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KEY TAKEAWAYS FROM THE PROPOSED STARK AND ANTI-KICKBACK RULES: WHAT YOU NEED TO KNOW TODAY

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PRESENTATION OVERVIEW

- What are Rules Trying to Accomplish?
- Impact on Physician Contracting
- Impact on FCA Cases – Recent Developments and Favorable Proposed Revisions
- Value-Based Safe Harbors and Exceptions
- Other Notable Safe Harbors and Exceptions

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Goals for the New Rules

- Remove Regulatory Barriers to Innovation
- Encourage Participation in Value-Based Arrangements
- Clarification/Simplification of Existing Stark/AKS Rules

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Impact on Physician Contracting

Impact on Physician Contracting

- Isolated Transactions Exception
  - Clarification of Existing CMS Policy
  - **New:** Temporary Noncompliance for Writing Requirement Proposal
  - **New:** Limited Remuneration to a Physician Exception
- Group Practice and Distribution of Overall Profits
  - Commentary Discussing Current Exception

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Existing Isolated Transactions Exception (§411.357(f))

- Currently Isolated Transaction Exception Protects:
  - ***"Isolated financial transactions"* so long as**:
    1. Remuneration is consistent with FMV and doesn't take into account the volume or value of referrals/other business
    2. Remuneration is commercially reasonable (even without referrals)
    3. No additional transactions between parties for 6 months

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Current Definition of “Transaction” (§411.351)

- **“<u>Transaction</u>” is**:
  - “an instance or process of two or more persons or entities doing business”
  - Meaning it includes not only “instances” of business, but also ongoing arrangements

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Clarification of Existing Policy and New Text

- **CMS Commentary and Revised Definition**:
  - An “isolated financial transaction” cannot include “a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).”
  - Uses example of call coverage or other service agreement

- **Current and Future Use of the Exception?**

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Temporary Noncompliance with **Writing** Requirement

- Existing special rule for temporary noncompliance signature requirements – evolution over last 5 years (§411.353(g)
  - Up to **90-days** to obtain signatures – arrangement must comply with *all other requirements* of the applicable exception
- Expansion to include temporary noncompliance with "writing" requirements – previously clarified "writing" can consist of a collection of documents
- **Note:** must still have an agreement between the parties prior to commencing services/paying compensation

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Limited Remuneration to a Physician (§411.357(z))

- Proposed **new** exception to Stark Law – flexibility for nonabusive business practices
- Key features:
  - Remuneration for items/services provided that does not exceed $3,500 annually (adjusted for inflation) – contrast with nonmonetary compensation exception
  - Does ***not*** require a writing
  - Does require that remuneration is FMV, commercially reasonable and not determined in a manner that takes into account the volume or value of referrals/other business generated

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Group Practice – Productivity Bonuses & Profit Shares

- Special rule permits “group practices” to distribute bonuses and profit shares based on income from designated health services (set(s) of five or more physicians within the group)
- Long standing debate about whether income pools could be divided by DHS-type – i.e. one pool for diagnostic imaging and separate pool for clinical lab services

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Group Practice – Productivity Bonuses & Profit Shares

- CMS clarifies policy and proposes revised regulatory text – recognizing ambiguity in existing language

- Income pools cannot be divided by DHS-type – distributions must be "derived from ***all*** the designated health services." (emphasis added).

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Impact on FCA Cases – Recent Developments and Favorable Proposed Revisions

Three Fundamental Requirements of Many Stark Exceptions

- Many Stark law exceptions include the following requirements:
  - Commercial reasonableness
  - Taking into account the volume or value of referrals or other business generated
  - Fair market value
- Proposed changes – goal is to establish bright-line, objective regulations
- Interplay between proposed regulations and FCA activity in recent years

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FCA Cases – Physician Compensation Arrangements under Stark

- CMS notes that according to commenters:
  - "False Claims Act case law has exacerbated the challenge of complying with these three fundamental requirements"
  - Lack of clear understanding is "one of the greatest risks" in structuring physician arrangements, since non-compliance could potentially be a predicate for FCA liability
- Examples of FCA activity in recent years:
  - *U.S. ex rel. Parikh v. Citizens Medical Ctr.*
  - *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*
  - *U.S. ex rel. Reilly v. North Broward Hospital District, et al.*
  - *United States ex rel. David Felten, M.D., Ph.D. v. William Beaumont Hospitals, et al*
  - Common themes?

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FCA Cases – Physician Compensation Arrangements under Stark

- *U.S. ex rel. Bookwalter v. UPMC* (3d Cir., Sept. 17, 2019)
  - Alleged improper indirect compensation arrangements with neurosurgeons. Court set a low bar to discovery.
  - Compensation: base salary and productivity bonus based on personally performed services
    - Creates a "correlation" between pay and referrals
  - Court notes that the following factors indicate "plausible claims" that compensation exceeded FMV:
    - Compensation exceeded collections
    - Compensation and productivity exceeded the 90th percentile
    - Bonus per "work unit" exceeded the Medicare reimbursement rate

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Commercially Reasonable

- No current definition and little guidance
- Key question: does the arrangement make sense as a means to accomplish the parties' goals?
- CMS clarifies a "widespread misconception," explaining that:
  - "Compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable"
  - The "determination of commercial reasonableness is not one of valuation"
- CMS finds commenter concerns compelling regarding the need in some situations for compensation at a loss
  - Community need, timely access to healthcare services, licensure or regulatory obligations, charity care, improvement of outcomes

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Commercially Reasonable

- Alternative proposals for new definition
  - Particular arrangement furthers a legitimate purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.
  - Alternative under consideration: the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.
- If exception includes language “even if no referrals were made,” that requirement must also be met

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Volume or Value of Referrals or Other Business Generated

- CMS notes a “lack of clear understanding” as to the “volume or value” standard
- Commenters expressed concern:
  - Determination includes an evaluation of subjective intent
  - Under current guidance and government position in enforcement actions, “parties can never be sure that their determination of the compensation to be paid under an arrangement with a referring physician will be insulated from scrutiny”

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Volume or Value of Referrals or Other Business Generated

- Proposes special rules
  - Does a mathematical formula incorporate referrals or business generated as a variable?
    - Example: decrease of office rental amount by $5 for each diagnostic test ordered
  - Is there a predetermined, direct positive or negative correlation between the volume or value of prior referrals/business generated and prospective rate of compensation?
    - Example: tiered system for determining compensation: $/wRVU is set at a higher or lower amount on renewal based on historic referrals
  - “Merely hoping for or even anticipating future referrals or other business is not enough”
- Not a clarification; proposed only

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Volume or Value of Referrals or Other Business Generated

- CMS expressly references commenters' concerns regarding *Tuomey* case language addressing "volume or value"
  - "the more procedures the physicians performed at the hospital, the more facility fees Tuomey collected, and the more compensation the physicians received in the form of increased salaries and productivity bonuses"
- CMS reaffirms its prior position: a personal productivity bonus does NOT take into account the volume or value of referrals solely because corresponding hospital services are billed each time

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Fair Market Value

- Statutory definition: “value in arms length transactions, consistent with the general market value”
  - Includes additional qualifications for leases generally and leases of office space
- Current regulatory definition: commenters, including valuators, expressed concern regarding application
- CMS – Congressional intent was not to deviate from general valuation principles and concepts

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Fair Market Value

- Proposed revisions to definition:
  - The value in an arm's length transaction, with like parties under like circumstances, of like assets or services, consistent with the general market value of the subject transaction.
    - "Fair market value" – the value to *hypothetical* parties
    - "General market value" – the value to the *actual* parties
  - CMS examples:
    - Example: Salary survey for orthopedics identifies $450,000 in a geographic location; particular physician is one of the top in the country, highly sought after by professional athletes. Significantly higher salary may be FMV.
    - Example: Salary survey for family practice physician identifies $250,000 nationally and no local surveys are available; lower salary may be FMV based on cost of living and hospital economic position.

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Indirect Compensation Arrangements

- CMS proposes two revisions, with little explanation
- First, is there an indirect compensation arrangement?
  - In the closest compensation link to the physician, the "aggregate compensation ~~varies with,~~ or takes into account~~,~~ the volume or value of referrals or other business generated"
- Second, what exceptions apply?
  - Other than new special rules with respect to value-based arrangements, the ONLY applicable exceptions are the indirect compensation arrangement exception or 42 CFR 411.355 (e.g., IOAS, AMC)

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Value-Based Safe Harbors and Exceptions

Value-Based Arrangements (Stark and AKS)

Stark	AKS
Full financial risk	Full financial risk
Meaningful downside risk to physician	Substantial downside financial risk (to value-based enterprise)
Value –based arrangements	Care coordination arrangements
	Patient engagement and support
Indirect value-based arrangements	
	Personal services arrangements*
Group practice (allocation of value-based reserve)*	

* Proposes revising an existing regulation, as opposed to proposing an entirely new exception/safe harbor.

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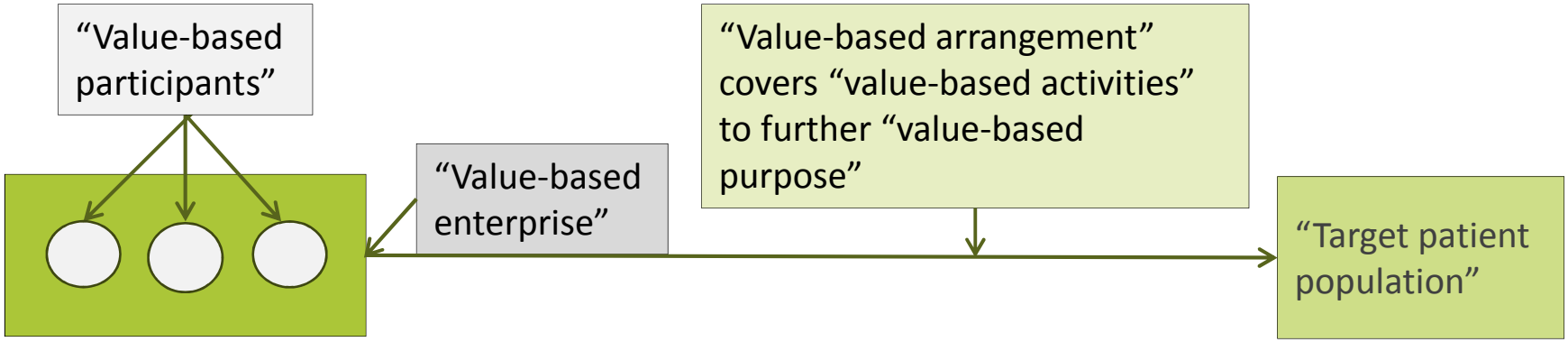
Value-Based Arrangements (Stark and AKS)



- **"Value-based participants"** = providers, e.g. hospitals, physicians, SNFs, home health, etc. (OIG excludes some)
- **"Value-based enterprise"** = two or more value-based participants collaborating to achieve value-based purpose, using a value-based arrangement and has an accountable body or person and governing document
- **"Value-based purpose"** = coordinating and managing care; improving quality; appropriately controlling costs; transitioning from volume to value
- **"Value-based activity"** = providing an item or service, taking action, or refraining from an action, all in furtherance of a value-based purpose
- **"Value-based arrangement"** = an arrangement for "value-based activity" by the value-based enterprise and/or its value-based participants
- **"Target patient population"** = an identified patient population selected by value-based enterprise or its value-based participants using "legitimate and verifiable criteria" set out in writing, in advance

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Value-Based Arrangements (AKS Care Coordination – Example)

- Hospital provides behavioral health nurse to SNF to follow selected patients at the SNF post-discharge from hospital:

1. Hospital and SNF establish outcome measures for SNF
2. They ensure provision of behavioral health nurse is commercially reasonable
3. Hospital and SNF sign written documentation setting forth terms, activities, target patient population, hospital's cost, SNFs contribution to cost, outcome measures
4. Remuneration is in-kind, primarily for value-based activity, etc.
5. Hospital's provision of nurse is unrelated to SNF's referral of patients who are not part of the target population and not covered by value-based arrangement
6. SNF pays at least 15% of hospital's cost of nurse
7. Value-based arrangement must be directly connected to coordination of care and management of target patient population
8. Arrangement does not include marketing to patients or recruiting patients
9. The value-based enterprise's accountable body or person monitors annually
10. The hospital does not and should not know the nurse's services are likely to be "diverted" to unrelated tasks

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Value-Based Arrangements (Key Takeaway)

- The proposed exceptions are broad and flexible
- The Stark exception is proposed, so it cannot yet be used
- The AKS safe harbor, while technically also proposed and thus not currently in effect, is valuable guidance for current and new arrangements
- Consider structuring new arrangements now to meet proposed safe harbor requirements, but use great caution if including physicians, because you must meet a current Stark exception

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Other Notable Safe Harbors and Exceptions

Other Notable Exceptions and Safe Harbors

- Technology-Related Safe Harbors/Exceptions
- Balancing use of technology innovation with fraud and abuse risks
- EHR Safe Harbor/Exception (proposed changes)
  - Among other things: removes sunset date, removes prohibition on donation of equivalent items or services, seeks comments on removal of or modification to 15% contribution requirement
- Cybersecurity Technology and Related Services Safe Harbor/Exception (new)
  - Recognition of growing threat of cyberattacks and risk to industry and patients
  - Would allow a non-monetary donation of cybersecurity technology and services (e.g., encryption software for a laptop, risk assessments), without requiring the recipient to contribute to the costs
  - Patients could potentially be recipients
- Value-Based Enterprise Participants – could potentially include healthcare IT companies

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Other Notable Exceptions and Safe Harbors

- New Exception added to Beneficiary Inducements CMP Exceptions:
  - Telehealth technologies for in-home dialysis patients
  - Follows on statutory exception added by the BBA of 2018
  - "While we are aware of the increasing proliferation of telehealth services, and the likely desire of other healthcare industry stakeholders to furnish telehealth technologies to patients receiving telehealth services," the statute and the corresponding exception are limited to in-home dialysis patients only

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Other Notable Exceptions and Safe Harbors

- Local Transportation
  - Extend distance for rural patients (from 50 to 75 miles)
  - Remove 25-mile limit on transportation at discharge
- Personal Services
  - Removed requirement that ***aggregate compensation*** must be set in advance – now requires ***methodology for determining compensation*** must be set in advance

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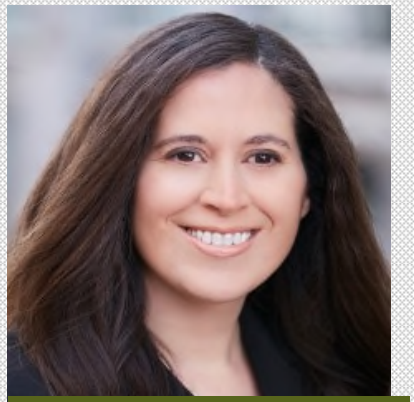
Thank you. Any Questions?



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