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Stark Law Overhaul

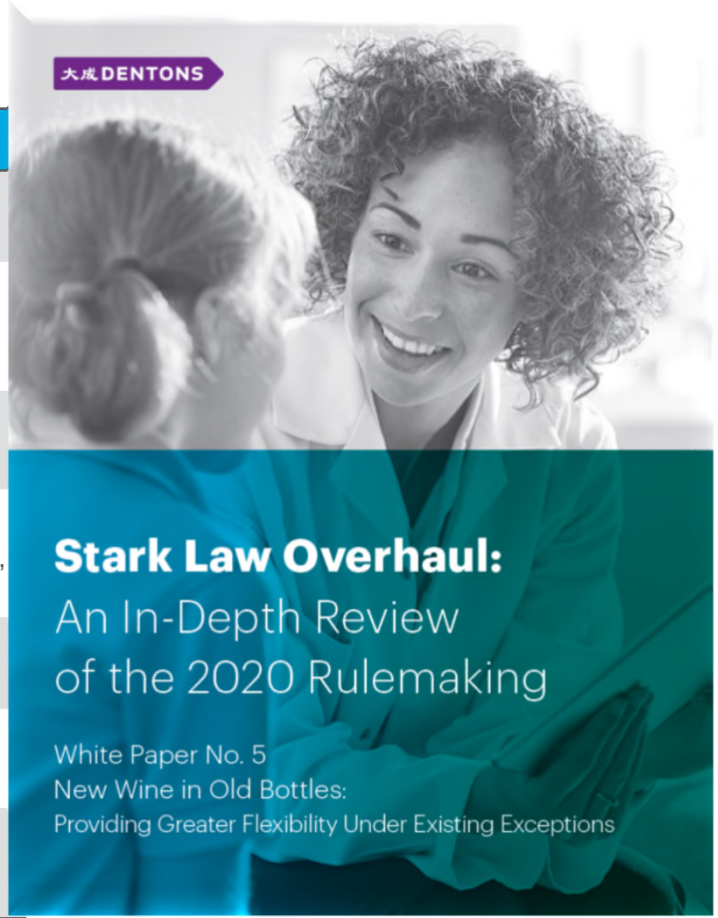
An In-Depth Series on CMS's New Final Rule

Webinar 5

New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions

Stark Law Overhaul Series

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



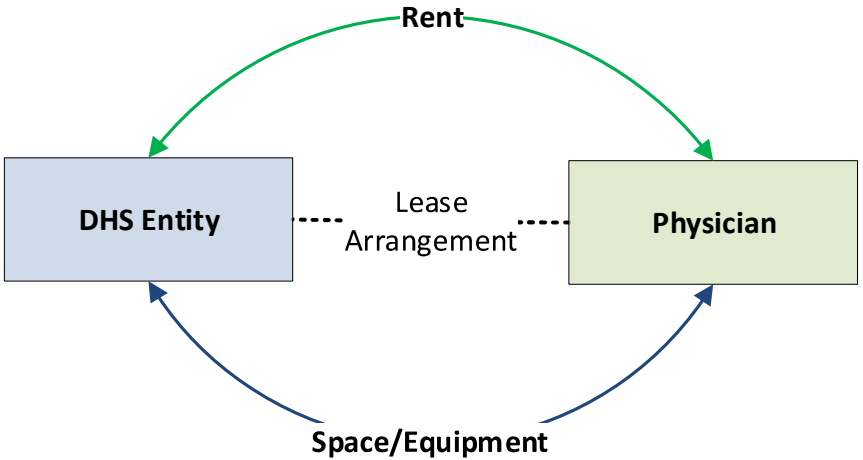
Agenda

- Space Rental Exception
- Equipment Rental Exception
- FMV Exception
- Recruitment Exception
- NPP Exception
- Unrelated to DHS Exception
- Physician Payments Exception
- Isolated Transactions Exception
- In-Office Ancillary Services Exception
- Q&A

Space and Equipment Rental Exceptions

Key Conditions

- Arrangement is set out in writing.
- Signed by the parties.
- Specifies the premises or equipment covered by the lease.
- Has a term of at least one year.
- Compensation is set in advance and consistent with fair market value.
- Space or equipment subject to the lease must be used ***exclusively*** by the lessee (“Exclusive Use Requirement”).



Exclusive Use Requirement

- Included in both statutory and regulatory versions of Exceptions
  - Intended to prevent “paper” or “sham” leases
- In 2004, CMS clarified that purpose of Requirement is to preclude **lessor** sharing space/equipment with **lessee**
  - Regulation amended to stipulate that the rented office space or equipment may not “be shared with or used by the lessor or any person or entity related to the lessor” when the lessee is using the office space or equipment.
  - Despite clarification, questions persisted: e.g., could multiple lessees share the leased space/equipment?

Final Rule

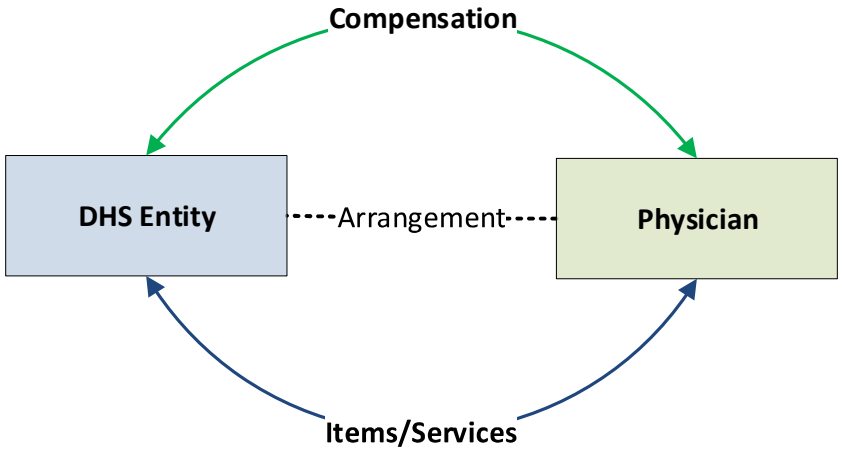
“Exclusive Use” means that the lessee (**and any other lessees of the same office space or equipment**) uses the office space or equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space or equipment.

FMV Exception

Key Conditions (Historically)

1. Arrangement is in writing, signed by the parties, covers only identifiable items or services.
2. Specifies the time frame (may be for any period of time and renewed any number of times).
3. Compensation set in advance and consistent with Volume/Value and FMV Standards.
4. Arrangement is commercially reasonable.
5. Arrangement does not violate AKS or any law governing billing or claims submission.
6. Services do not involve counseling or promotion of activity that violates any law.

NOTE: Expressly excludes space rentals (unclear whether equipment rentals excluded).



Change 1: Expansion/Clarification Regarding Lease Arrangements

Pre-Final Rule	Final Rule
Compensation resulting from an arrangement between an entity and a physician … for the provision of items or services **(other than the rental of office space)** by the physician… to the entity, or by the entity to the physician…	Compensation resulting from an arrangement between an entity and a physician … for the provision of items or services **or for the lease of office space or equipment** by the physician … to the entity, or by the entity to the physician…

- **Rental of Office Space Expansion**
  - No exclusive use requirement (but CMS retains AKS condition as substitute safeguard).
  - No one year term requirement (but parties may not enter into more than one arrangement for the same office space during the course of a year).
- **Rental of Equipment Clarification**
  - Although not explicitly carved out, stakeholders unsure whether FMV Exception could be used for rental of equipment. CMS makes it clear that the FMV Exception **can** be used to protect equipment rental arrangements.

Change 2: Writing Requirement

Pre-Final Rule	Final Rule
The “writing” must specify (i) the “timeframe for the arrangement” and (ii) the “compensation that will be provided under the arrangement.”	The “writing” must specify (i) the “timeframe for the arrangement,” (ii) the compensation that will be provided under the arrangement,” and (iii) the “**items, services, office space, or equipment covered under the arrangement**.”

- FMV exception always required arrangements to be in writing.
- Added obligations are in line with conditions imposed under other exceptions.
- Important for physicians and DHS Entities to be aware that they now (explicitly) apply to the FMV Exception as well.

Change 3: Holdover Provisions

Pre-Final Rule

Certain exceptions—e.g., Space Rental and Personal Services Exceptions, **but not FMV Exception**—permitted arrangement to comply with exception even after arrangement "expired," provided certain conditions satisfied:

- Immediately preceding arrangement had term of at least one year.
- Holdover immediately follows arrangement expiration and is on same terms/conditions as immediately preceding arrangement.
- Arrangement continues to be commercially reasonable and consistent with FMV.

Final Rule

Commenters

- Lobbied CMS to include holdover provision in the FMV Exception.
- Acknowledged the Exception permits multiple renewals, but note that new documentation arguably required for each renewal.

CMS

- Declines to extend holdover to FMV Exception but clarifies that as long as the terms of arrangement don't change, renewals under the FMV Exception are not required to be in writing.

Takeaway: "Renewals" provision serves same purpose as "holdover" provision.

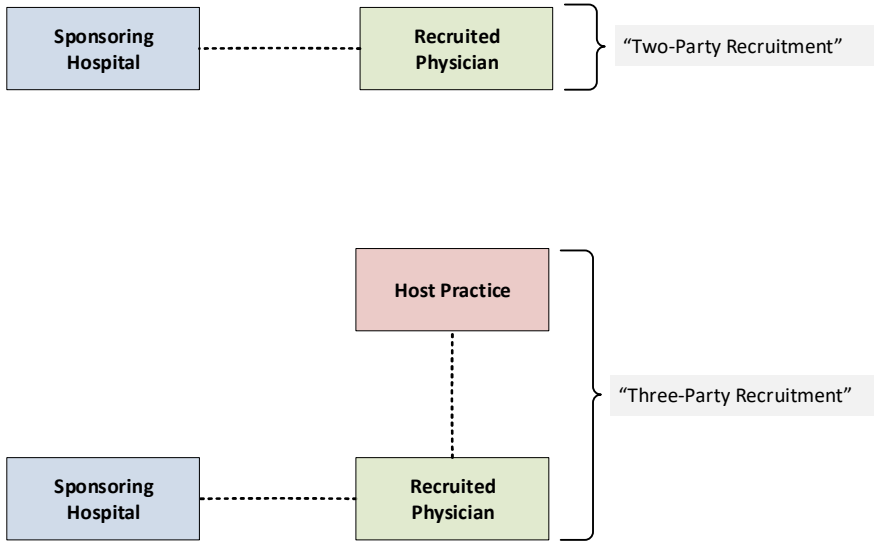
Change 4: Required Referrals

- **Required Referrals Special Rule**
  - If physician's compensation is conditioned on referrals to a particular provider, practitioner or supplier, then the following conditions must be met:
    - The compensation otherwise satisfies the requirements of an applicable exception, is set in advance, and consistent with FMV.
    - The referral requirement is in writing and signed by the parties, relates solely to the physician's services covered by the arrangement, and is reasonably necessary to effectuate the legitimate business purposes of the arrangement.
    - The referral requirement **does not apply** if (i) patient expresses a preference for a different provider, (ii) patient's insurer determines the provider, or (iii) referral is not in the patient's best medical interests in the physician's judgment.
- **Final Rule**
  - CMS incorporates the Required Referrals Special Rule into the FMV Exception (by reference). The Rule's conditions must be satisfied if the arrangement provides for remuneration to:
    - **physician** that is conditioned on her referrals to a particular provider, practitioner, or supplier; or
    - **group** that is conditioned on one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier.

Physician Recruitment Exception

Overview

- Hospital provides benefits (e.g., moving expenses, income guarantee) to Recruited Physician to induce her to relocate to service area and become member of medical staff.
- Recognizing benefits, Congress and CMS create statutory and regulatory exception for certain physician recruitment arrangements.
- Recruitment Exception addresses both Two-Party and Three-Party Recruitments.
- In 2007, CMS clarified that in a Three-Party Recruitment, the written recruitment agreement must be signed by Hospital, Recruited Physician and Host Practice.



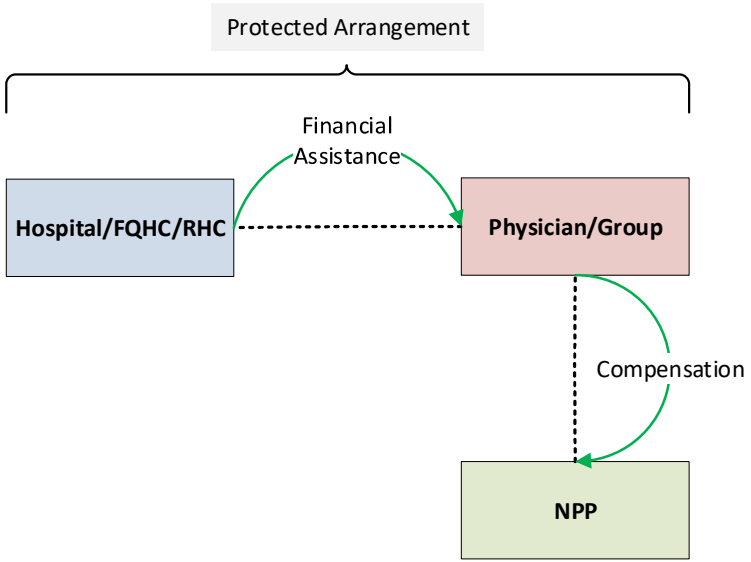
Three-Party Recruitments: Who Must Sign?

- **Question: When Host Practice receives no financial benefit from recruitment arrangement, does it need to sign the recruitment agreement?** Examples:
  - Recruited Physician joins Host Practice but Hospital pays recruitment benefits to Recruited Physician directly.
  - Host Practice passes all remuneration received from Hospital to Recruited Physician, serving only as an intermediary.
  - Recruited Physician joins Host Practice after income guarantee period, but before the "community service" repayment obligation is completed.
- **Answer: No.**
  - CMS concluded that in the above examples, no compensation arrangement exists between Host Practice and Hospital and, therefore, Host Practice does not need to sign the recruitment agreement.
  - Host Practice must sign the recruitment agreement only if (1) the remuneration is provided indirectly to Recruited Physician through payments made to Host Practice, **and** (2) Host Practice does not pass all such remuneration through to Recruited Physician.

NPP Recruitment Exception

Overview

- 2015: CMS creates exception for payments to physicians/groups by hospitals/FQHCs/RHCs to compensate NPPs—PAs, NPs, certified nurse specialists, certified nurse midwives, clinical social workers, and clinical psychologists—to provide patient care services.
- Goal: address (i) changes in delivery/payment systems and (ii) projected shortages in primary care workforce.
- Exception has many requirements, including restrictions on providing assistance if, within prior year, NPP has:
  - practiced in Hospital's GSA, or
  - been employed or engaged to provide patient care services by a physician/physician group that has a location in the Hospital's GSA.



Final Rule Clarifies Prior Service and Arrangement Timing Rules

- Do the services provided by an individual before they became an NPP constitute “patient care services”?
  - **No**. CMS replaced references to “patient care services” with “NPP patient care services.”
- Do the services provided in Hospital’s GSA by an individual before they became an NPP constitute “practicing” in such GSA?
  - **No**. CMS replaced references to “practiced” with “furnished NPP patient care services.”
- Must the compensation arrangement between the Hospital and the physician/group begin before the physician enters into the compensation arrangement with the NPP?
  - **Yes**. Allowing a Hospital to reimburse a physician/physician group for overhead costs of *current* employees already serving patients in the Hospital’s GSA would not serve CMS’s goal of increasing access to needed care.

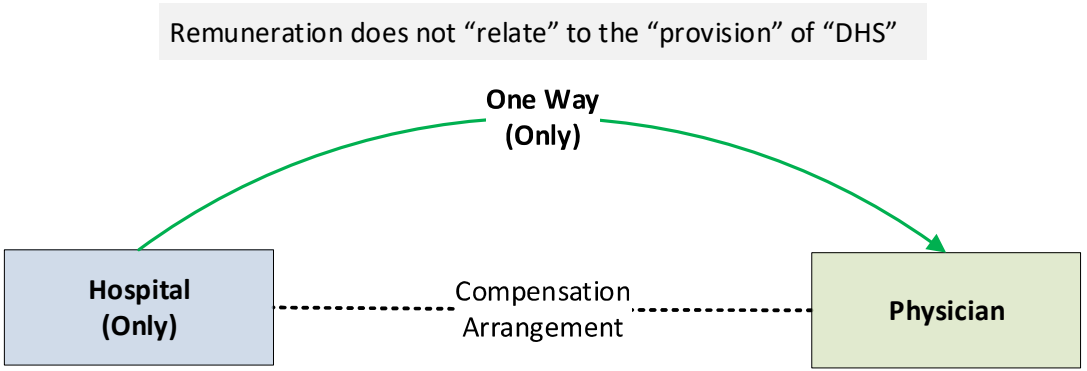
Unrelated to DHS Exception

Overview

Statutory Exception

Protects remuneration "provided by a hospital to a physician if such remuneration does not **relate** to the **provision** of **designated health services**."

- Exception has two built-in limitations.
  - Only covers one type of DHS Entity: **hospitals**.
  - Only covers remuneration flowing **from hospital to physician** (and not vice versa).
- But other than that, the Exception is quite broad/ protective on its face.



What Does it Mean to “Relate” to the “Provision” of “DHS”?

“DHS”

- Defined by statute and regulation
- Includes hospital inpatient services and hospital outpatient services (as well as nine other categories of items/services)

“Provision”

- The “act or process of providing”

“Relate”

- The fuzziest, most malleable of the three
- X and Y are “related” if they are “logically” or “causally” “connected” in some way

Examples

So, remuneration is “related” to the “provision” of “DHS” if the remuneration is logically or causally connected to the provision of DHS.

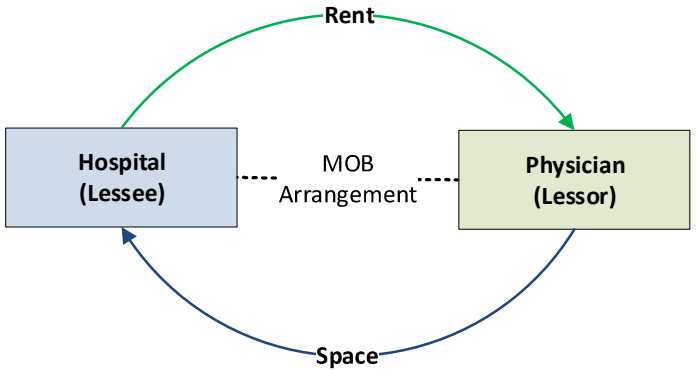
Related to Provision of DHS
Hospital employs Physician for $400,000 per year to furnish inpatient hospital procedures.

Not Related to Provision of DHS
Hospital pays Physician $10,000 to climb Mount Everest.

Unclear

- Physician owns warehouse and Hospital rents space there from Physician to store medical records.
- Hospital considering new EHR system and hires Physician (whose group adopted same system years ago) to provide consulting services to Hospital.
- Physician owns MOB; Hospital rents one floor in MOB for use by Hospital’s employed PCPs.

MOB Example: Unrelated to DHS v. Space Rental



Space Rental Exception Conditions	Unrelated to DHS Exception Conditions
• Writing	No
• Signature	No
• One-Year Term	No
• Set in Advance	No
• FMV Standard	No
• Volume/Value Standard	No

Regulatory Exception: 2004 - 2019

Statutory Exception

Protects remuneration "provided by a hospital to a physician if such remuneration does not **relate** to the **provision** of **designated health services**."

Regulatory Exception

Protects remuneration "provided by a hospital to a physician if the remuneration does not relate, **directly or indirectly**, to the furnishing of DHS. To qualify as 'unrelated,' remuneration must be **wholly** unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. **Remuneration relates to the furnishing of DHS if it**—

(1) Is an **item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles**;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician."

Proposed Rule (2019)

- CMS concedes its interpretation has been "too restrictive." To give "appropriate meaning" to the exception, CMS proposes shifting focus from cost reporting principles to whether the remuneration relates to the provision of **patient care services**.
- Under Proposed Rule, remuneration would not relate to the provision of DHS if was not related to "the provision of patient care services."
  - A "service" **would not** relate to provision of patient care services if it "could be provided by a person who is not a licensed medical professional."
  - An "item" **would** relate to provision of patient care services" if it is used in "the diagnosis or treatment of patients" or "to communicate with patients regarding patient care services."

Related to Provision of DHS

- Payment for call coverage services.
- Payment for medical director services.
- Payment for utilization review services.
- Payment for medical supplies/equipment.
- Payment for clinical office space.

Not Related to Provision of DHS

- Payment for "administrative services… pertaining solely to the business operations of a hospital."

Final Rule (2020)

- The majority of commenters “supported [CMS’s] efforts to restore utility to the statutory exception.”
- A few commenters, however, expressed concern that the expansion of the Unrelated to DHS Exception, “especially without substantial guidance and examples of its application, would risk program or patient abuse.”
- CMS did not unpack these concerns in the Final Rule or explain why the “guidance” and “examples” it **already** provided in the Proposed Rule were not sufficiently “substantial.”
- Instead, and disappointingly, the agency just kicks the can down the road…

> *Given the concerns raised by commenters, we are not finalizing our proposed revision to [the Unrelated to DHS Exception] at this time. We are continuing to evaluate the best way to restore utility to the statutory exception, and we may finalize revisions to the [Exception] in [a] future rulemaking.*

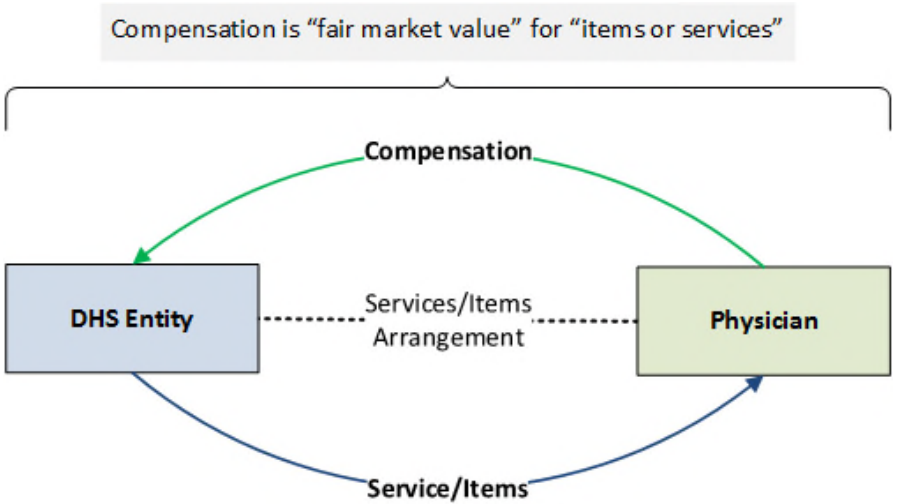
Physician Payments Exception

Overview

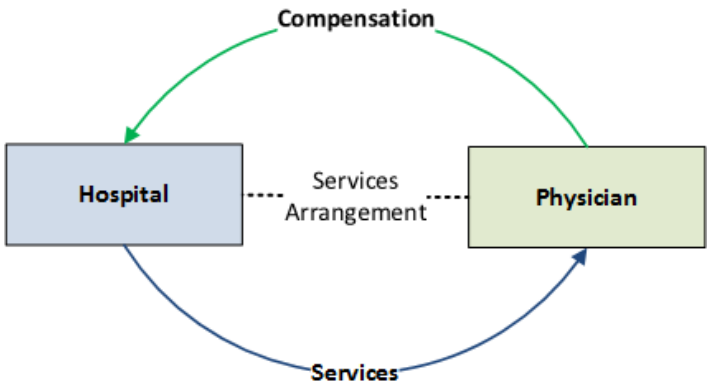
Statutory Exception

Generally protects "[p]ayments made **by a physician**" to an entity "as compensation" for "**items or services**" if they are "furnished at a price that is consistent with **fair market value**."

- Exception only covers remuneration flowing **from physician to hospital** (and not vice versa).
- But other than that (and like Unrelated to DHS Exception) quite broad/protective on its face.
- Only **one** condition: payments/price must be consistent with **FMV**.



Services Example: Physician Payments v. FMV Exceptions



FMV Exception Conditions	Physician Payments Exception Conditions
• Writing	No
• Signature	No
• Set in Advance	No
• FMV Standard	Yes
• Volume/Value Standard	No
• Comm. Reasonableness	No

Regulatory Exception: 2004 - 2019

Statutory Exception	Regulatory Exception
Generally protects "[p]ayments made **by a physician**" to an entity "as compensation" for "**items or services**" if they are "furnished at a price that is consistent with **fair market value**."	Generally protects "[p]ayments made by a physician (or his or her immediate family member) . . . [t]o an entity as compensation for any . . . items or services that are furnished at a price that is consistent with fair market value, **and that are not specifically excepted by another provision in [Sections] 411.355 through 411.357 (including, but not limited to, [Section] 411.357(l)).** "Services" in this context means services of any kind (not merely those defined as "services" for purposes of the Medicare program in § 400.202 of this chapter).

Proposed and Final Rules

- **Proposed Rule** (2019)
  - CMS agrees it had “unreasonably narrowed the scope of the statutory exception.”
  - Proposed amending regulation to preclude reliance on Physician Payments Exception only if another **statutory** exception is available.
  - Generally speaking, the only statutory exceptions that apply to payments (i) by a physician (ii) to a DHS entity are for the **lease** of space or equipment.
  - Thus, if a physician is **purchasing** items or services from a DHS Entity, the parties would **not** need to use the **regulatory** FMV Exception, with its writing, signature, set in advance, volume/value, etc. conditions. Instead, they could use the Physician Payments Exception, with its single (FMV) condition.
- **Final Rule** (2020)
  - Proposed Rule **adopted**.
  - Substantial new flexibility for any arrangement between a physician and DHS Entity where (i) the physician is paying the DHS Entity for items/services and (ii) the payments are not to lease space or equipment.

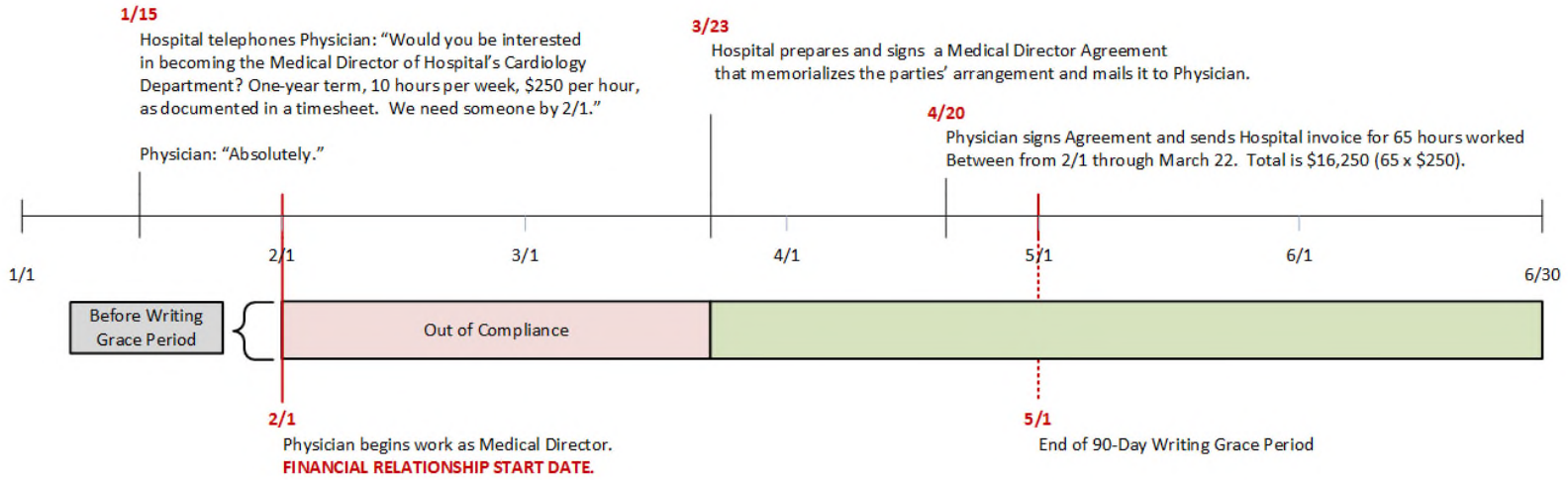
Isolated Transactions Exception

Overview

- **Statutory Version**. An isolated financial transaction—"such as a one-time sale of property or practice"—will be protected if:
  - FMV, Volume/Value, and Commercial Reasonable Standards met.
  - Any other requirements imposed by HHS are met.
- **Regulatory Version.** Imposes additional conditions and two definitions.
  - No additional transactions for six months (unless are protected under another exception).
  - Defines "transaction" to mean "an instance or process of two or more persons or entities doing business."
  - Defines an "isolated transaction" to mean one involving either (i) "a single payment between two or more persons or entities" or (ii) "a transaction that involves integrally related installment payments."

Single Payment for Multiple Services

- **Proposed Rule**.
  - Parties trying to use Isolated Transactions Exception to "protect service arrangements where a party makes a single payment for multiple services provided over an extended period of time." For example, parties turning to the Exception "when they discover . . . that they failed to set forth the . . . arrangement in writing, and thus" can't rely on" the Personal Services or FMV Exceptions.



Single Payment for Multiple Services

- **Proposed Rule (cont.)**
  - This is not permitted. Congress made it clear that the types of transactions the Isolated Transactions Exception is meant to exempt are “a one-time sale of property” or “a one-time sale of a practice,” each of which is a “unique, singular transaction.”
  - If a physician provides “multiple services to an entity over an extended period of time, remuneration in the form of an in-kind benefit has passed repeatedly from the physician to the entity receiving the service prior to the payment date.”
  - “The provision of remuneration in the form of services commences a compensation arrangement **at the time the services are provided**, and the compensation arrangement must satisfy the requirements of an applicable exception **at that time** . . .”
- **Final Rule**
  - CMS declines to revisit its position: “We do not believe that the Congress would have required ongoing service arrangements to meet all the requirements of [the Personal Services Exception, for example,] including writing, signature, 1-year term, and set in advance requirements, and then permit parties to sidestep these requirements by making a single, retrospective payment for multiple services relying on the [Isolated Transaction Exception].”

Settlements of Bona Fide Dispute

- **Hypothetical**
  - HHA contracts with Physician to provide medical director services starting January 1 on a part-time basis for one year for $200 per documented hour. The parties enter into a written, signed agreement that meets all the conditions of the FMV Exception.
  - Over the course of the year, Physician submits monthly invoices, which include timesheets indicating the days she worked and the number of hours she worked on those days.
  - Over course of the agreement, HHA pays Physician at total of $24,000 for **120 hours** of service.
  - Shortly after receiving her final payment from HHA, Physician writes letter to HHA, stating that she actually worked a total of **130 hours** and, as such, is due an additional **$2,000** (i.e., 10 hours x $200).
  - According to Physician, she was not paid for (i) three hours she worked in February, (ii) four hours she worked in August, and (iii) three hours she worked in November.
  - Although HHA believes the better argument is that the 12 timesheets reflect a total of 120 hours worked, and not 130 hours, HHA agrees that the February, August and November timesheets are not models of clarity.

Settlements of Bona Fide Dispute

- Can HHA and Physician enter into a settlement agreement regarding the disputed amount—e.g., can HHA pay Physician $1,000 in settlement of her $2,000 claim—and protect that arrangement under the Isolated Transactions Exception"?
- CMS: **Yes**.
  - Isolated Transactions Exception "is applicable to a compensation arrangement arising from the settlement of a **bona fide dispute**, even if the dispute originates from a service arrangement where multiple services have been provided over an extended period of time."
  - "[S]ettlement of a bona fide dispute arising from an arrangement is fundamentally different from making a payment, including a single payment, for items or services provided under the arrangement."
  - "[T]he cornerstone of a settlement of a bona fide dispute, as opposed to a payment for items or services, is that one or more of the parties forgoes **a good faith claim** to be paid more under the arrangement than the party actually receives."
- CMS amends both exception and definition of "isolated financial transaction" to specifically reference the "forgiveness of an amount owed in settlement of a bona fide dispute."

In-Office Ancillary Services Exception

Background

- **Purpose.** Protect the furnishing of certain types of DHS furnished personally by:
  - A physician who is a member of the same "group practice" as the referring physician, or
  - An individual who is supervised by another physician in the "group practice."
- **Group Practice**
  - Consists of a practice of two or more physicians.
  - Two or more physicians are deemed part of the same "group practice" if the conditions set forth in 42 C.F.R. § 411.352 ("Section 352") are satisfied.
  - Several conditions concerning manner of compensation.
- **Group practice compensation.** "Overall profits" and "productivity bonuses" that are:
  - calculated in a reasonable and verifiable manner, and
  - not directly related to the volume or value of the physician's referrals.

What Constitutes “Overall Profits”?

Pre-Final Rule	Post Final Rule
“Overall profits means the group’s entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians.”	“Overall profits means the **profits derived from *all* the designated health services of any component of the group that consists of at least five physicians**, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.” (Emphasis added.)

Changes Impacting Overall Profits

- **Effect of Final Rule**
  - Organizational and substantive changes to Section 352(i) of group practice definition relating to distribution of overall profits.
- **Final Substantive Changes**
  - Split-pooling
  - Categories vs. Payers
  - Medicaid
  - Five or more physicians
- **Delayed Effective Date**
  - To allow practices time to “adjust their compensation methodologies,” CMS delayed the effective date of the changes to overall profits until January 1, 2022.

Overall Profits: Split-Pooling

- **What is split-pooling?**
  - Sharing profits from one type of DHS with one subset of physicians in a group practice and the profits from another type of DHS with another subset of physicians in the group practice.
  - Example: Practice “provides both clinical laboratory services and diagnostic imaging services [both DHS] to its patients,” and practice “distribute[s] the profits from clinical laboratory services to one subset of its physicians and distribute[s] the profits from diagnostic imaging to a different subset of its physicians.”
- **Is split-pooling permitted?**
  - In Proposed Rule, CMS says “no,” and proposes revising text of Section 352(i) to make this clear.
- **Stakeholder pushback.**
  - Split pooling “allow[s] physicians to receive profit shares more closely related to the services they referred, their specialty, the services they provide, or the expenses they have personally incurred.”
  - Prohibiting split-pooling permits “physicians who have no treatment involvement in the designated health services” to be “rewarded financially” nonetheless.
- **Final Rule**. CMS sticks to its guns: Split-pooling not permitted.

Overall Profits: Distribution Methodology

- **Flexibility Regarding Creating Components of 5+.** Although split-pooling prohibited, group practice may establish components of at least five physicians by including physicians with:
  - similar practice patterns,
  - same practice in the location,
  - similar years of experience,
  - similar tenure with the group practice, or
  - other criteria determined by the group practice.
- **Flexibility Regarding Distribution Methodologies**. Group practice may use different distribution methodologies for different components of 5+. So if Group practice (i) furnishes clinical laboratory, diagnostic imaging, and radiation oncology services, and (ii) has divided its physicians into three components (A, B, and C) of five physicians, it may, for example, distribute as follows:
  - Component A: Per-capita distribution methodology.
  - Component B: Permissible personal productivity methodology.
  - Component C: Any third methodology that does not directly relate to the volume/value of referrals.

Q&A

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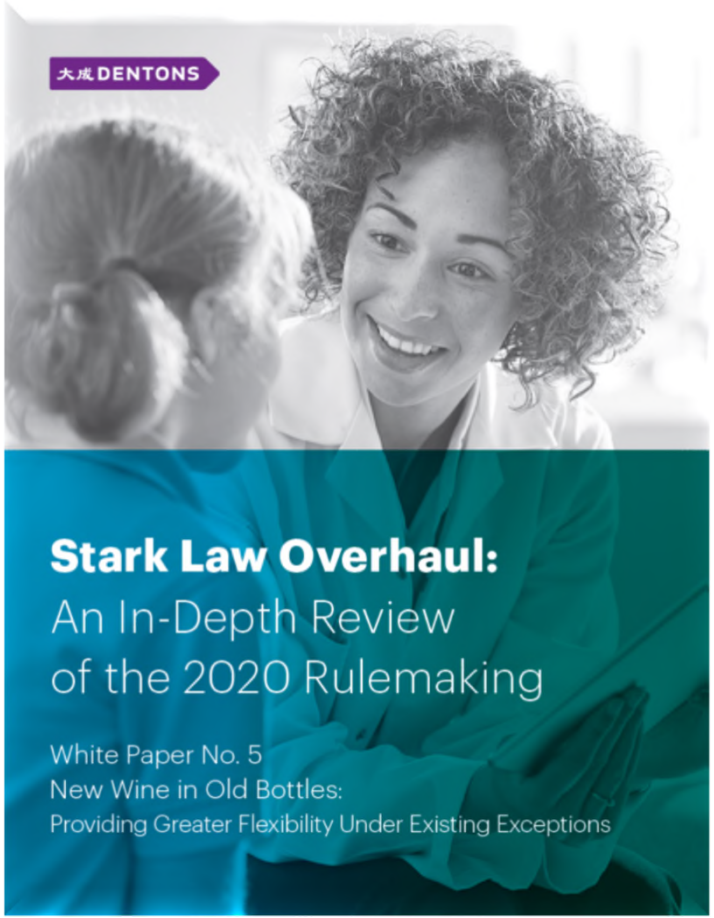

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