Proposed Revisions to the Stark Law and Anti-kickback Statute: What You Need to Know

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Agenda

- Introduction
- New Exceptions/Safe Harbors for Value-Based Arrangements
- EHR/Cybersecurity Exceptions/Safe Harbors
- Other Key Stark Law Changes
  - New Exceptions
  - Definitions and Clarifications
- Other Key Anti-Kickback Statute (“AKS”) Changes
  - New Safe Harbors
  - Definitions and Clarifications
- Civil Monetary Penalty (“CMP”) for Beneficiary Inducements
- Wrap Up and Next Steps

Proposed Regulations

- Why pay attention to proposed rules?
- In general, no Immediate Effect
  - Numerous CMS and HHS “clarifications” that appear binding
- Not a sure thing
  - CMS/HHS have proposed many things in the past
- Subject to Notice-and-Comment → Final Regulations
  - Agencies accepting comments through end of year
- Trend of overlap and consistency
- Differences based on distinctions between Stark and AKS
- Other developments?

Value-Based Arrangements

Exceptions & Safe Harbors

Exceptions/Safe Harbors for 3 Categories of Value-Based Arrangements

- Purpose of Proposed Regulations
- Three New Exceptions/Safe Harbors:
  - Full Financial Risk (greatest financial risk, greatest flexibility)
  - Large Financial Risk (compromise + complexity)
  - Less Risk (reduced financial risk, added complexity)
- Themes:
  - Collapsing requirements together
  - Scope of protection depends on level of financial risk assumed
  - Applies to Medicare and Non-Medicare Beneficiaries
  - Other potential exceptions may still apply
  - Common definitions
  - Forgiving “technical” violations (Stark, not AKS)
- Stark and AKS proposals are similar with some distinctions
  - AKS safe harbors generally more complex than Stark

Key Concepts for Value-Based Exceptions & Safe Harbors

Value-Based Activity	• Provision of item or service; taking of action; refraining from action • Does not include making a referral
Value-Based Arrangement	• Arrangement for provision of at least one value based activity for the target population between or among the Value-Based Enterprise and VBE participants
Value-Based Enterprise	• Two or more VBE participants • Accountable body or person responsible for financial and operational oversight • Governing document
Value-Based Purpose	• Coordinating and managing care • Improving quality of care • Reducing costs without reducing quality • Transitioning from volume to value
Target Patient Population	• Identified patient population selected by VBE using legitimate and verifiable criteria set out in advance in writing

- Stark (42 CFR §411.351); AKS (42 CFR § 1001.952(ee))

Who Can Qualify for Exceptions & Safe Harbors?

- Remember differences between Stark and AKS:
  - "Physicians", "immediate family members", "entities" vs. "whoever:
- "Value Based Participants" ("VBPs")
  - An individual or entity that engages in at least one value-based activity as part of a VBE (Stark)
- Certain parties specifically excluded:
  - AKS : Excludes pharmaceutical manufacturers; DMEPOS manufacturers, distributors and suppliers; and laboratories
  - Stark: CMS "considering" whether certain parties (e.g., pharma manufacturers, DMEPOS manufacturers, distributors; laboratories etc.) should be carved out

“Full Financial Risk” (Exception and Safe Harbor)

- Broadest scope of protection
- Common Requirements;
  - VBE at full financial risk
    - “Financially responsible on a prospective basis for the cost of all patient care” covered by the payor (Stark)
  - Remuneration is for, or results from, value-based activities
  - Inclusion of CMP—no inducement to reduce or limit medically necessary services
  - No "swapping" — cannot be conditioned on referrals of patients who are not part of target population or business not covered by VBA
- Stark (42 CFR § 411.357(aa)(1); AKS (42 CFR § 1001.952(gg))

"Full Financial Risk" (Exception and Safe Harbor)

- Differences between Exception and Safe Harbor:
  - AKS
    - Volume/value requirement
    - Signed writing between parties, term of 1 year
    - Accept full financial risk from payor for at least 1 year
    - Cannot claim separate payment for any items or services covered
    - No funding or payment from non-VBE participants (e.g., labs, DMEPOS)
    - No marketing or patient recruitment activities
    - Limitations on remuneration (no ownership)
  - Stark
    - No writing requirement
    - Must accept full financial risk for entire term of agreement
    - Records must be maintained for at least 6 years
    - Permits conditioning referrals (subject to modified rule)

"Meaningful Downside/Substantial Financial Risk" Exception and Safe Harbor

- Different standards for "Downside" Financial Risk under Stark and AKS
  - See next slide
- General Requirements
  - Does not protect ownership/investment interests
  - Must be in writing
    - AKS: Need all "material terms", including how recipients meaningfully share in risk, "cost" of remuneration, etc.
    - Stark: Description of nature and extent of physician's downside risk must be in writing
  - No inducement to reduce or limit medically necessary services
  - Must protect patient choice and physician's ability to make decisions in best interest of patients
  - No "swapping" — cannot be condition on referrals of patients who are not part of target population or business not covered by VBA

"Meaningful Downside/Substantial Financial Risk" Exception and Safe Harbor

- Balance between flexibility because of assumption of some (not full) downside risk

Key Distinction	
AKS	**Stark**
VBE must be at "substantial downside financial risk". 4 ways to do this: • Shared savings w/repayment obligation (at least 40% of shared losses) • Episodic or bundled payment arrangement w/ repayment obligation (at least 20% of total losses) • Specific prospectively set population-based payments (TCOC) • Specific partial capitation payments	**No requirement for VBE to be at risk**
VBE participant must "meaningfully share" in downside financial risk. 3 ways to do this: • 8% of total VBE risk to payor; • Partial or full capitation (not IPPS or "like" methodologies); or • Meet Stark exception for physician with meaningful downside risk	**Physician is at "meaningful downside financial risk" if VB purpose not met.** 2 ways to do this: • Responsible to pay entity no less than 25% of value of remuneration received under VBA; or • Financially responsible to entity on prospective basis for defined set of items and services

- Stark (42 CFR § 411.357(aa)(2); AKS (42 CFR § 1001.952(ff))

"Meaningful Downside/Substantial Financial Risk" Exception and Safe Harbor

- Differences in Stark/AKS Proposals
  - AKS
    - Volume/value of referrals
    - VBE has assumed (or is contractually obligation to assume within 6 months) substantial downside risk from payor
    - Remuneration is:
      - Used "primarily" to engage in value based activities for which VBE is at substantial downside financial risk
      - Directly connected to one or more of VBE's purposes, including care coordination and management of care for target population
    - No marketing or patient recruitment activities
  - Stark
    - Remuneration is for and results from value-based activities for patients in target population
    - Remuneration is "set in advance" (Stark definition)
    - Records must be maintained for at least 6 years

Value-Based Arrangements (Stark) or Care Coordination Arrangements (AKS)

- Most restrictive of the new exceptions/safe harbors (and for AKS, complex)
- General Requirements
  - Must be set forth in writing and signed by parties and specify key terms
  - No inducement to reduce or limit medically necessary services
  - Must protect patient choice and physician's ability to make decisions in best interest of patients
  - No "swapping" — cannot be condition on referrals of patients who are not part of target population or business not covered by VBA

- Stark (42 CFR § 411.357(aa)(3); AKS (42 CFR § 1001.952(ee))

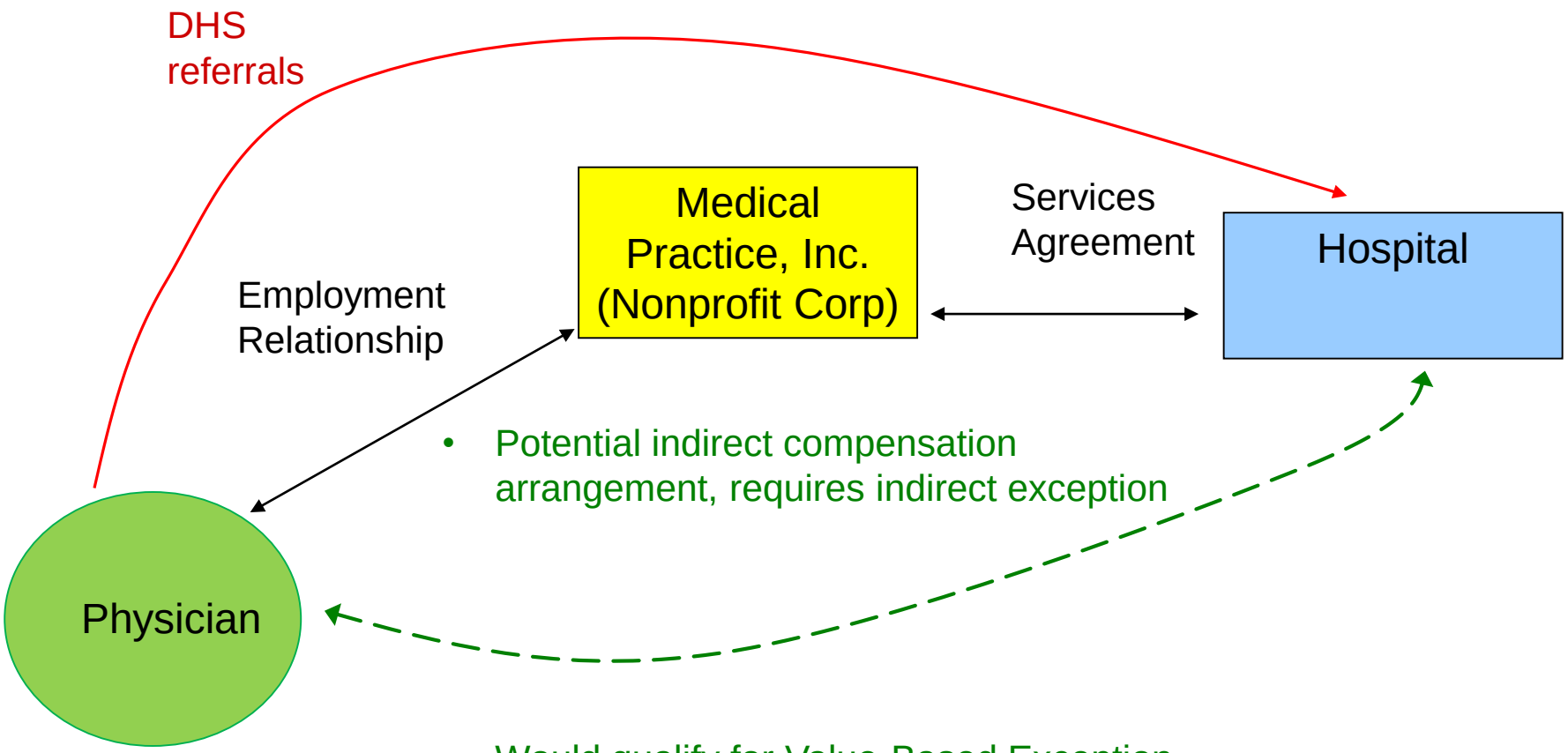
Value-Based Arrangements (Stark) or Care Coordination Arrangements (AKS)

- Differences between Stark and AKS Proposals
  - AKS
    - Only protects non-monetary remuneration
    - Must specify one or more specific, evidence-based outcome measures
    - Recipient must pay at least 15% of costs (one-time or reasonable intervals) Remuneration is:
      - Used "primarily" to engage in value based activities that are directly related to care coordination and management of care for target population
    - Must specify offeror's costs of remuneration
    - Volume/value of referrals
    - No marketing or patient recruitment activities
    - Requirement to monitor and assess performance no less frequently than annually; and terminate within 60 days if determined value-based arrangement is unlikely to further coordination, results in major quality deficiencies, or unlikely to meet outcome measures
  - Stark
    - Protects monetary and non-monetary remuneration
    - Performance or quality standards against which recipient is measured are optional
    - Remuneration is for and results from value-based activities for patients in target population
    - Payment methodology is "set in advance"
    - Records must be maintained for at least 6 years

Relationship between VB Exceptions and Indirect Compensation Rules

- Under current regulations, the only exception available for “indirect compensation arrangement” is “indirect compensation exception”
  - 42 CFR § 411.357(p)
- Proposed regulations would allow certain indirect compensation arrangements to rely on value-based arrangement exceptions
  - 42 CFR § 411.357(aa)

Indirect Compensation Analysis



- Potential indirect compensation arrangement, requires indirect exception

- Would qualify for Value-Based Exception under proposed regulations

Patient Engagement

- New, Proposed Safe Harbor
  - 42 CFR § 1001.952(hh)
- Exception to definition of “remuneration”
  - Also serves as exception from definition of remuneration for purposes of CMP
- Protects arrangements for patient engagement tools and supports to improve quality, health outcomes, and efficiency
  - Applies to tools furnished directly by VBE participants to patients in target patient population
  - Idea is that these tools will help ensure patients receive the medically necessary care and other non-medical, but health-related, items and services that they need and ultimately help improve adherence to treatment regimens.

Patient Engagement (continued)

- Limited to in-kind tools and supports
  - "in-kind, preventative items, goods, or services, or items, goods or services such as health related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health, that have a direct connection to the coordination and management of care of the target patient population."
- Excludes gift cards, cash, and any cash equivalent
- Limited to $500 annually (retail value)
  - Limited exceptions for financial need

Patient Engagement (continued)

The incentives and supports must advance one of the following goals:

- Adherence to a **treatment regimen** as determined by the patient's licensed health care provider.
- Adherence to a **drug regimen** as determined by the patient's licensed health care provider.
- Adherence to a **follow-up care plan** established by the patient's licensed health care provider.
- **Management of a disease or condition** as directed by the patient's licensed health care provider.
- Improvement in **evidence-based, measurable health outcomes** for the patient or for the target patient population
- Ensuring **patient safety**; or
- Some combination of the above.

CMS-Sponsored Models

- New, Proposed Safe Harbor
  - 42 CFR § 1001.952(ii)
- Provides separate safe harbor to protect CMS-sponsored models, such as those designed by the CMS Innovation Center.
- Would largely, if not entirely, replace OIG's current model-by-model fraud and abuse waiver process
- Does not extend to commercial and private insurance arrangements that may operate alongside, but outside, a CMS-sponsored model

Cybersecurity and EHR Exceptions/Safe Harbors

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AKS:
Cybersecurity Safe Harbor

- New, Proposed Safe Harbor
  - 42 CFR § 1001.952(jj)
- OIG acknowledges need for protection of patient information
  - "*The healthcare industry and the technology used to deliver healthcare have been described as an interconnected 'ecosystem' where the 'weakest link' in the system can compromise the entire system*"
- Provides standalone protection for donations of cybersecurity technology and related services
- Donations must meet five conditions
- Donation of hardware is excluded

Stark:
Cybersecurity Technology Exception

- 42 CFR § 411.357(bb)
- Protect nonmonetary remuneration in the form of certain cybersecurity technology and related services
  - As with AKS safe harbor, excludes hardware
  - Considering alternative proposals that would allow for the donation of certain hardware
- Donation must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity
- No recipient contribution requirement
- Need written documentation

AKS:
EHR Donation Safe Harbor

- Revisions to Safe Harbor
  - 42 CFR § 1001.952(y)
- Removes sunset provision
- Updates the interoperability provisions consistent with Office of National Coordinator for Health Information Technology
  - Provides textual clarifications to “deeming” provision
  - Implements statutory definition of “information blocking”
- Retains 15% recipient cost-sharing requirement, but proposes elimination or reduction for small or rural practices.
- Clarifies application to cybersecurity technology
  - Cybersecurity software and services have always been protected under this safe harbor
  - Broadens protection (but not as broad as new cybersecurity safe harbor)

Stark:
EHR Exception

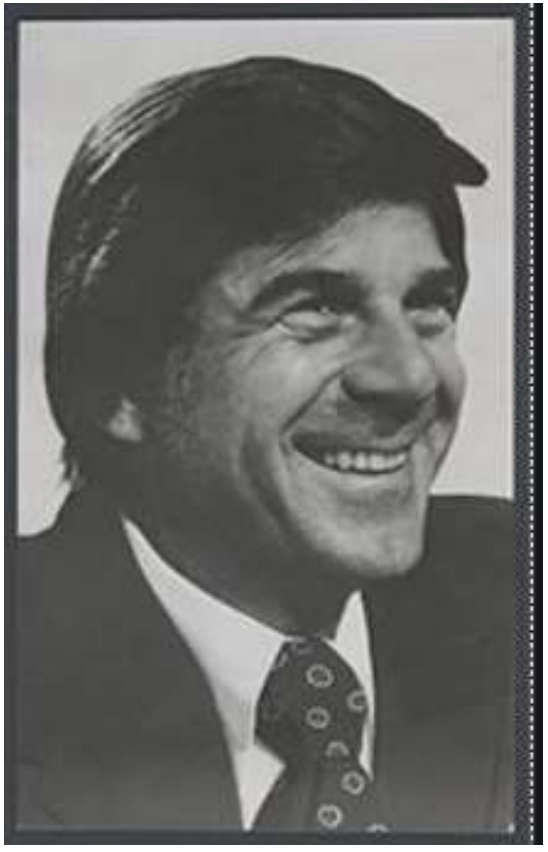
- 42 CFR § 411.357(w)
- Proposed changes intended to be consistent with OIG
- Removes sunset provision
- Interoperability
  - The “deeming” provision
  - Implements statutory definition of “information blocking”
- Retains 15% recipient cost-sharing requirement
- Clarifies application to cybersecurity technology

Proposed Changes to Key Stark Law Definitions

- Key Stark Law definitions
  - Commercial Reasonableness
  - Volume or Value of Referrals/Other Business Generated
  - Fair Market Value
- Series of False Claims Act cases
  - Bad facts make bad law
  - Regulatory risks and compliance burdens have increased
- CMS experience with SRDP
- Responses to 2018 CMS/OIG RFI
- Proposed definitions apply only to Stark Law

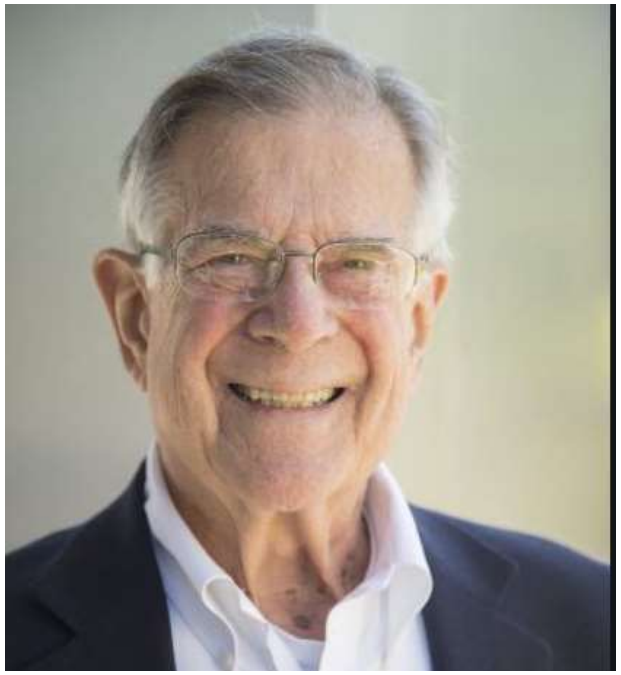
Stark Law History

- Stark I statute; passed in 1989; fairly limited in scope
- Stark II statute; passed January 1, 1995; broad array of services included
- Stark I final regulations; effective September 13, 1995
- Stark II proposed regulations, issued in 1998 (led to 13,000 comments!)
- Phase I Stark II regulations; most provisions effective 2002 (led to only 140 comments)
- Phase II Stark II regulations; effective 2004



Stark Law History

- Phase III Stark regulations; effective 2007
- Inpatient Prospective Payment System (“IPPS”) Final Rule for 2009, issued in 2008
- Waivers related to the Shared Savings Program established by the ACA issued in 2015
- Additional exceptions issued in 2016 Physician Fee Schedule
- June 30, 2016, Senate White Paper
- 2018 CMS and HHS RFI



Commercially Reasonable

- Why is this important?
  - What is the current definition?
- Proposed definition:
  - The particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements
- Alternative definition:
  - 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
- Both would make clear that an arrangement that is not profitable can still be commercially reasonable
- Commercial reasonableness is separate concept than FMV
- To be added to Stark Law definitions (42 CFR § 411.351)

Taking Into Account the Volume or Value of Referrals or Other Business Generated

- Currently defined at 42 CFR § 411.354(d)(2) and (3) as situations where compensation deemed not to take into account volume/value of referrals or other business generated
- Proposed regulations create new deeming tests for situations where compensation will be considered to take into account volume/value of referrals or other business generated
- Four new standards (mirror each other)
  - Compensation from an entity to a physician takes into account (1) volume or value of referrals or (2) other business generated
  - Compensation from a physician to an entity takes into account (3) volume or value of referrals or (4) other business generated
- Goal is to have an objective, mathematical standard
  - To be added as 42 CFR § 411.354(d)(5) and (6)
- Current rules also stay can be used

Volume or Value and Other Business Generated

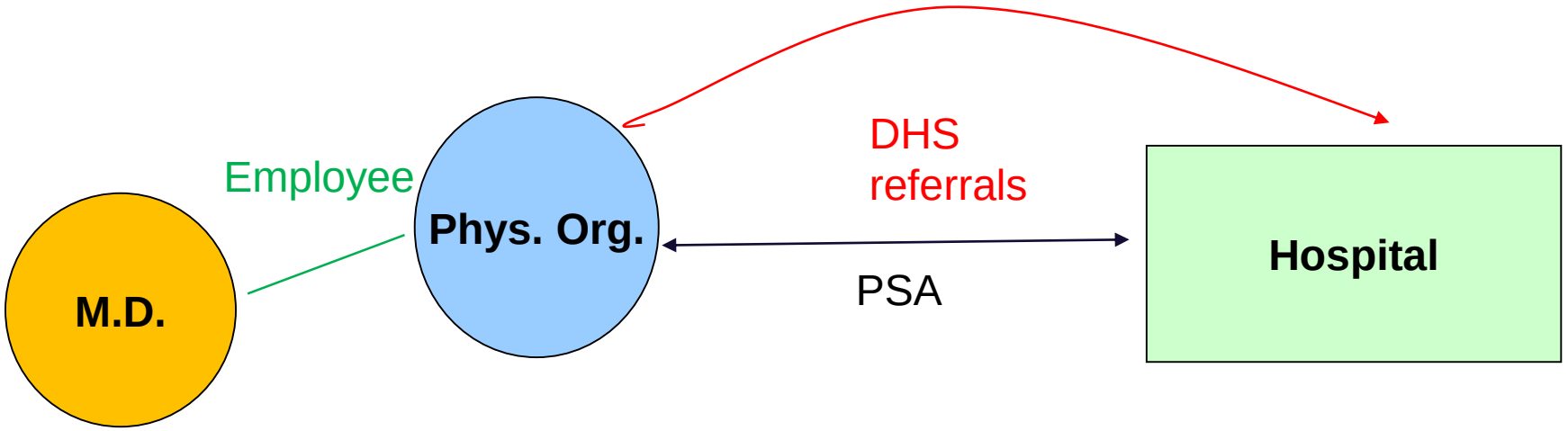
- Focus is whether there is a predetermined, direct positive or negative correlation between the volume or value of the physician's referrals (or other business generated for the entity) and the rate of compensation paid to or by the physician (or an immediate family member of the physician) in order for the compensation to violate the volume or value standard or the other business generated standard
- A positive correlation between 2 variables exists when one variable increases as the other increases or one variable decreases as the other decreases
- A negative correlation between 2 variables exists when one variable increases as the other decreases or when one variable decreases as the other increases
  - E.g., physician's rent for office space decreases after he hits a predetermined target of referrals to lessor
- CMS trying to help parties apply an "If X, then Y" standard

Volume or Value of Referrals from *Physician* to Entity

- Compensation from entity to physician takes into account volume of value of referrals only if:
  - Formula used to calculate physician's (or immediate family member's) compensation includes the physician's referrals to 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; or
  - There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined
    - E.g., if prior referrals were X, then compensation for the remainder of the term is Y
- Test for "other business generated" follows same approach

Example: Volume or Value of Referrals from *Physician* to Entity

- Option 1
  - $125 per wRVU for MD professional services
  - For each professional services, corresponding facility charge generated (billed by hospital)
- Option 2
  - M.D. paid % of collections for personally performed services + % of collections from pool that includes DHS MD orders but does not perform

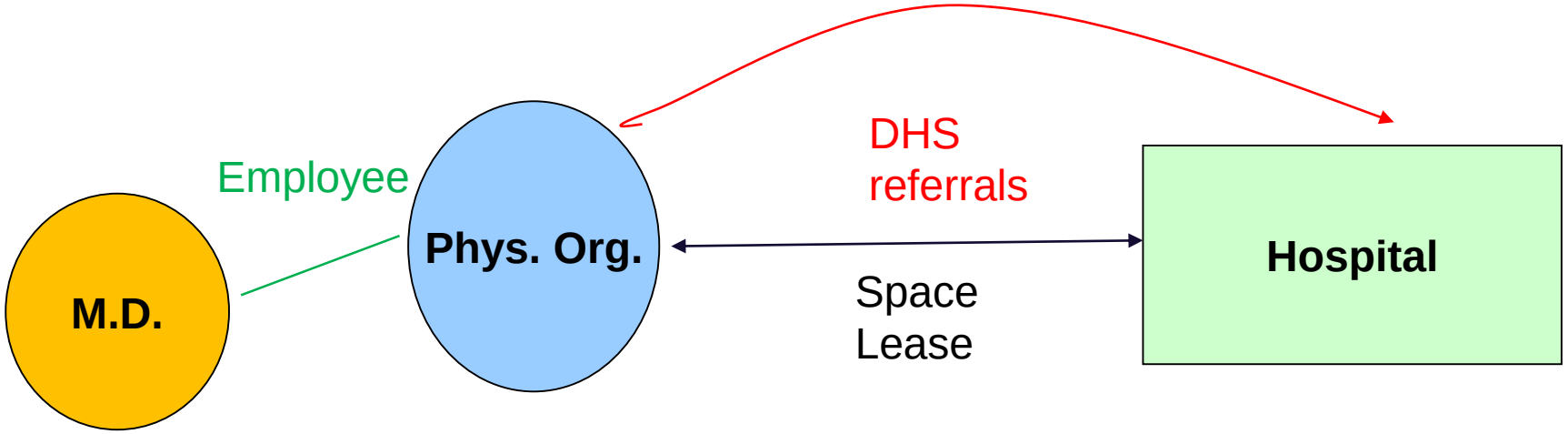


Compensation from Physician to Entity

- Compensation from physician (or immediately family member) to entity takes into account volume of value of referrals only if:
  - Formula used to calculate entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity; or
  - There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined
    - E.g., if prior referrals were X, then compensation for the remainder of the term is Y
- Test for "other business generated" follows same approach

Example: Compensation from Physician to Entity

- Option 1
  - Group leases space for $5000/month
  - Lease rate decreases by $5 for each diagnostic test ordered by M.D. and furnished in hospital outpatient dept.
- Option 2
  - Hospital offers to change rate for next term such that it would be $2500/month (if MD in top half of admissions) or $5500/month (bottom half)



Volume or Value and Other Business Generated

- Challenges in understanding and applying current terms:
  - *U.S. ex rel. Drakeford v. Tuomey* decision
  - Correlation theory
  - Problems with tracking referrrals
  - Does “taking into account” question introduce intent into a strict liability law?
- CMS offers helpful clarifications on several issues:
  - Employed physician — productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (DHS) are billed each time the employed physician personally performs a service
  - Also applies to independent contractor physicians where exception met
  - Compensation arrangements — an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula — even when the entity bills for DHS that correspond to such personally performed services — and the compensation will not take into account the volume or value of the physician's referrals
  - New rules not relevant to proposed Value Based Exceptions
- Should reduce concern about wRVU compensation models between physicians and hospitals
- New rules not applicable to AKS and its Safe Harbors

Directing Referrals in a Value Based World

- Current regulations (42 CFR §411.354(d)(4)) permits directed referrals if specified conditions are met to preserve patient choice, insurer's determinations, and protect medical judgment as to best interest of patient

- Proposed regulations:
  - Clean up standards (e.g., clarify distinction between FMV and volume/value of referrals)
  - Modify test to clarify when it can be used
  - Adds as an element to Value Based Exceptions

Fair Market Value

- Revised 3 part definition with separate definition for general market value
- FMV: value in an arm's length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction
  - Language for rental of equipment and rental of office space also modified
  - Removes “taking into account” language
- Defines "general market value“: the price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.
  - Separate definition of “general market value” for rental of office space/equipment
- All found at 42 CFR § 411.351

Fair Market Value

- CMS' intent to shift focus on analysis between hypothetical parties and look to the actual parties and the actual transaction
- No reason Congress intended to require a standard different than what is used in valuation community
- Changes focus to facts and circumstances analysis that looks to what is happening between parties at issue:
  - E.g., ortho. surgeon paid substantially more than $450K (survey data) because of unique skills, expertise = FMV
  - E.g., family practice MD paid substantially less than $250K (survey data) because working in low cost area with low reimbursement = FMV

Definition of “Group Practice”

- Revisions to “profit share” and “productivity bonus” components of regulatory definition
  - Adds the concept of VB Arrangements and the distribution of profits related to DHS directly attributable to physician participation in value-based arrangements
    - Deemed not to relate directly to the volume/value of referrals
  - Clarifies applicability of volume/value standard to compensation within group practice
  - Overall profits means the profits derived from all DHS of any component of at least 5 physicians
  - Profits from all DHS must be aggregated and distributed, with profit shares not determined in any manner that directly takes into account (directly related to) the volume or value of the physician's referrals
    - Cannot distribute profits from DHS on a service-by-service basis
- 42 CFR § 411.352

Conscious Uncoupling of Stark and AKS

- CMS removes AKS and compliance with Federal/State Law
  - No longer believe it is necessary
  - Congress did not require
  - Does not impact liability under AKS

Addressing “Technical” Noncompliance

- CMS has authority to determine alternative methods for satisfying requirements of an exception (though it cannot waive violations)
- Based on 2018 BBA and SRDP experience, CMS has reconsidered its position on noncompliance with signature and writing requirements:
  - Would permit short periods of noncompliance at outset of arrangement before terms established in writing
  - Must meet all other requirements of an applicable exception and can memorialize in writing and obtain signatures within 90 consecutive calendar days
- Arrangements can be set in advance without a writing
  - Text message may suffice!
- Confirms electronic signatures are valid
- 42 CFR § 411.354(e)

Definitions:

Designated Health Services

- Proposed rule clarifies that hospital inpatient services do ***not*** constitute DHS if the services do not affect payment under the Medicare IPPS
- CMS declined to extend the clarification to hospital outpatient services
- Comments sought on whether the proposal should be extended to analogous services by hospitals that are not paid under the IPPS

Definitions:

Physician

- Proposed rule eliminates an ambiguity in the current regulation by simply cross-referencing to the general Medicare definition of physician at 42 U.S.C.§1395x(r)
  - Doctor of medicine or osteopathy
  - Doctor of dental surgery or dental medicine
  - Doctor of podiatric medicine (for limited purposes)
  - Doctor of optometry (for limited purposes)
  - Chiropractors (for limited purposes)

- Physician Assistants and Nurse Practitioners are not "physicians"

Definitions:

Referral

- Proposing to revise the definition of “referral” to explicitly state that a referral cannot be an "item or service" for which payment may be made under the Stark statute or regulations

Definitions:

Remuneration

- Currently "remuneration" excludes:
  - Furnishing of items, devices, or supplies, (not including surgical items, devices or supplies) used solely to:
    - Collect, transport, process or store specimens for the entity providing the items, devices or supplies; or
    - Order or communicate the results of test or procedures for the entity furnishing the items, devices or supplies
- Proposed rule
  - Removes the exclusion for surgical items, noting that focus should be on whether the “used solely" criteria is met
  - Clarifies the “used solely” requirement
    - The inquiry should be based on how the items are actually used, not whether they *could* be used for a purpose other than one or more of the permitted purposes
    - Clarifies that items used for infection or contamination control, e.g., sterile gloves, would not meet the “used solely" criteria

Definitions:

Isolated Financial Transactions

- Proposed rule creates a new free-standing definition of “isolated financial transactions” which:
  - includes a one-time sale of property or a practice, or similar one-time transaction;
  - does not include a single payment for multiple or repeated services (such as a payment for services previously provided, but not yet compensated).
- Proposed Rule retains the general definition of "transaction" as an instance or process of two or more persons or entities doing business

Period of Disallowance

- Proposing to delete the rules on the period of disallowance at § 411.353(c)(1) in their entirety
  - CMS notes that it considers the current rule to be "overly prescriptive and impractical"
- CMS commentary
  - No definite rules for establishing when financial relationship has ended
    - A case-by-case facts and circumstances analysis
  - General principles
    - Period of disallowance begins when the relationship fails to meet all requirements of an exception and ends either when it comes into compliance or when the relationship concludes
    - One way to establish that period of disallowance has ended is to follow steps from old rule
    - Intent in deleting the rule is to no longer prescribe the particular steps for ending the period of noncompliance

Period of Disallowance (cont.)

CMS provides general guidance:

- Erroneous over or underpayment of contractual compensation due to administrative error does not create a period of disallowance if detected and "trued up" before the agreement expires
  - Not necessarily “turning back the clock” or retroactively “curing” noncompliance; rather, part of effective compliance program.
- If fail to timely identify and rectify the error:
  - Consider the nature of the issue. For example, if the actual payment amount was FMV, the potential noncompliance may relate to the failure to properly document the actual arrangement
  - Here, could look to proposed special rule for writing and signature requirements, coupled with the clarification of the writing requirement, to establish that the actual amount of compensation provided was set forth in writing within 90 days via a collection of documents, including documents evidencing the course of conduct.
- If no safety valves are available, the entity may need to recoup excess compensation in order to end the period of disallowance

Limited Remuneration to a Physician

- Creates exception for non-abusive business practices
  - 42 CFR § 411.357(z)
- Applies to furnishing of items and services by physician
- Remuneration must not:
  - exceed $3,500 annually
  - be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; or
  - exceed fair market value for the items or services provided by the physician
- The compensation arrangement must be commercially reasonable.

Ownership or Investment Interests

- Titular Ownership or Investment Interest
  - Extend concept of rules governing ownership or investment interests at 42 CFR § 411.354(b)
  - CMS reasoned that if physician does not have right to distribution of profits or proceeds of sale, no financial incentive to make referrals
- Employee Stock Ownership Program
  - Excludes from the definition of “ownership or investment interest” an interest in an entity that arises through participation in an ESOP
  - CMS believes this merits the same protection as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity

Rental of Office Space or Equipment

- Exclusive use clarified (42 CFR § 411.357(a) and (b))
  - "Purpose of the exclusive use rule is to prevent sham leases where a lessor 'rents' space or equipment to a lessee, but continues to use the space or equipment during the time period ostensibly reserved for the lessee
  - Proposed rule clarifies that multiple lessees can use same rented office space or equipment at the same time as long as lessor is excluded

- Fair market value exception (42 CFR 411.357(l))
  - Reconsidered policy and proposed to make exception available to protect arrangements for the rental or lease of office space
  - Prohibits percentage-based and per-unit of service compensation for office space
  - Does not require 1-year term

Remuneration Unrelated to Provision of DHS

- 42 CFR § 411.357(g)
- Modification to broaden application of the exception
- Delete current provisions and propose language that incorporates the concept of patient care services as the determining factor when remuneration for an item or services is related to the provision of DHS
  - Remuneration from hospital to physician does not involve DHS if the remuneration is for items or services not related to patient care services
- If a services can be provided legally by a person who is not a licensed medical professional, *and* the service is of the type typically provided by such person, payment is unrelated to the provision of DHS and may be protected by this exception.
  - Service deemed to be not related to the provision of patient care services

Payments by a Physician

- 42 CFR § 411.357(i)
- Reconsidered position regarding availability of the regulatory exception for certain compensation arrangements
- Under proposed rule, parties would generally be able to rely on this exception to protect fair market value payments by a physician to an entity for items or services furnished by the entity, even if a regulatory exception at § 411.35 may be applicable
  - Not available to protect compensation arrangements specifically addressed by one of the statutory exceptions (e.g., rental of office space or equipment).
- CMS stressed that the "items or services" furnished by the entity may not include cash or cash equivalents

Recruitment

- Physician
  - 42 CFR § 411.357(e)
  - If physician practice is not receiving any financial benefit from the recruitment agreement, it is not necessary to obtain a signature from the group

- Nonphysician Practitioner (NPP)
  - 42 CFR § 411.357(x)
  - Proposing to change references to “patient care services” to “NPP patient care services”
    - And to change references to “referral” to “NPP referral”

  - “NPP patient care services” mean:
    - Direct patient care services furnished by an NPP that address the medical needs of specific patients or any task performed by an NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement.
  - Replacing term “practiced” with "furnished NPP patient care services"

Anti-kickback Statute

OIG's "Guiding Principles" for AKS Changes

- Permit beneficial innovations in health care delivery
- Avoid regulations that limit innovation, push people towards narrow channels
- Provide safe harbor protection that is useful for a wide range of provider types and sizes
- Create clear, objective, and flexible rules
- Create appropriate safeguards to protect beneficiaries and Medicare
- OIG recognizes its rules are "more restrictive" than CMS' with Stark, due to AKS' backstop nature

Personal Services and Management Contracts Safe Harbor

- Proposed modification of existing safe harbor and expansion to protect outcomes based arrangements
  - 42 CFR § 1001.952(d)
- Would provide protection to certain “outcomes-based” payment arrangements
  - Measurably improving care, or
  - Materially reducing costs
  - Specific detail related to acceptable “evidence-based, valid outcome measures”
  - Excludes pharmaceutical company, manufacturer, distributor, DMEPOS supplier, or laboratory
  - Also excludes payments that relate solely to internal cost savings
  - Fair market value payment, commercially reasonable, does not take into account referrals, methodology set in advance, does not incent the reduction of medically necessary care
  - 1 year term, written agreement signed in advance of commencement

Personal Services and Management Contracts Safe Harbor

- Modifies existing safe harbor to make much more flexible
- Eliminates requirement that aggregate payment be set out in advance (i.e., the full amount)
  - Instead, requires payment methodology be set out in advance
  - Similar to Stark Law exception for fair market value arrangements and personal services arrangements
- Also eliminates requirement that part-time needed to have complete schedule, precise length of intervals and exact charge for intervals set out in written agreement

Warranty

- Revisions to Safe Harbor
  - 42 CFR § 1001.952(g)
- Protects warranties for one or more items and related services upon certain conditions (“Bundled Warranties”)
- Warranty must cover at least one item
  - No protection for service-only arrangements
- Remuneration capped at cost of the items/services subject to the warranty
- Expressly excludes beneficiaries from reporting requirements applicable to buyers
- Defines warranty directly (rather than relying on the reference to 15 U.S.C. § 2301(6))
- No protection for service-only arrangements Adds criteria for protection of bundled warranties

Local Transportation

- Revisions to Safe Harbor
  - 42 CFR § 1001.952(bb)
- Expand distance allowed for residents in rural areas
  - Increased from 50 miles to 75 miles
- Removes any distance limitation for inpatients upon discharge
  - Transportation home after discharge does not pose the same level of risk
  - Considering whether this should be expanded to permit transportation after discharge to any location (and not just a residence) (e.g., another healthcare facility)
- Clarifies that ride-sharing arrangements are permissible

Civil Monetary Penalty for Beneficiary Inducements

ACO Beneficiary Incentive Program

- New AKS Safe Harbor
  - 42 CFR § 1001.952(kk)
- Implements provision of Bipartisan Budget Act of 2018, which carved out ACO Beneficiary Incentive Programs from definition of illegal remuneration
  - Proposed rule codifies exception to definition of remuneration
  - Did not establish any additional conditions or requirements
- Protects incentive payment made by ACO to assigned beneficiary who receives payment as part of an ACO Beneficiary Incentive Program
- Also serves as exception from definition of remuneration for purposes of CMP

Telehealth Technologies for In-Home Dialysis

- New Exception
  - 42 CFR § 1003 110(10)
- Implements statutory change included in Bipartisan Budget Act of 2018
- Adds an exception to the definition of “remuneration” that allows telehealth technologies to be provided on a monthly basis to ESRD patients receiving in-home dialysis
- “Telehealth technologies” means:
  - Multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention, or ongoing care management—paid for by Medicare Part B—between a patient and the remote healthcare provider.
  - Telephones, facsimile machines, and electronic mail systems are not telehealth technologies.

Final Thoughts

Questions?

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