

## **A Practice Guide to Assessing Compliance with the Physician Self-Referral Law (fka Stark) in the Context of Physician Practice Acquisitions**

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**Obligatory Disclaimer:**  
**These views are our own, not**  
**necessarily those of our firm or our**  
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**“Anyone who isn’t confused really  
doesn’t understand the situation.”**

**Edward R. Murrow**



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## **Physician Practice Transactions— *Why are We Here Today?***

- While they have slowed somewhat over the past year, physician practice transactions have become a staple of private equity, hospital, and other investors strategy.
- With movements to site neutral payments continuing, there is less incentive to provide ancillary services in an HOPD thus, a continued demand for physician practices and ASCs.
- This presentation is going to use a series of hypotheticals to discuss common (and less common but tricky) physician self-referral (Stark) issues that can arise during a physician practice acquisition.
- We will discuss views from both buyer and seller counsel perspectives and potential strategies for each.



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## Setting the Table & What Have You

- DudeCare P.C. is a 50 plus physician urology practice. It is owned by a cohort of 15 physicians. DudeCare PC produces significant ancillary revenue and includes service lines for clinical laboratory services, advanced imaging, lithotripsy, physician therapy, and certain prosthetics and orthotics (and provides these services to Medicare, Medicaid, and Commercially insured patients).
- DudeCare PC's owners would like to retire in the next 5 years and have decided they would like to "sell" some interests in the practice to a private equity investor, Treehorn Investments ("Treehorn").
- Treehorn has signed a "Letter of Intent" offering \$120 million representing a 60% stake in DudeCarePC, subject to financial and legal due diligence. Both parties are engaging health regulatory counsel to represent them in the transaction.
  - ***As Buyer's counsel, what are some things you would be most interested in/concerned about?***
  - ***As Seller's counsel, what would you want to do to prepare for a group to be "sold"?***

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## PSL/Stark Law in a Nutshell

Referral and billing prohibitions apply only when all 6 are present:

- A physician
- Makes a referral
- For designated health services (DHS)
- Payable by Medicare (and Medicaid, indirectly)
- To an entity
- With which the physician (or an immediate family member) or the physician organization in whose shoes the physician stands has a financial relationship (which could be a direct or indirect ownership or investment interest in the entity or a compensation arrangement with the entity).

If all 6 elements are present → Exceptions

PSL is a strict liability statute. If implicated, the arrangement must meet an exception, and the intentions of the parties are not relevant.



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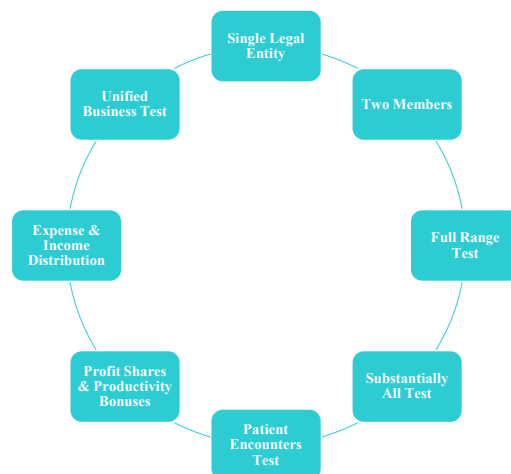
## PSL/Stark Law Compliance: “Services” exceptions

- If satisfied, they permit referrals of designated health services on a referral-by-referral basis
  - Language in regulation indicates that the prohibition on referrals does not apply to arrangements that meet the in-office ancillary services exception
- Services exceptions are located at 42 C.F.R. § 411.355
- Limited availability of certain “services” exceptions
  - Exception for physician services available only to entities that qualify as “group practices” under 42 C.F.R. § 411.352
  - Exception for in-office ancillary services available only to physicians in solo practice and entities that qualify as “group practices” under 42 C.F.R. § 411.352
- In-office ancillary services exception (“IOASE,”) or the physician services exception) does not have requirements regarding commercial reasonableness, fair market value, and the volume or value of referrals or other business generated by the physician (although the group practice definition limits compensation to be “indirectly” related to the volume or value of referrals—more to come)



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## Requirements for qualification as a “group practice”



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## Diligence Questions Focused on Meeting the Group Practice Definition

- ▶ As buyer's counsel, focus on all the components of the group practice definition
  - ▶ How many physician owners, physician employee and physician independent contractors?
  - ▶ Any physician member (i.e., owner or employee) furnish services outside the practice? If so, how many and what type of services?
  - ▶ Does the practice operate any subsidiary entities? If so, what is the ownership structure of the subsidiary entity?
  - ▶ How many locations does the group practice operate? What services are furnished in each location?
  - ▶ What types of DHS are furnished by the group practice?
  - ▶ How are group physician compensated?



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## What happens if you fail to qualify as a “group practice”?

- ▶ Must use other exceptions to protect DHS referrals to the practice (which is an “entity” for purposes of the PSL) by physician owners and physicians with compensation arrangements with the practice (employees and independent contractors)
- ▶ Most compensation arrangement exceptions include one, two, or all three of the following requirements—
  - ▶ Commercially reasonableness
  - ▶ Fair market value for items and services actually provided by the physician
  - ▶ Meets the volume or value requirement (i.e., cannot be determined in any way that takes into account the volume or value of the physician's referrals to the practice)
    - ▶ With respect to physicians who are not *bona fide* employees of the practice, the other business generated by the physician for the practice



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## What happens if you fail to qualify as a “group practice”?

- ▶ Services exceptions are applicable only to specified DHS and do not apply to the most common services furnished by a physician practice.
- ▶ Bad News: You likely cannot find any exception to protect the investment interest of the physician owners.
- ▶ What do you do now???



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## Does the Compensation Abide?

- **Scenario 1:**
  - During health regulatory diligence buyer's counsel reviews Dude P.C.'s historical physician compensation practices.
  - All physician owners and employees are paid a base draw and some type of productivity incentive.
    - Owners receive a “productivity bonus” based on their personally performed service and “incident to services”, 40% of their collections for non-DHS services, and a share of any profits from DHS and non-DHS services.
    - DHS profits have historically been aggregated in components of five+ physicians, ***except last year a physician owner retired leaving a component with four physicians.***
  - Employed physicians receive everything the owners receive except the profit shares.



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## ***Compensation to physicians in a group***

- ▶ No physician who is a *member* of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals (42 C.F.R. §411.352(g))
- ▶ Exception for profit shares and productivity bonuses, which may be indirectly related to the volume or value of the physician's referrals (42 C.F.R. §411.352(i))
- ▶ "Based on" and "related to" are statutory terminology
  - ▶ CMS indicated in the MCR final rule that it interprets the requirements of 42 C.F.R. §§411.352(g) and (i) to incorporate the volume or value standard as it relates to a physician's referrals
  - ▶ When determining whether the physician's compensation, share of overall profits, or productivity bonus is based on, is directly or indirectly related to, or takes into account the volume or value of the physician's referrals to the group practice, the special rule at 42 C.F.R. §411.354(d)(5) applies.
    - ▶ 85 FR 77558-59



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## **The volume or value standard: Compensation to a Physician**

- Compensation from an entity furnishing DHS to a physician takes into account the volume or value of referrals [or other business generated] only if—
  - The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to [or other business generated by the physician for] the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity
- A positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases. 42 C.F.R. §411.354(d)(5)



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## Share of overall profits (current regulation)

- ▶ A *physician in the group practice* may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of DHS referred by the physician
- ▶ “Overall profits” means—
  - ▶ The group’s entire profits derived from all the DHS payable by Medicare; or
  - ▶ The profits derived from DHS payable by Medicare of any component of the group practice that consists of at least 5 physicians
- ▶ Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician’s referrals of designated health services.
- ▶ “All of All” or “All of at least 5”



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## Overall profits “deeming provisions”

Profit share will be deemed not to relate directly to the volume or value of referrals under any of the following circumstances—

- The group’s profits are divided *per capita*
- Profits derived from designated health services are distributed based on the distribution of the group practice’s revenues attributable to services that are not designated health services payable by any Federal health care program or private payor
- Revenues derived from designated health services constitute less than 5 percent of the group practice’s total revenues, and the allocated portion of those revenues to each *physician in the group practice* constitutes 5 percent or less of his or her total compensation from the group



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## Productivity bonuses

- ▶ *A physician in the group practice* may be paid a productivity bonus based on services that he or she has personally performed, services “incident to” such personally performed services, or both
  - ▶ Provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician
    - ▶ Exception: the productivity bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services “incident to” the physician’s personally performed services
- ▶ Must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician’s referrals of designated health services



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## Scenario 1A: Discussion:

### Reminder:

- All physician owners and employees are paid a base draw and some type of productivity incentive.
  - Owners receive a “productivity bonus” based on their personally performed service and “incident to services”, 40% of their collections for non-DHS services, and a share of any profits from DHS and non-DHS services.
    - DHS profits have historically been aggregated in components of five+ physicians, except last year a physician owner retired leaving a component with four physicians.
  - Employed physicians receive everything the owners receive except the profit shares.
- *If you are buyer’s counsel, what if any concerns do you have?*
- *If you are seller’s counsel, what follow-up questions might you ask to see if you can avoid PSL non-compliance or otherwise mitigate any actual or potential overpayment?*



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## Alternate Scenarios:

**1B:** Same facts as before, except in this scenario Dude P.C., had a compensation plan that explicitly stated that if a “component” of physicians falls below five in any given year, the physicians will be assigned to other components.

**1C:** Assume that all physicians are aggregated into components of five or more physicians. However, Dude P.C. treats Medicare Advantage derived DHS as “commercial” dollars and pays each physician 40% of collections of these revenues rather than distributing as part of the DHS profit pool?



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## Alternate Scenarios (1C cont):

- **42 CFR 411.355(c) Services furnished by an organization (or its contractors or subcontractors) to enrollees.**
  - Broad services exception providing protection for services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization).
- ***Would this impact Dude P.C.’s ability to satisfy the group practice definition?***
  - 42 CFR 411.352(g): No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in paragraph (h) of this section.



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## Alternate Scenarios

- Assume that Dude P.C. pays physicians directly based on the volume or value of their DHS referrals. However, it only offers a small amount of DHS payable by Medicare whereby they meet both elements of the “*di minimis*” deeming provision at 42 CFR § 411.352(i). That is, revenues derived from DHS constitute less than 5% of Dude P.C.’s total revenues and the portion of those revenues distributed to each physician constitutes 5% or less of the physician’s total compensation from the group.
- Importantly however, Dude P.C. has been using a significant number of independent contractor physicians to perform patient services. Specifically, approximately 35% of patient services are performed by independent contractor physicians of Dude P.C.
- ***Does this raise any risk from a PSL perspective?***



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## Physician-patient encounters:

*Members (typically owners or employees although other types of physicians may qualify) must personally conduct no less than 75 percent of the physician-patient encounters of the group practice*

**Key Point:** Effectively limits the number of independent contractor physicians a group practice can have providing direct patient care services because independent contractors are not “members” of the group practice.



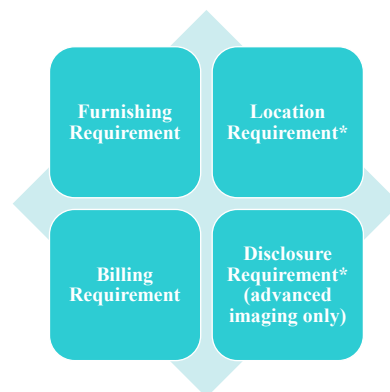
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## Location, Location, Location

### Hypothetical 2:

- For seven (7) years and continuing until today, Dude P.C., has been shipping outpatient prescription drugs and catheters to patients homes who have trouble ambulating to the office. Patients include Medicare beneficiaries whereunder the catheters are covered under Medicare Part B, and the outpatient prescription drugs, for the most part, are covered under the patient's Medicare Part D benefit.
- Dude P.C., bills Medicare (Part B & D) for these respective services.
- *If you are buyer's counsel, what risks are you worried about?*
- *If you are seller's counsel, what arguments do you have? Are there any pathways to avoid FCA risk (if any)?*

## 4 Requirements of the IOAS Exception



## The Requirements of the In-Office Ancillary Services Exception—Furnishing Services

### 1. Furnishing of Services

- DHS must be personally furnished by
  - The referring physician
  - A physician who is a member (i.e., owner or employee) of the same group practice
  - An individual who is supervised by the referring physician or another physician in the group practice (i.e., owner, employee or independent contractor).



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## The Requirements of the In-Office Ancillary Services Exception—Location

### 2. Location Requirement

DHS must be furnished in 1 of 2 locations:

- In a “**centralized building**” used by the group practice for the provision of some or all its DHS
    - This is generally met for “full time” practice locations – those leased 24/7/365 and **not shared** (either subleased from or to other entities)
  - If the space is “part-time” or shared in any way, then the DHS will typically need to be furnished in the “**same building**” in which the referring physician or group practice furnishes physician services (some of which must be unrelated to the furnishing of DHS)
    - Several sets of circumstances can qualify under “same building” test, but generally a complex set of hours requirements, which can be found at 411.355(b)(2)(i)
    - Generally, requires office to be open at least 8 hours a week, and cannot be a “DHS-only” location (e.g., a lab, imaging suite, etc.)
- Key question for this inquiry is what does it mean to “furnish” DHS in either the “same building” or a “centralized building”



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## CMS FAQ (9/20/21)

*“Where are items considered to be “furnished” for purposes of the “location requirement” of the exception for in-office ancillary services at 42 C.F.R. §411.355(b)(2)? If prosthetic or orthotic devices, such as intermittent catheters, are mailed to the patient from a location that qualifies as a “same building” or “centralized building,” are they considered to be furnished in a location that satisfies the requirement at 42 C.F.R. §411.355(b)(2)?”*

- **CMS Response:** “The “location requirement” at 42 C.F.R. §411.355(b)(2) requires that the patient receive the item in the physician’s office. Put another way, items that are designated health services to which the exception is applicable, such as intermittent catheters (which are prosthetic devices), fall within the scope of the exception for in-office ancillary services only when a patient directly receives the item in the physician’s office and in a manner that is sufficient to meet applicable Medicare billing and coverage rules. The “location requirement” at 42 C.F.R. §411.355(b)(2) would not be satisfied if a patient receives an item by mail outside the physician’s office, as it would not be dispensed to the patient in the office. This is true regardless of whether Medicare coverage and payment rules would permit the supplier to mail the item to the patient and bill the Medicare program for the item.” (Emphasis added)



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## **Community Oncology Alliance v. Becerra, et al (U.S. Dist. Court, D.C., Civ. Action No. 23-cv-2168)**

- An alliance representing physician oncology practices challenged CMS’ interpretation of the location requirement of the IOAS Exception.
- Argued that the location requirement is met if the item is dispensed to a patient in a manner that is sufficient to meet applicable Medicare payment and coverage rules (and contending that mailing prescription drugs to patients does meet Medicare payment and coverage rules).
- DC District Court disagreed, stating “the regulations state that a [DHS] is ‘furnished’ ... in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.”
- As to the meaning of “dispensed to a patient,” the Court stated:
  - “The best reading of this language is that there is no dispensing to a patient until the item has been received by the patient; the act of dispensing to the patient therefore occurs where the patient receives it. As a result, a prescription drug that is mailed to a patient at her home is not dispensed to that patient in the physician’s office.”



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## Hypo 2A Cont...

- Assume you determine there may be some actual or potential non-compliance related to satisfying the “location” requirement of the IOASE.
  - How might you manage fraud and abuse risk in a manner that moves the transaction forward?
    - Indemnity?
    - Purchase Price Adjustment?
    - Self Disclosure?

## ***But See Limits on CMS's Self-Referral Disclosure Protocol***

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved  
OMB No. 0938-1106  
Expires: XX/XX

### **FINANCIAL ANALYSIS WORKSHEET: CMS-10328**

#### **I. INSTRUCTIONS FOR THE FINANCIAL ANALYSIS WORKSHEET**

##### **A. Financial Analysis**

The disclosing party must provide a financial analysis of the potential overpayment based on the 6-year lookback period at § 401.305(f). Disclosing parties only report overpayments in Medicare Parts A and B through the SRDP. CMS does not directly pay providers and suppliers for services furnished under Medicare Parts C or D or Medicaid. Therefore, the SRDP is not the appropriate administrative remedy for overpayments arising from services furnished pursuant to prohibited referrals if the services are paid for under Medicare Parts C or D or Medicaid. (Unless otherwise requested by CMS, disclosing parties are not required to report the actual amount of remuneration between the parties). The financial analysis worksheet must be submitted in Excel®-compatible format; please lock the worksheet for editing before submitting. For each physician included in the disclosure, the



### ESCROWS, PURCHASE PRICE ADJUSTMENTS, INDEMNITY AND WHAT HAVE YOU—HOW TO ADDRESS PSL ISSUES IN TRANSACTION DOCUMENTS

- When you discover actual or potential PSL non-compliance, what are the options for how to address the issue in transaction documents?
  - What are some considerations from a seller's perspective?
  - What do you want to protect as a buyer?
  - Besides escrows, are there other ways to account for risk?
  - What do you do when there may not be viable disclosure pathways (re: Part D)?



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### Hypothetical #3—No man, you're Lebowski P.C.; we're the Dude (P.C.)

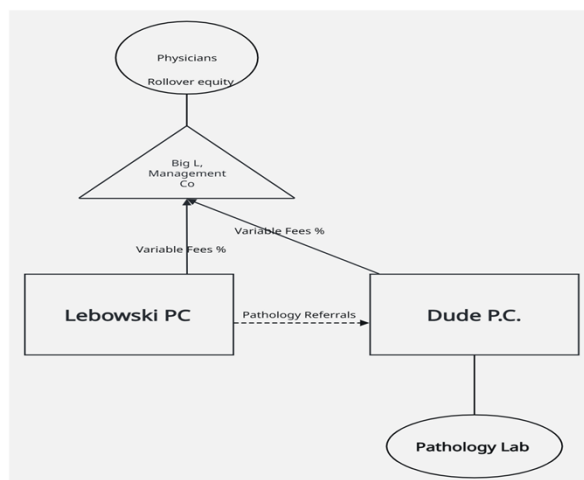
- Assume that Treehorn goes forward with the Dude P.C. acquisition and continues to "bolt on" other practices to its urology portfolio and acquires Lebowski P.C.
- Seeing economies of scale of using the existing in-house laboratory of Dude P.C., physicians in Lebowski P.C. make referrals for pathology services to Dude P.C.'s laboratory.
- Importantly, Treehorn established a Managed Services Organization ("MSO") for Corporate Practice of Medicine reasons and granted both Dude P.C. and Lebowski P.C. physicians roll-over equity in the same MSO.
- The MSO manages both Dude P.C. and Lebowski P.C. The management fee for both entities is a percentage of revenues.
- Assume Dude P.C. and Lebowski P.C. each independently qualify as group practices and individually satisfy the In-Office Ancillary Services Exception.
- ***As buyer's counsel, to Treehorn, should you have PSL concerns?***



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## Illustration of Hypo 3



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## Does Physician Rollover Equity Create a Compliance Bummer?

CMS has said:

- “Some...exceptions operate to exclude certain categories of services from the reach of section 1877 of the Act.... ***In effect, services described in these exceptions are not DHS for purposes of the statute.*** These service-based exceptions include the physicians’ services exception, ***in-office ancillary services exception***... in § 411.355 ... ***Thus, even if there is an indirect compensation arrangement between a referring physician and an entity furnishing DHS, these exceptions may apply to referrals of the particular services described in the exception. Referrals of DHS that do not fit in a services-based exception would be prohibited unless the indirect compensation arrangement fits in the new exception for indirect compensation arrangements.***” 66 FR 856,867 (Jan. 4, 2001)(emphasis added)

***Does Dude P.C. create an indirect compensation arrangement?***

***What about Lebowski P.C.?***

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## PHYSICIAN COMPENSATION: ROLLOVER EQUITY – INDIRECT COMPENSATION

An indirect compensation arrangement exists if **all the conditions** below exist:

- Between the referring physician and the entity furnishing DHS there exists **an unbroken chain** of any number of persons or entities that have financial relationships between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link); and
- The referring physician **receives aggregate compensation** from the person or entity in the chain with which the physician has a **direct financial relationship** that **varies with the volume or value of referrals or other business generated** by the referring physician for the entity furnishing the DHS; **and**
- The amount of compensation that the physician receives **per individual unit**—
  - (i) Is not fair market value for items or services actually provided;
  - (ii) Could increase as the number or value of the physician's referrals to the entity furnishing DHS increases, or could decrease as the number or value of the physician's referrals to the entity decreases;
  - (iii) Could increase as the amount or value of the other business generated by the physician for the entity furnishing DHS increases, or could decrease as the amount or value of the other business generated by the physician for the entity furnishing DHS decreases; or
  - (iv) Is payment for the lease of office space or equipment or for the use of premises or equipment.
- The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.



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# QUESTIONS?



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## THANK YOU! REACH OUT WITH ADDITIONAL QUESTIONS/COMMENTS

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