



CMS Proposes Far-Reaching Stark Changes

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Stark Regulations

- What is Stark?
- How do these proposed changes fit in?
- What is the purpose/effect of the proposed changes?
- Are more changes coming?



Reassignment/Purchased Diagnostic Test Rule

- Would add anti-markup rule to both PC and TC
- Would add it for purchased tests and reassigned tests
- Excludes tests performed by independent laboratories
- Defines “net charge” for markup purposes as excluding cost of space or equipment leased to performing physician
- Seeks comments on how to prevent group practices from marking up TC for imaging provided in “centralized building”

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In-Office Ancillary Services Exception

- CMS is concerned that scope has gone beyond services that are part of office visit and medically necessary for that office visit
- CMS asks whether “certain services” should no longer qualify
- Whether changes are necessary to definition of “same building” and “centralized building”
- Whether non-specialists should be able to rely upon the exception to provide specialized services

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Unit of Service (Per Click) Payments in Space and Equipment Lease

- Proposes to prohibit per click rent in the space and equipment lease exceptions:
 - When physician leases space or equipment to a DHS entity; and
 - The DHS entity uses the leased space or equipment to furnish services to patients referred to the entity by the physician lessor
 - What about when the lessor is the DHS entity?



Percentage Compensation

- Proposes limiting the type of percentage compensation that qualifies as “set in advance” to percentage compensation based on personally performed physician services
- This could bar many common percentage compensation arrangements with individual physicians
 - practice management agreements
 - expense-sharing arrangements
 - pay-for-performance incentives
 - “risk pool” payments

Note: Indirect compensation arrangements are not affected





Services Furnished “Under Arrangements”

- Would revise the definition of “entity” to cover **not** only the person or entity that is paid by Medicare for DHS (current definition) but also the person or entity that either provides the DHS or causes a claim to be presented for the DHS
- So, physician owners of an entity providing services “under arrangements” would need an ownership exception for their referrals
- Currently, such arrangements are analyzed only under the “indirect compensation arrangement” exception



Stand in the Shoes

- CMS is concerned with indirect relationships involving DHS entities where an entity is between the physician and the DHS entity
- Proposes to collapse the two entities as one where the DHS entity owns or controls another entity to which a physician refers patients
- No specific wording for this proposed rule is offered



Alternatives to Stark Exceptions For Technical Non-compliance

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- Self-disclosure
- All but the “form” requirements of the exception are met
- Inadvertence
- No knowledge of mistake
- Prompt corrective action
- No risk of abuse
- Limited time period of non-compliance
- No on-going federal investigation or other proceeding

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Period of Disallowance for Noncompliant Financial Relationships

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- Case by case or prescribed period of time?
- Shorten by unwind and payback?
- Barred for a period of time (even after period of disallowance) from using an exception?

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Others

- Ownership or Investment Interest in Retirement Plans
- Burden of Proof
- Obstetrical Malpractice Insurance Subsidies

What to do Now?

- Wait to see if/when changes occur?
- Review existing arrangements?
- Develop potential exit or unwind strategies?
- Change deals in development?
- Also: Stay tuned for “Phase III” Stark regulations



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Questions & Answers



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