Stark Law, Anti-kickback Statute and CMP Final Regulations: What You Need to Know

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Agenda

- Introduction
- Exceptions/Safe Harbors for Value-Based Arrangements
- EHR/Cybersecurity Exceptions/Safe Harbors
- Other Key Stark Law Changes
  - The Big Three
  - New Exceptions
  - Definitions and Clarifications
- Other Key Anti-Kickback Statute (“AKS”) Changes
  - New Safe Harbors
  - Definitions and Clarifications
- Civil Monetary Penalty (“CMP”) Law
- Questions

Proposed v. Final Regulations

- Proposed regulations issued Oct. 17, 2019
  - Stark, 84 Fed. Reg. 55766
  - AKS / CMP, 84 Fed. Reg. 55694
- Based on “Regulatory Sprint to Coordinated Care”
- Subject to Notice-and-Comment → Final Regulations
  - Agencies accepted comments through end of 2019
- Trend of overlap and consistency
- Differences based on distinctions between Stark and AKS
- Aug. 2020, CMS / HHS announced delay in publishing final rule until summer 2021
- Final regulations issued Dec. 2, 2020
  - Stark, 85 Fed. Reg. 77492—77682
  - AKS / CMP, 85 Fed. Reg. 77684—77895

Final Rule: General Themes

- Consistency, while recognizing differences between the two laws
- Interpret the prohibition narrowly and the exceptions broadly
- Parties can continue to use existing exceptions / safe harbors to insulate value-based arrangements
- CMS / CMMI programs can continue to issue specific fraud and abuse waivers
- Traditional protections (e.g., FMV) replaced with new protections needed to address unique concerns arising in VB care (e.g.., no “cherry picking” or “lemon dropping”)
- More risk assumed in value-based arrangements, more flexibility under new rules
- Some ideas abandoned in Final Rule—no “price transparency” for example
- Added flexibility for providers to assist each other with EHR and cybersecurity technology acquisition and maintenance
- More leeway to incent patients to obtain care from providers
- Stark Law changes on FMV, commercial reasonableness and volume / value apply only to Stark (not AKS, IRS or state laws on fraud and abuse, such as mini-Stark laws)

Value-Based Arrangements

Exceptions & Safe Harbors

Value-Based Exceptions / Safe Harbors

- Three New Exceptions/Safe Harbors:
  - Full Financial Risk (greatest financial risk, greatest flexibility)
  - Large Financial Risk (compromise → complexity)
  - Less Risk (reduced financial risk, more 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 between Stark and AKS
- Exceptions and safe harbors are similar with some distinctions
  - AKS safe harbors generally more complex than Stark

Key Value-Based Principles

Value-Based Activity	• Provision of item or service; taking of action; refraining from action • Must be reasonably designed to achieve at least one VB Purpose • Proposed Stark rule provided this does not include making a referral. Final Stark rule walks this back, providing that care planning activities that meet definition of "referral" quality as "taking an action" • For AKS, making a referral, on its own, is not a VB Activity
Value-Based Enterprise	• Two or more VBE participants • Collaborating to achieve at least one VB Purpose • Each of which is a party to a VB Arrangement with the other or at least one other VBE Participant in the VB Enterprise • Accountable body or person responsible for financial and operational oversight • Governing document indicating the VB Enterprise and how the VBE Participants intend to achieve its VB Purposes

- Stark (42 CFR §411.351); AKS (42 CFR § 1001.952(ee)(14))

Key Value-Based Principles

VBE Participant	• A person or entity that engages in at least one value-based activity as part of a value-based enterprise
Value-Based Purpose	• Coordinating and managing care of TPP • Improving quality of care for TPP • Reducing costs / expenditures without reducing quality of care for TPP • Transitioning from delivery / payment system based on volume to mechanisms based on value (quality, cost control) for TPP
Target Patient Population	• Identified patient population selected by VBE using legitimate and verifiable criteria set out in advance in writing and that further the VB Enterprise's VB Purposes
Value-Based Arrangement	• Arrangement for provision of at least one value based activity for the TPP to which the only parties are (1) a VB Enterprise and one or more of its VB Participations; or (2) VBE participants in the same VB Enterprise.

- Stark (42 CFR §411.351); AKS (42 CFR § 1001.952(ee)(14))

Who Can Qualify for Exceptions / Safe Harbors?

- Remember differences between Stark and AKS:
  - "Physicians", "immediate family members", "entities" vs. "whoever":
- Value Based Participants and Value Based Enterprises (AKS); Value-Based Arrangement (Stark)
  - Definition largely consistent between Stark and AKS
- Exclusions from Stark?
  - Stark: in Proposed Rule, CMS considered whether certain parties (e.g., pharma manufacturers, DMEPOS manufacturers, distributors; laboratories etc.) should be carved out
  - Stark Final Rule does not exclude any parties
- Certain parties specifically excluded from AKS safe harbors:
  - Excludes pharmaceutical manufacturers, distributors, wholesalers; PBMs, entities that sell or rent DMEPOS; device / supply manufacturers, distributors, wholesalers; compounding pharmacies; and laboratory companies.
  - Narrow exception under care coordination safe harbor for limited technology companies

Key Concepts in Stark VB Exceptions

- No requirement that compensation be consistent with fair market value of the VB Activities and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity
- VB Arrangement exception requires commercial reasonableness (other two do not)
- Full financial risk does not require set in advance (other two do)
- No separate exception for CMS / CMMI sponsored programs
- No financial contribution requirement from the recipient of remuneration under any of the VB Exceptions
- Exceptions are prospective only
- VB exceptions apply to commercial arrangements as well as Medicare.
- Compensation arrangement only exceptions (not applicable / relevant to physician ownership interests)
- All three exceptions can protect monetary and non-monetary remuneration

Key Concepts in Anti-kickback Statute VB Safe Harbors

- Certain entities / categories of providers are not eligible
- Monetary remuneration protected under 2 of the 3 new safe harbors
- Nonmonetary remuneration protected under all 3
- No requirement of fair market value or broad prohibition on compensation taking into account the volume or value of referrals (narrower restriction on volume / value of referrals outside of targeted patient population)
- Care coordination safe harbor does require a financial contribution
- OIG believes arrangements that meet Stark Law exceptions can still violate AKS.
- VB safe harbors extend to commercial arrangements
- Care coordination safe harbor requires commercial reasonableness (others do not)
- Safe harbors are prospective only
- Safe harbors do not protect ownership / investment interests
- While complex (particularly care coordination safe harbor), improvements from proposed rule

Full Financial Risk Exception & Safe Harbor

- Common Requirements:
  - VBE at full financial risk:
    - Financially responsible on a prospective basis for the cost of all patient care items / services covered by the payor (Stark)
    - Financially responsible on prospective basis for cost of all health care items / services covered by payor for each patient in TPP for term of at least one year (AKS)
  - 12-month phase-in period under both Stark and AKS
  - Does not protect ownership / investment interests
  - Inclusion of CMP—no inducement to reduce or limit medically necessary services
  - Remuneration does not take into account volume/value of referrals or condition remuneration on referrals outside of TPP or business not covered by VBA (AKS)
  - Remuneration not conditioned on referrals of patients outside of TPP or business not covered under VBA (Stark)
  - Records must be maintained for at least 6 years
- Stark (42 CFR § 411.357(aa)(1); AKS (42 CFR § 1001.952(gg))

Full Financial Risk Exception & Safe Harbor

- AKS:
  - Signed writing between parties, specifies all material terms including VB Activities and term
  - Accept full financial risk from payor for at least 1 year
  - Cannot claim separate payment for any items or services covered
  - Remuneration is directly connected to 1 or more the VBE's VB Purposes
  - Remuneration cannot be exchanged or used for marketing services furnished by VBE or VBE Participants to patients or for patient recruitment activities
  - Quality assurance program for services rendered to TPP
- Stark:
  - No writing requirement
  - Must accept full financial risk for entire duration of arrangement (for which parties seek protection)
  - Permits conditioning referrals (subject to modified rule (requirement must be in writing and respect patient / payor preference)
  - Remuneration is for, or results from, value-based activities undertaken by recipient of remuneration for patients in TPP

Meaningful Downside / Substantial Financial Risk Exception & Safe Harbor

- General Requirements:
  - Protects monetary / nonmonetary remuneration
  - Does not protect ownership/investment interests
  - Must be in writing
    - AKS: Need all “material terms”, including how recipients meaningfully share in risk, evidencing substantial downside risk, VBAs, TPP and type of remuneration.
    - Stark: Description of nature and extent of physician's downside risk must be in writing
  - No inducement to reduce or limit medically necessary services
  - Permits conditioning referrals (requirement must be in writing and respect patient / payor preference)
  - Remuneration does not take into account volume/value of referrals or condition remuneration on referrals outside of TPP or business not covered by VBA (AKS)
  - Remuneration not conditioned on referrals of patients not part of TPP or business not covered under VBA (Stark)
  - Must be at meaningful risk for entire duration of VB Arrangement
  - Records must be maintained for at least 6 years

Meaningful / Substantial Financial Risk

Key Distinctions	
AKS	**Stark**
VBE must be at <u>substantial downside financial risk</u> from the payor. 3 ways to do this: • Shared savings w/repayment obligation (at least 30% of shared losses) • Clinical episode of care w/ repayment obligation (at least 20% of total losses) • Partial capitation payment (prospective, per-patient payment designed to produce material savings)	**No requirement for VBE to be at risk**
VBE participant must <u>meaningfully share</u> in downside financial risk. 2 ways to do this: • Assumes 2-sided risk for at least 5% of total VBE risk pursuant to VBE's assumption of substantial downside risk; • Receives prospective, per-patient payment for predefined set of services / items furnished to TPP and does not bill payor for predefined items / services	**Physician is at <u>meaningful downside financial risk</u> if VB purpose not met.** To qualify, physician must be: • Responsible to pay entity <u>no less than 10%</u> of value of remuneration received under VBA. • Means physician must repay or forgo no less than 10% of remuneration under VB Arrangement

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

Meaningful / Substantial Financial Risk

- AKS
  - VBE has assumed (or is contractually obligation to assume within 6 months) substantial downside risk from payor for at least one year
  - Remuneration is:
    - Used “predominantly” to engage in VB Activities that are directly connected to services / items for which VBE has assumed substantial downside financial risk, unless exchanged in manner that meets all other safe harbor conditions
    - Directly connected to at least 1 of 3 VBE's purpose for TPP (care coordination and management of care, improving quality or reducing costs to, growth in expenditures of payors without harming quality)
  - Remuneration cannot be exchanged or used for marketing services furnished by VBE or VBE Participants to patients or for patient recruitment activities
- Stark
  - Remuneration is for and results from value-based activities by recipient for patients in target population
  - Methodology to determine remuneration must be "set in advance" (Stark definition)
  - Focus is on “physician” having risk (not the entity having risk)
  - No phase-in period permitted

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

- General Requirements;
  - Must be set forth in writing and signed by parties and specify key terms (TPP, remuneration, VB Purpose, outcome measures etc.)
  - No inducement to reduce or limit medically necessary services
  - Must protect patient choice, independent medical judgment and physician's ability to make decisions in best interest of patients
  - Cannot condition on referrals of patients who are not part of TPP, or volume / value of any other business generated that is not part of VB Arrangement (AKS)
  - Ongoing monitoring requirement to ensure parties have furnished VB activities, whether VB activities will further VB purpose and progress towards achieving any outcome measures
  - Parties must terminate VB activity if not furthering VB purpose
  - Grace period for terminating ineffective VB activity
  - Must be commercially reasonable
  - Records must be maintained for at least 6 years
- Stark (42 CFR § 411.357(aa)(3); AKS (42 CFR § 1001.952(ee))

Care Coordination Arrangements (AKS)

- Only protects non-monetary remuneration
- Used predominantly to engage in VB Activities that are directly connected to coordination and management of care for TPP and does not result in more than incidental benefit to persons outside TPP
- Cannot induce VBE Participants to furnish medically unnecessary services
- Must specify one or more specific outcome measures that are monitored, assessed and prospectively revised as needed
- Must 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
  - Or apply corrective action plan to remedy deficiencies and then terminate if remedy does not occur within 120 days
- Recipient must pay at least 15% of offeror's costs or FMV of remuneration (paid one-time or at reasonable, regular intervals)

Care Coordination Arrangements (AKS)

- Writing must specify offeror's costs of remuneration (and accounting methodology used to determine costs) or the FMV of remuneration
- Remuneration cannot be exchanged or used for marketing services furnished by VBE or VBE Participants to patients or for patient recruitment activities
- Special rules for "limited technology participants" and "digital health technology"
  - Any remuneration by limited technology participant cannot be conditioned on recipient's use of items or services made, distributed or sold by limited technology participant
- Arrangement must be in writing and signed in advance of, or contemporaneous with, commencement of VB Arrangement and any material changes
- Remuneration cannot be diverted, resold or used by recipient for unlawful purpose

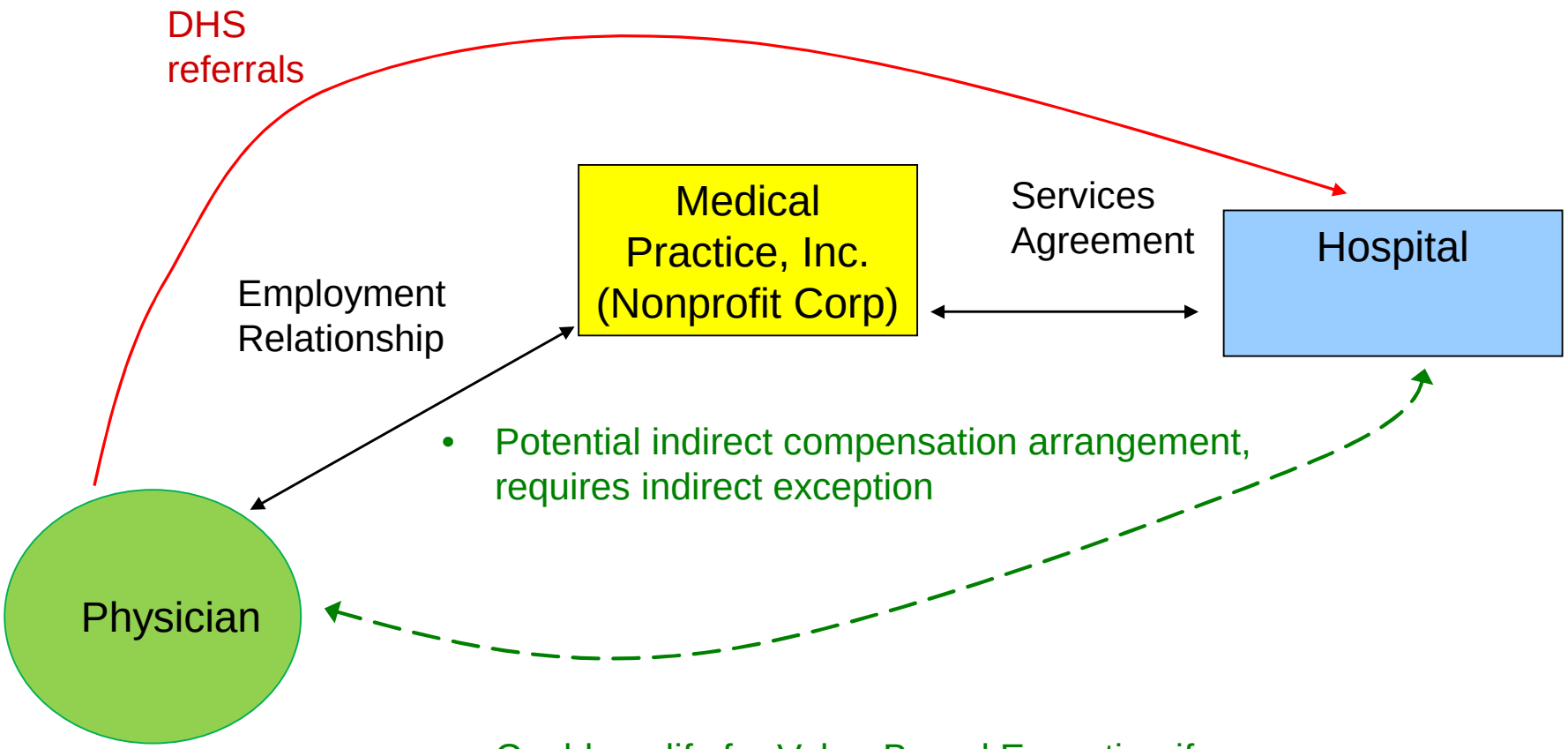
Value-Based Arrangements (Stark)

- Protects monetary and non-monetary remuneration
- Remuneration must be for or result from VB Activities undertaken by recipient for patients in TPP
- Outcome measures against which recipient is measured are optional
- If outcome measures are used, they must be objective and measurable and determined prospectively (including if any changes are made)
- Payment methodology is set in advance
- Remuneration not conditioned on referrals of patients not part of TPP or business not otherwise covered under VB Arrangement

Relationship between VB Exceptions and Indirect Compensation Rules

- Historically, the only exception available for indirect compensation arrangement is indirect compensation exception
- Final rule permits certain indirect compensation arrangements to rely on VB exceptions
  - Available for indirect compensation arrangements that include a VB Arrangement to which the physician (or physician organization under stand in the shoes) is a direct party
- Clarifies use of risk sharing exception in indirect arrangements (exception can be used in indirect arrangements in which DHS entity is an MCO or IPA)
- Clarifies scope of risk sharing exception in general

Indirect Compensation Analysis



- Potential indirect compensation arrangement, requires indirect exception

- Could qualify for Value-Based Exception if employment relationship is a VB Arrangement

Patient Engagement

- New Safe Harbor
  - 42 CFR § 1001.952(hh)
- 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 that VBE is a participant in
  - 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 (examples provided in proposed rule- below but deleted in Final Rule to avoid interpretation as an exhaustive list)
  - "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 cash, and any cash equivalent
- Limited to $500 annually (retail value)
- Cost sharing waivers not allowed under Final Rule
- Can’t use benefit to market services
- Can’t condition based on insurance coverage/ payor
- Records must be maintained for six years

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 professionals..
- Adherence to a **drug regimen** as determined by the patient's licensed health care professionals.
- Adherence to a **follow-up care plan** established by the patient's licensed health care professionals.
- **Prevention or management of a disease or condition** as directed by the patient's licensed health care professionals.
- Ensuring **patient safety**; or
- Some combination of the above.

CMS-Sponsored Models

- New 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.
- Replace OIG's current model-by-model fraud and abuse waiver process and puts a lot of responsibility on CMS to determine application
- 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 Safe Harbor
  - 42 CFR § 1001.952(jj)
- OIG acknowledges need for protection of patient information
- Provides standalone protection for donations of cybersecurity technology and related services
- Donations must meet five conditions
- Donation of hardware can be covered if the other conditions to the safe harbor are met (not intended to allow multifunctional hardware)
- No monetary limit

Stark:
Cybersecurity Technology Exception

- 42 CFR § 411.357(bb)
- Protect nonmonetary remuneration in the form of cybersecurity technology and related services
  - As with AKS safe harbor, the final rule makes a change from the proposed rule in that it does allow hardware to be donated
- 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
- Retains 15% recipient cost-sharing requirement, but eliminates requirement that contribution be made in advance
- 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)
- Changes intended to be consistent with OIG
- Removes sunset provision
- Interoperability
  - Final rule decided to forego specific prohibition of "information blocking"
- Retains 15% recipient cost-sharing requirement
- Clarifies application to cybersecurity technology

Changes to Key Stark Law Definitions

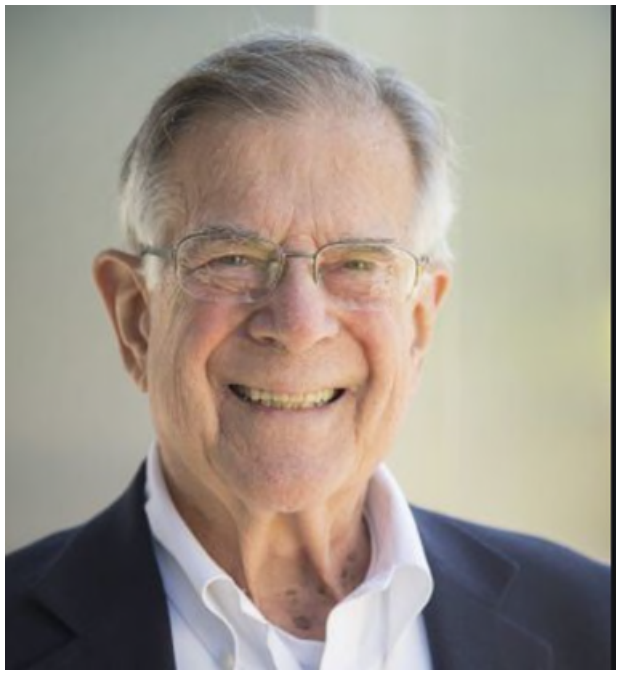
- Key Stark Law definitions:
  - Commercial Reasonableness
  - Volume or Value of Referrals/Other Business Generated
  - Fair Market Value
- Series of False Claims Act cases
  - Bad facts make bad law
  - Regulatory risks and compliance burdens have increased
  - “According to stakeholders and commenters on the proposed rule, False Claims Act … case law has exacerbated the challenge of complying with these three fundamental requirements”
- CMS experience with SRDP
- Responses to 2018 CMS/OIG RFI
- Revised definitions apply only to Stark Law; no bearing on AKS, CMP, IRS, QPP or state laws

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
- 2019 Proposed Rule
- Aug. 27 2020 (85 Fed. Reg. 52940) CMS announced 1-year delay



Commercially Reasonable

- CMS only addressed once (1998 proposed rule):
  - Arrangement appears to be sensible, prudent business agreement from the perspective of particular parties involved, even in absence of referrals
- 2019 Proposed rule offered two alternative definitions:
  - The particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements
  - 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
- 2020 Final rule adopts following definition:
  - Particular arrangement furthers a legitimate business purpose of the parties to arrangement and is sensible, considering their characteristics, including their size, scope and specialty
  - An arrangement that is not profitable for one or more parties can still be commercially reasonable
- Commercial reasonableness is separate concept than FMV
- Definition does not apply to AKS
- Added to Stark Law definitions (42 CFR § 411.351)

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

- Historically, addressed in 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 (and final) regulations created new, "objective" 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
- New guidelines added at 42 CFR § 411.354(d)(5) and (6)
- Current standards remain in place, though modified to reflect new definitions:
  - (d)(2) and (3) do not apply to compensation that takes into account volume, value, other business generated

Volume or Value and Other Business Generated

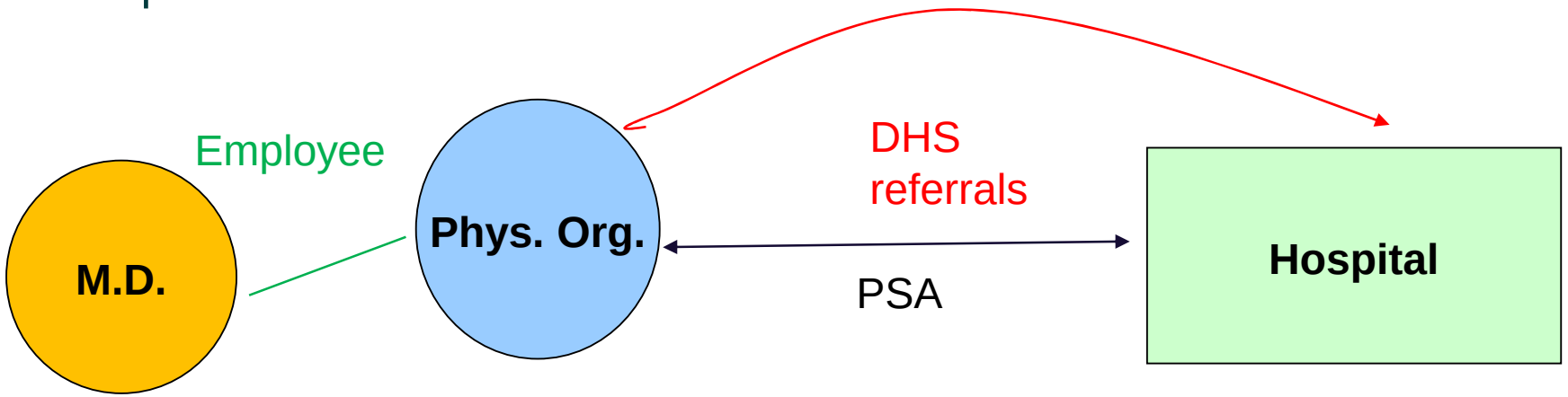
- Focus is whether there is a predetermined, direct positive or negative correlation between the volume or value of the physician's referrals (or other business generated for the entity) and the rate of compensation paid to or by the physician (or an immediate family member of the physician) in order 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

Compensation from Entity to Physician

- 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
  - CMS did not finalize proposed rule standard on "predetermined, direct correlation" as another trigger for volume / value standard
- Test for "other business generated" follows same approach

Example: Does Compensation from Entity to Physician Take Into Account Volume or Value of Referrals?

- Option 1
  - $125 per wRVU for M.D. 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 M.D. orders but does not perform

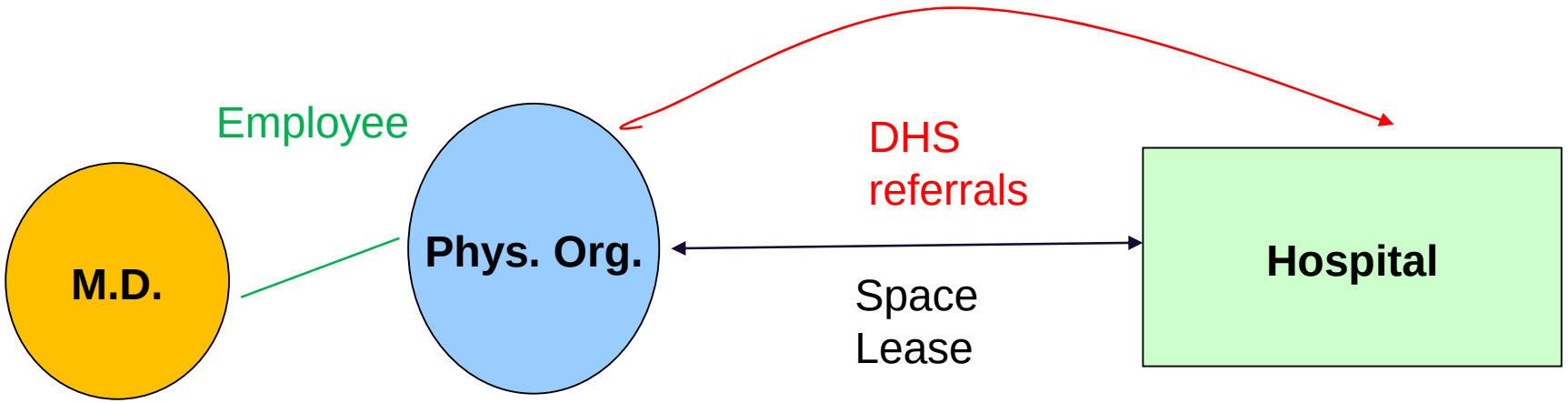


Compensation from Physician to Entity

- 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
  - CMS did not finalize proposed rule standard on "predetermined, direct correlation" as another trigger for volume / value standard
- Test for "other business generated" follows same approach

Example: Does Compensation from Physician to Entity Take Into Account Volume or Value of Referrals?

- 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 / Value & Other Business Generated

- Challenges in understanding and applying current terms:
  - *U.S. ex rel. Drakeford v. Tuomey* decision
  - Correlation theory
  - Problems with tracking referrals
  - Does “taking into account” question introduce intent into a strict liability law?
- CMS reaffirms 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 Value Based Exceptions
- Should reduce concern about wRVU compensation models between physicians and hospitals
- New rules not applicable to AKS and its Safe Harbors

Other Volume / Value Developments

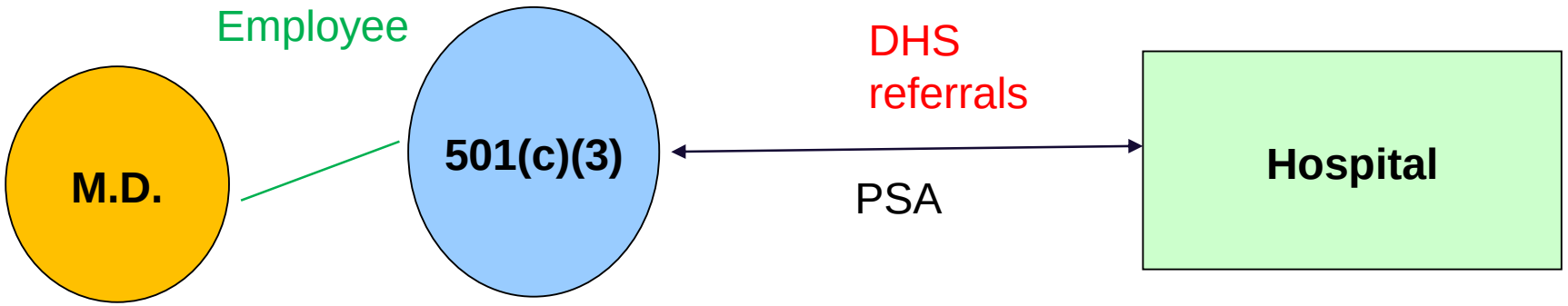
- New rules on determining volume / value based on correlation not applicable for all Stark exceptions. Following are exempt:
  - Medical staff incidental benefits, professional courtesy, community-wide health information systems, e-prescribing, EHRs and cybersecurity
- CMS did not finalize method in Proposed Rule under which fixed rate compensation would be viewed as having been determined in manner that took volume / value, other business generated into account
- CMS removed modifier “directly or indirectly” from many exceptions
  - Concept is “implicit” in volume / value standard
  - Payment can still “indirectly” related to volume / value under certain exceptions
- New “catch all” prohibition against making existence of comp. arrangement or amount of comp contingent on volume / value of referrals to particular party.
- Any requirement to make referrals (as permitted by Stark) may require physician refer an established percentage or ratio to particular party.

Indirect Compensation Developments

- Old rule: 3 part test: (1) unbroken chain of financial relationships; (2) referring physician receives aggregate compensation from link in chain with which physician has direct financial relationship that varies with volume or value of referrals or other business generated for DHS entity (even if unit-based comp. is FMV); and (3) DHS entity has knowledge
- New rule: Aggregate compensation varies with volume or value of referrals or other business generated by referring physician for DHS entity and the individual unit of compensation received by the physician or immediate family member:
  - Is not FMV for items / services provided;
  - Includes the physician's referrals to the DHS entity as a variable, resulting in an increase or decreases in the physician's (or family member's) compensation that positively correlates with the number or value of physician's referrals to entity;
  - Includes other business generated by the physician for the entity furnishing DHS as a variable, resulting in an increase or decreases in the physician's (or family member's) compensation that positively correlates with the physician's generation of other business for the entity;
- Same definition of "positive correlation"
- New rule still requires unbroken chain of financial relationships and knowledge by DHS entity

Example: Is this an Indirect Compensation Arrangement?

- Chain of financial relationships?
- Employee's compensation?
  - Option 1: MD paid $120/wRVU. Consistent with FMV.
  - Option 2: MD paid $450,000/year. Consistent with FMV.
  - Option 3: MD paid $100/wRVU + 15% of hosp. dept. profit from services billed by hosp. under OPPS.
- Hospital knowledge?



Directing Referrals

- Historic 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
- Final regulations added variety of changes:
  - Nether existence of comp. arrangement nor amount of comp. can be contingent on number or value of referrals to particular party (regardless of whether comp. does not take into account volume / value of referrals or other business generated).
  - Requirement to make referrals can mandate physician to refer established percentage or ratio to particular party
  - Added (d)(4) requirement as specific element in numerous exceptions
  - Clarifies set in advance standard

Fair Market Value: Revamped Definition

- Revised 3 pronged definition of FMV each of which includes its own “general market value” component:
  - General definition of FMV
  - Definition of FMV specific to equipment rental
  - Definition of FMV specific to space rental
- 3 separate definitions of general market value (specific to the type of transaction at issue):
  - Asset acquisition
  - Compensation for services
  - Rental of equipment or space
- All still included at 42 CFR 411.351, but divided into various subparts for easier reference

Fair Market Value: 3 Prongs

- General: 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
- Equipment: with respect to the rental of equipment, the value in an arm's- length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.
- Space: value in an arm's length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General Market Value: 3 Prongs

- Assets: price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
- Compensation: compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.
- Rentals: price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

Fair Market Value: Other Takeaways

- Value of physician's services should be the same regardless of identity of purchaser
- Survey data appropriate starting point, but not always the end of the story:
  - Common arrangements, where services required are same regardless of identity of physician v. unique need (inability to recruit cardiothoracic surgeon)
- Not outside of FMV just because comp. exceeds specific percentile
- Reaffirms analysis regarding payment above / below survey data (focus is facts and circumstances analysis that looks to what is happening in "subject transaction"):
  - 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

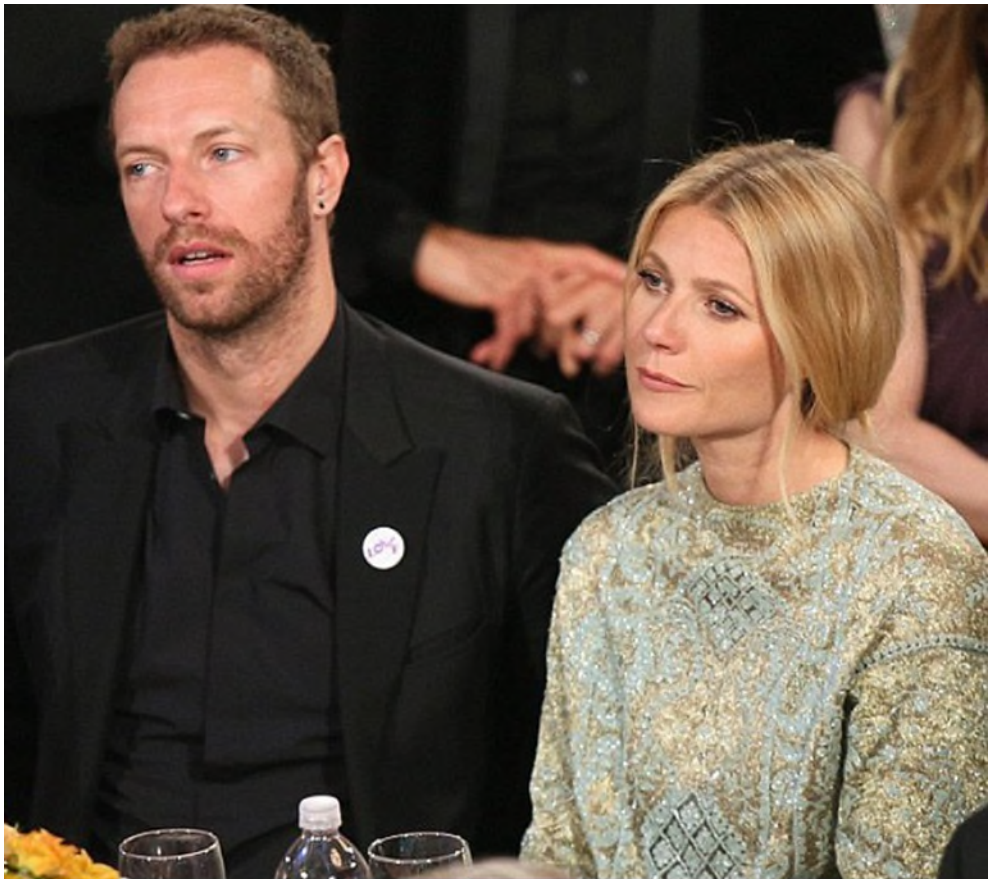
Definition of “Group Practice”

- Changes delayed until Jan. 1, 2022
- Clarifies application of profit share rules for group practices participating in Value-Based Arrangements:
  - 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 take into account the volume/value of referrals
- Restructures portion of regulation addressing “profit shares” and “productivity bonuses”:
  - Clarifies applicability of volume/value standard to compensation within group practice
  - Goal is to enable groups to have more certainty about whether compensation paid as profit shares / productivity bonuses takes volume / value of referrals into account and, if so, whether there is direct or indirect connection to referrals
  - Numerous changes to make language consistent and clarify various principles

Definition of “Group Practice”

- Other changes include:
  - Overall profits means the profits derived from all the DHS of any component of at least 5 physicians (which may include all physicians in group)
  - If there are fewer than 5, overall profits means the profits from all DHS of the group
  - 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
    - Profits from all DHS of any component of at least 5 physicians must be aggregated before distribution
    - Can use different method for distributing profits between group components of at least 5 physicians
    - Cannot use different distribution methods within same components (no “split pooling”)
    - Cannot use different methodologies to distribute profits from different types of DHS within component
  - Removed reference to Medicaid from definition of overall profits

Conscious Decoupling of Stark and Anti-kickback Statute



- Removes element from most Stark exceptions that arrangement not violate Anti-kickback Statute or federal state laws governing billing / claims submission
  - No longer believe it is necessary, Congress did not require and does not impact liability under AKS
- Did not remove AKS standard from FMV exception (removed billing requirement though)

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:
  - Permits limited periods of noncompliance with writing and/or signature requirements at outset of arrangement
  - Must meet all other requirements of an applicable exception and parties must memorialize in writing and / or obtain signatures within 90 consecutive calendar days
- If set in advance is part of the relevant exception, parties must meet it during the 90-day “grace” period
- Confirms electronic signatures are valid
- Deleted previous rules at 411.353(g) and moved into new section of regulations at 42 CFR § 411.354(e)(3) and (4)

Modifications to “Set in Advance” Rule

- Proposed rule did not include any changes to set in advance requirement
- Final rule addresses modifying compensation during arrangement’s term while remaining in compliance with set in advance rule:
  - All requirements of applicable exception must be met on the effective date of modified compensation / modified formula
  - Modified compensation / formula determined before furnishing of the services, items, space, equipment at issue
  - Before furnishing services, items, space, equipment for which modified compensation to be paid, formula is set forth in writing in sufficient detail to permit objective verification
  - Parties cannot use the 90 day period to put modified comp. in writing (new “grace period” not available)
- “Material” modifications to the compensation terms are subject to change
- CMS also offers examples of how compensation can be set in advance:
  - Text messages, emails (even informal), internal notes to file, similar payments between parties from prior arrangements, generally applicable fee schedules, other documents recording similar payments for similarly situated physicians

Definitions: Designated Health Services

- Final rule clarifies that hospital inpatient services do ***not*** constitute DHS if the services do not increase payment to hospital under specific PPS:
  - Acute care hospital inpatient (IPPS)
  - Inpatient rehab facility (IRF PPS)
  - Inpatient psych facility (IPF PPS)
  - Long-term care hospital (LTCH PPS)
- CMS declined to extend the clarification to hospital outpatient services

Definitions: Physician

- Final 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

- Final Rule clarifies the definition of “referral” to explicitly state that a referral is not an "item or service" for which payment may be made under the Stark statute or regulations
- As an example, if the intent is to compensate a physician for providing referrals, there is no way that an arrangement like that could be covered by the personal services exception

"Oh my God — I just remembered I can fly."

Definitions:

Remuneration

- Previously definition of "remuneration" excluded:
  - 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
- Final rule
  - Removes the carve out from 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

- Final 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; also forgiveness of an amount owed as part of a bona fide dispute (only the dispute and not the financial arrangement giving rise to the dispute).
  - does not include a single payment for multiple or repeated services (such as a payment for services previously provided, but not yet compensated).

Period of Disallowance

- Final Rule deletes the rules on the period of disallowance at § 411.353(c)(1) in their entirety
  - CMS notes that it considers the old 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 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.
- What if the parties don’t agree to rectify the error?
  - Is litigation required?

Limited Remuneration to a Physician

- Final Rule creates exception for non-abusive business practices
  - 42 CFR § 411.357(z)
- Applies to furnishing of items and services by physician, a physician's employee, wholly owned entity or locum tenens physician (but not an independent contractor)
- Remuneration must not:
  - exceed $5,000 annually (up from $3,500 in proposed rule)
  - exceed fair market value for the items or services provided by the physician
- The compensation arrangement must be commercially reasonable even if no referrals were made between the parties.
- If remuneration is conditioned on referrals, the relationship must satisfy the conditions at 411.354(d)(4)

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
  - Final 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))
  - Final rule makes this exception available to protect arrangements for the rental or lease of office space
  - No exclusive use requirement but there is a no AKS violation requirement
  - Changed so this exception now prohibits percentage-based and per-unit of service compensation for office space and equipment
  - This exception does not require a 1-year term like the office space and equipment exception

Remuneration Unrelated to Provision of DHS

- 42 CFR § 411.357(g)
- Proposed Rule sought modification to broaden application of the exception
- Final Rule decided not to modify this exception because of the difficulty managing a more broad exception

Payments by a Physician

- 42 CFR § 411.357(i)
- Reconsidered position regarding availability of the regulatory exception for certain compensation arrangements
- Under the Final Rule, parties are 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)
  - Changed references to “patient care services”

    to “NPP patient care services”
    - Changed references to “referral” to “NPP referral”
  - “NPP patient care services” means:
    - 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

- 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

Personal Services and Management Contracts Safe Harbor (cont)

- Modifies existing safe harbor and expands it to protect outcomes based arrangements
  - 42 CFR § 1001.952(d)
- Provides 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, PBMs, 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

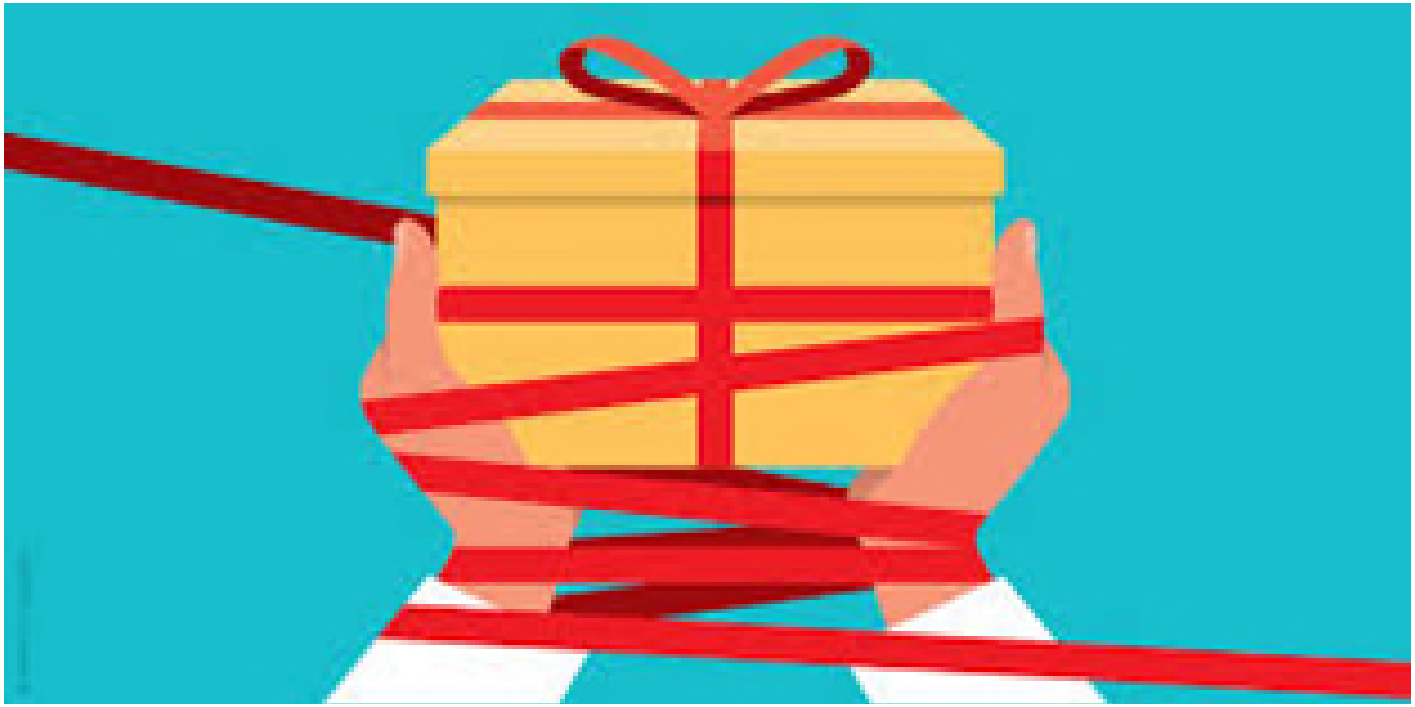
Warranty Safe Harbor

- 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 Safe Harbor

- 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
  - OIG decided not to expand safe harbor 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
  - Final 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:
  - hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for the diagnosis, intervention, or ongoing care management.
  - Final rule does not specifically allow or exclude specific technology (e.g. fax machine could potentially be telehealth if it meets other requirements)

Final Thoughts

Value Based Arrangements

Clarifications and Expansions

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