a strict liability statute that makes a wide swath of conduct **presumptively** unlawful.
- Parties can only **rebut** this presumption by establishing that their arrangement (or the services at issue) fit **squarely** into a Stark Law exception.
- This might make sense if there was a direct and reliable correlation between (i) a particular arrangement failing to meet every single condition of an exception and (ii) that same arrangement implicating the Stark Law's policy objectives—but often there is no such correlation.
- Most arrangements get tripped up on one or more technical requirements of an exception, and **there is no correlation between a failure to meet a technical requirement and the likelihood of overutilization, patient steering, etc**.



# Example: FMV Exception

## Principal Substantive Requirements

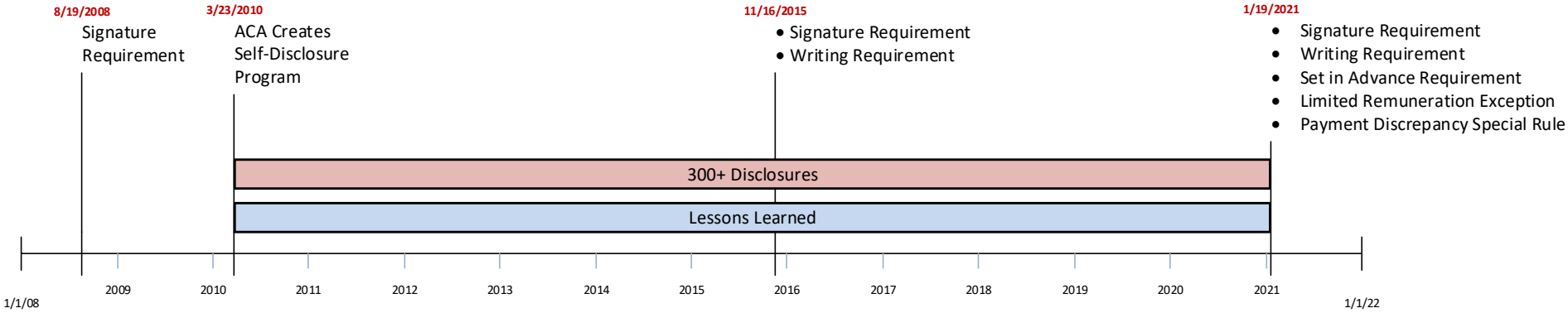
- Compensation must be "consistent with **fair market value**."
- Compensation must not be "determined in any manner that takes into account the **volume or value of referrals** or **other business generated** by the referring physician."
- Arrangement "would be **commercially reasonable** even if no referrals were made between the parties."

## Technical Requirements

- Arrangement must be "**in writing**" that specifies (i) the "services covered under the arrangement," (ii) the "compensation that will be provided under the arrangement," and (iii) the "timeframe for the arrangement."
- Arrangement must be "**signed by the parties**."
- Compensation must be "**set in advance**."

# Timeline

Beginning in 2008, accelerating in 2015, and continuing through the Final Rule in 2020, CMS has taken a number of important steps to reduce the number of arrangements that violate the Stark Law based on technical irregularities that do not materially implicate any of the statute's public policy objectives.

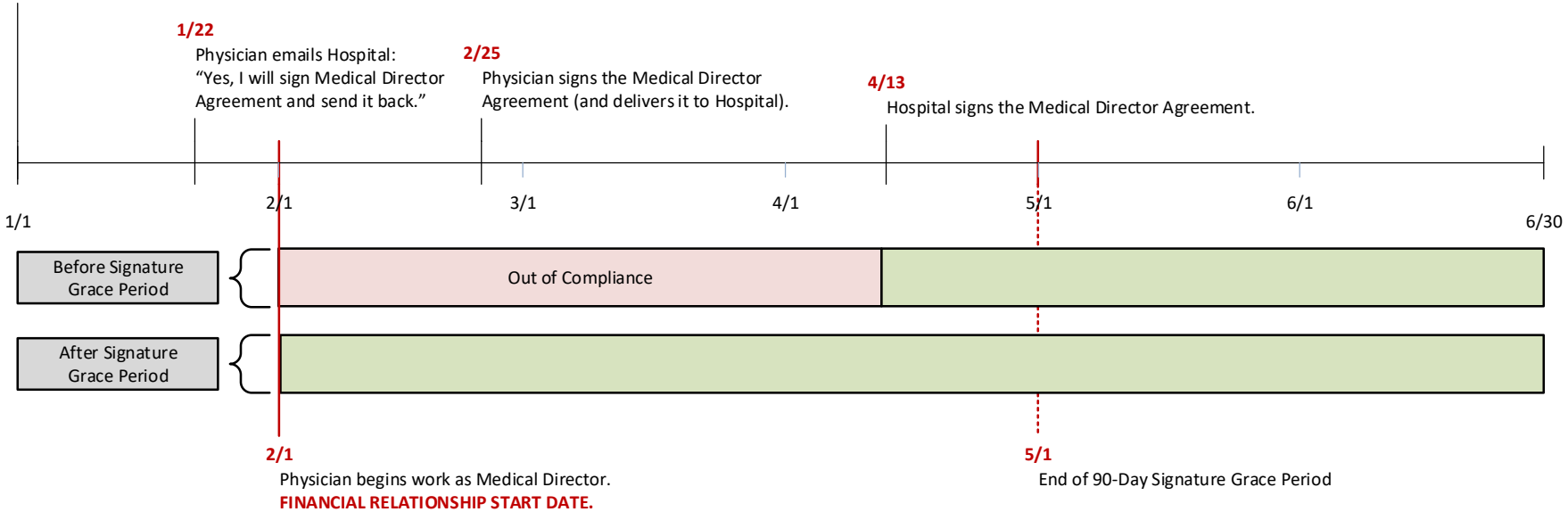


# Technical Requirements: Signature Requirement

# When Does the Signature Requirement Have To Be Met?

**1/1**

Hospital emails Physician: "Would you be interested in becoming the Medical Director of the 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. Apologies for the rush!"



# What is the Relationship Between the Signature and Writing Requirements?

- **Best practice:** Satisfy all conditions of Writing Requirement **before** obtaining signatures necessary to satisfy Signature Requirement.
- But it's not clear that's actually **required**.
- In 2015, CMS provided in preamble that a signature will satisfy the Signature Requirement if:

  [1] the signature is "on a contemporaneous writing documenting the arrangement" and

  [2] 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."

- See White Paper for a hypothetical.

# What is a “Signature”?

- Traditional “wet” signature.
- Anything else?
  - Email?
  - Email with a “signature block” (e.g., name, title, contact information)?
- For a number of years, CMS has suggested (in preamble) that an “electronic signature” might suffice.
- In the Final Rule, CMS codified this “longstanding policy” in a new special rule that defers to federal and state law regarding electronic signatures.

## Signature Requirement Special Rule

“In the case of any signature requirement in this subpart, such requirement may be satisfied by an [1] **electronic** or [2] **other signature** that is **valid under applicable Federal or State law**.”

# Technical Requirements: Writing Requirement

# Substance of Writing

- There “is no requirement … that an arrangement be documented in a single formal contract.”
- Depending on the facts and circumstances, “a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties,” may suffice.

## Examples

- Written communications between parties (e.g., email)
- Meeting minutes
- Documents authorizing payment for services
- Fee schedules
- Call coverage schedules
- Accounts payable records
- Accounts receivable records
- Time sheets
- Invoices
- Check requests
- Checks

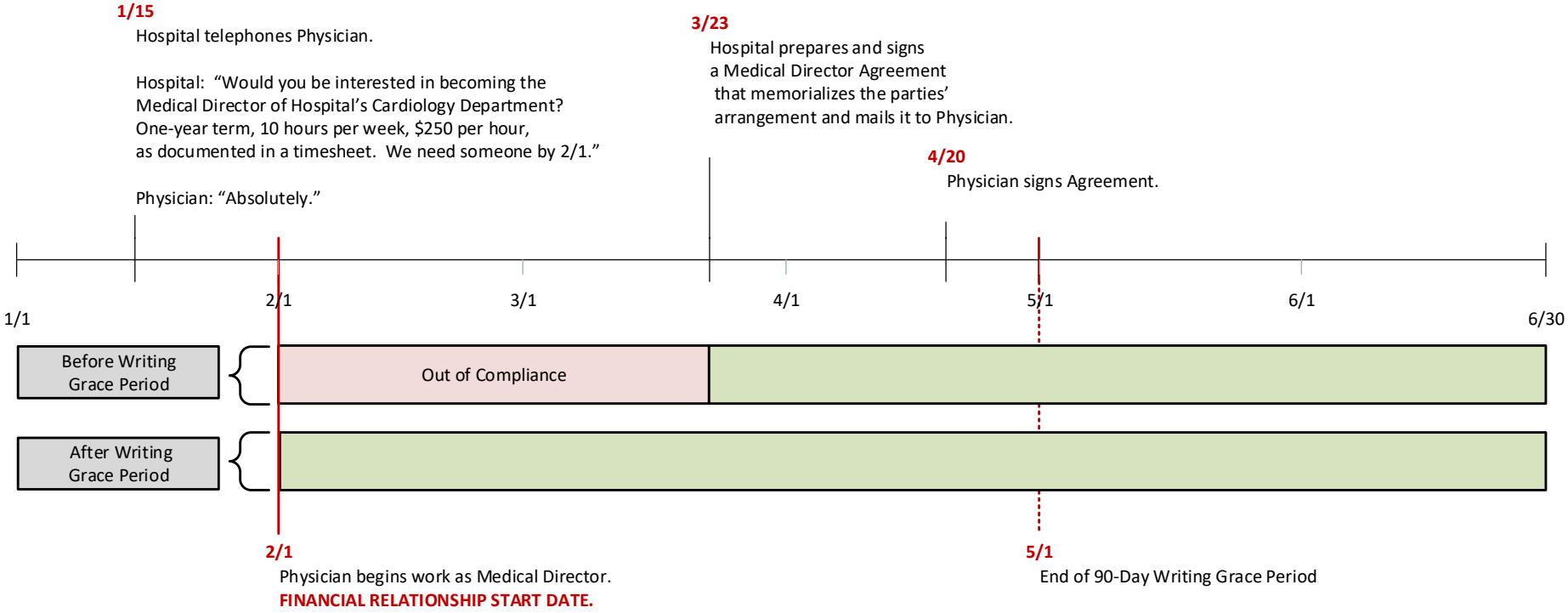
# Timing of Writing

- Importantly, Final Rule creates a brand new **Writing Requirement Grace Period**.
- Grace period for Signature Requirement dates back to 2008.
- CMS reluctant to adopt a similar grace period for Writing Requirement.
- In the Final Rule, CMS finally broke down. (*See* box text.)
- Let's apply the new grace period to a hypothetical.

## Writing Requirement Grace Period

Writing Requirement will be met as long as (i) the compensation arrangement at issue "fully complies with an applicable exception" in every other respect 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").

# Hypothetical



# Technical Requirements:
# Set in Advance Requirement

# Background

- A number of exceptions require compensation paid by DHS entity to physician, for example, to be "set in advance." We refer to this as the **Set in Advance Requirement**.
- In most cases, whether the Set in Advance Requirement is met is straightforward.
  - If Hospital and Physician execute a written agreement on January 1 pursuant to which (i) Physician will furnish medical director services for one year starting on February 1 and (ii) Hospital will pay Physician $60,000 for those services in 12 monthly installments of $5,000, the compensation ($60,000 per year), which is set forth in a signed writing on January 1, is clearly "set in advance" of the parties compensation arrangement, which begins February 1.
- But three questions have arisen over time, relating to:
  - What **types** of compensation are considered "set in advance"?
  - Does the compensation at issue have to be reduced to **writing** before the compensation arrangement begins in order to be considered "set in advance"?
  - Can parties **modify** compensation during the term of an arrangement and still meet the Set in Advance Requirement? And, if so, under what circumstances?

# Set In Advance Special Rule

- The following types of compensation are "**deemed**" set in advance **if set out in writing** at the outset of the arrangement.

## Aggregate Compensation

- Hospital pays Physician $60,000 per year for medical director services.

## Time-Based

- Hospital pays Physician $150 per hour for consulting services.

## Per Unit or Per Service

- Hospital pays Physician $200 for each Procedure X Physician performs.

## Specific Formula

- In exchange for Service X, Hospital pays Physician 10% of collected revenues for Service X

# Set In Advance Special Rule (cont'd)

- In the Final Rule, CMS notes the writing(s) that can be used to demonstrate compliance with the Set in Advance Special Rule are as broad as those that can be used to demonstrate compliance with the Writing Requirement.
- They include "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."

# To Be “Set in Advance” Must the Compensation Terms Be in Writing?

- The Final Rule makes clear that the answer is “**no**,” other than for modification/amendment of compensation terms (see next slide).
  - If the compensation terms are in writing at the outset of the arrangement they generally will be “deemed” set in advance (under the Set in Advance Special Rule).
  - But even compensation terms that are not “**deemed**” set in advance may still **be** “set in advance.”
- In the absence of a writing, whether compensation is “set in advance” will depend on the facts and circumstances.
  - According to CMS, “compensation 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.”
- **Be careful:** 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 (e.g., the Writing Requirement).
  - So best practices are to reduce compensation terms to writing as soon as possible, or at least within 90 days.

# Can You Modify Compensation Terms?

- The Final Rule makes clear the answer is "**yes**." Although CMS previously suggested as much in preamble, in the Final Rule, the agency codifies—and significantly liberalizes—its position in the regulations themselves.
- Under the new rule, the compensation or formula may be modified **at any time during the course of a compensation arrangement**" if three requirements are met:
  1. All requirements of an applicable exception are satisfied as of the effective date of the modified compensation or formula.
  2. 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."
  3. 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**."
- **Important**: "[T]here 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."

# Limited Remuneration To A Physician Exception

# Background

- Notwithstanding significantly increased flexibility 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 of these technical requirements, but that do not necessarily pose a material risk of program or patient abuse.
- CMS provides an example in the Final Rule.

> *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.*

# Background

- In essence, CMS recognized that over and above the flexibilities it has introduced with respect to the Stark Law's technical requirements, DHS entities still found themselves needing "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."
- Given that arrangements such as this are "unlikely to cause overutilization or similar harms to the Medicare program," CMS created a new **Limited Remuneration To A Physician Exception**.

# Conditions

- 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**," provided four conditions 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."
  4. If the remuneration "is conditioned on the physician's referrals to a particular provider, practitioner, or supplier," the arrangement satisfies the directed referral requirements set forth in Section 411.354(d)(4).
- If arrangement involves "lease"/"use" of space/equipment, the parties may not use percentage- and unit-based compensation formulas.

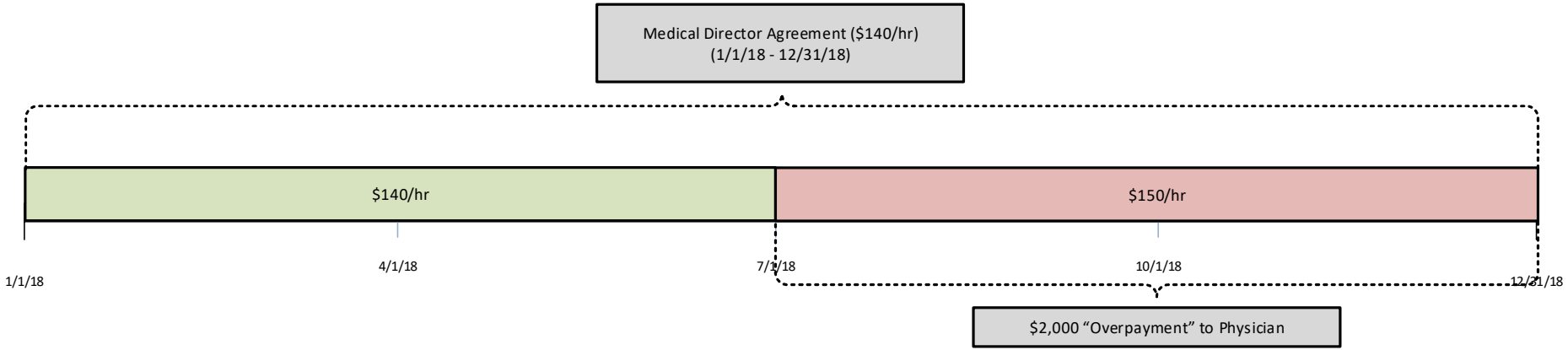
# Notes

- **One-Way**. Protects payments by DHS Entity to physician but not vice versa.
- **Physicians Only**. Protects payments to physician but not immediate family members (IFMs).
- **Cap Adjusted Annually**. $5,000 cap applies to 2021; it will be adjusted annually for inflation.
- **Flexible**. The exception essentially is an "account" or "fund" that can be "drawn down" each year to protect (i) part of one arrangement, (ii) an entire arrangement, or (iii) multiple arrangements. CMS example: if "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.
  - Protection attaches for as long as $5,000 cap is not exceeded, even if arrangement remains non-compliant under other exceptions after $5,000 is exhausted.
  - Exception may be combined with other exceptions.
- **SITS**. If a DHS entity "pays a physician organization ["PO"] $1,000 under [the Limited Remuneration Exception] for lease of the [PO]'s equipment, and the [PO] 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."

# Payment Discrepancy Special Rule

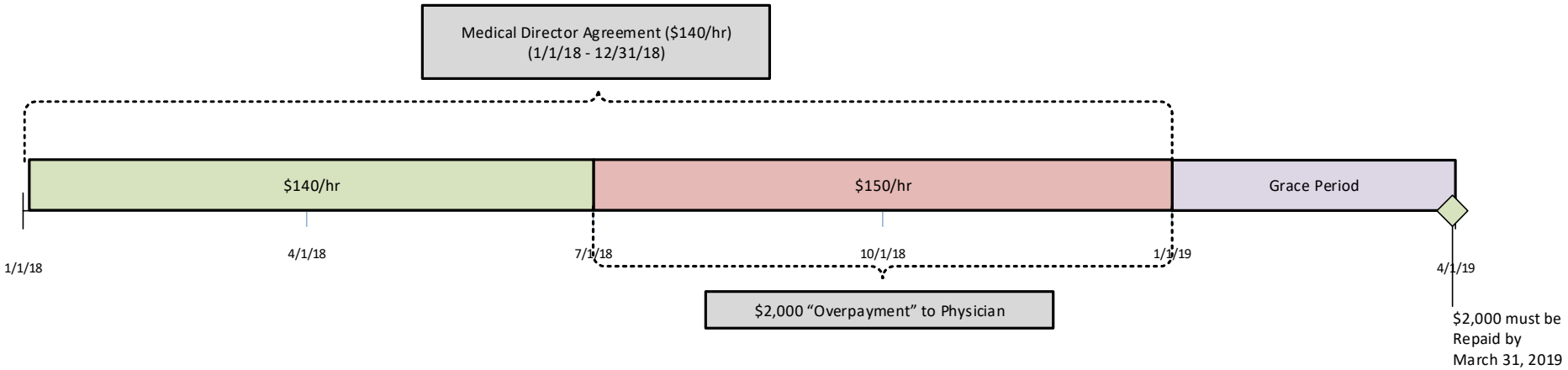
# Background

- 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. We'll use a hypothetical to guide our discussion.



# New Payment Discrepancy Special Rule Conditions

- **Unintended Error Condition**. Overpayment/underpayment must have resulted from "an administrative or other operational error"—i.e., it must have been "unintended."
- **90-Day Condition**. The discrepancy must have been identified and any amounts due and owing repaid within 90 days of the expiration/termination of compensation arrangement.

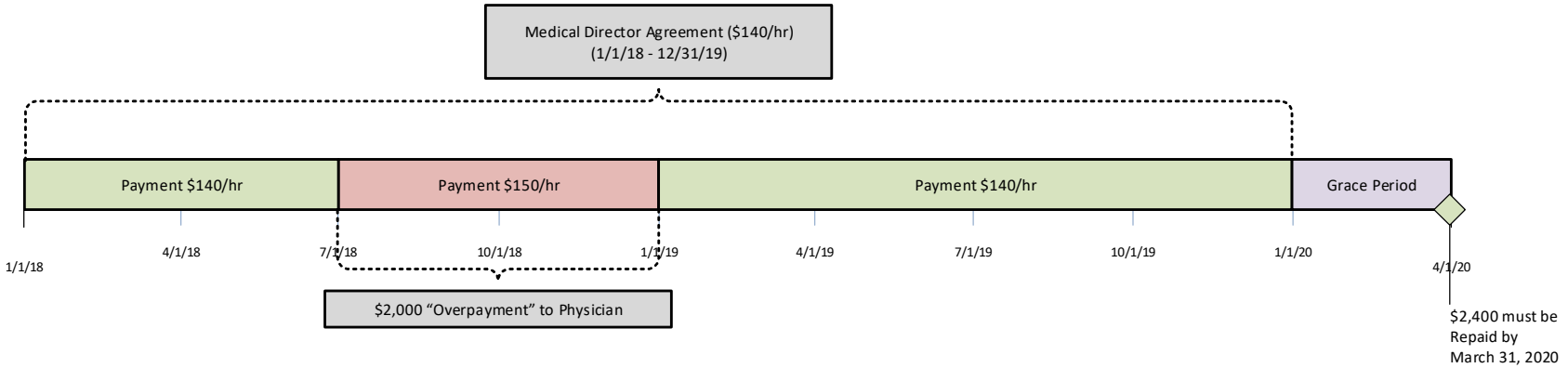


# Unintended Error Condition

- What does it mean exactly for a payment discrepancy to be “unintended”?
- CMS suggests one way: the payment discrepancy is “due to a typographical error entered into an accounting system.”
- But what else would qualify? CMS doesn’t provide any additional examples, but in the context of our hypothetical, 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 Medical Director Agreement 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.
- Hopefully, CMS will confirm this, or a similar interpretation, in the near term.

# 90-Day Condition

- What does it mean for a payment discrepancy to be resolved within 90 days of the expiration or termination of “a compensation arrangement”?
- How does the rule apply to multi-year arrangements?



# 90-Day Condition

- What about:
  - Arrangements that auto-renew?
  - Arrangements that do not auto-renew but are extended by the parties?
  - Arrangements that are extended consistent with the Stark Law's holdover arrangement provisions?
  - Arrangements that are subject to amendments unrelated to the arrangement's start and end dates (i.e., term)?
- Presumably the rule is as follows: 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 under the arrangement.
- Once again, hopefully, CMS will confirm this in the near future.

# Q&A

# Speaker Contact Information


Gadi Weinreich
Partner
D+1 202 408 9166
gadi.weinreich@dentons.com



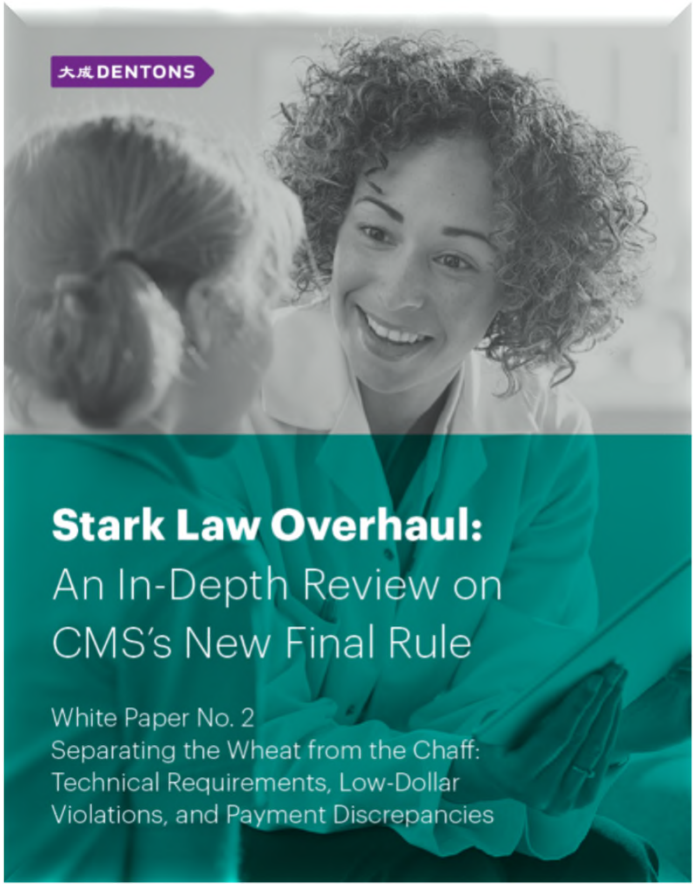
Christopher G. Janney
Partner
D+1 202 408 9151
christopher.janney@dentons.com



Samantha Groden
Senior Managing Associate
D+1 415 882 5056
samantha.groden@dentons.com



Margo Wilkinson Smith
Associate
D+1 202 408 9149
margo.smith@dentons.com

# Thank you

**Dentons US LLP**
1900 K Street NW
Washington, DC 20006
United States

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. www.dentons.com.