Modernizing Fraud and Abuse:

A Review of the CMS and OIG Final Rules

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Agenda

- Value-Based Arrangements
  - Key Definitions
  - Safe Harbors & Exceptions
  - Patient Engagement Provisions
- Fundamental Terminology & Other Significant Changes
  - Stark Law Fundamental Terminology Changes
  - Other Significant Stark Law Changes
  - Other Significant AKS Changes
- EHR & Cybersecurity Arrangements

Value-Based Arrangements

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Overarching Value-Based Framework

Unlike the traditional fee-for-service payment system, which rewards providers for the volume of care delivered, a value-driven health care system is one that pays for health and outcomes. Delivering better value from the health care system will require the transformation of established practices and enhanced collaboration among providers and other individuals and entities. The purpose of this rulemaking is to . . . remove potential barriers to more effective coordination and management of patient care and delivery of value-based care.

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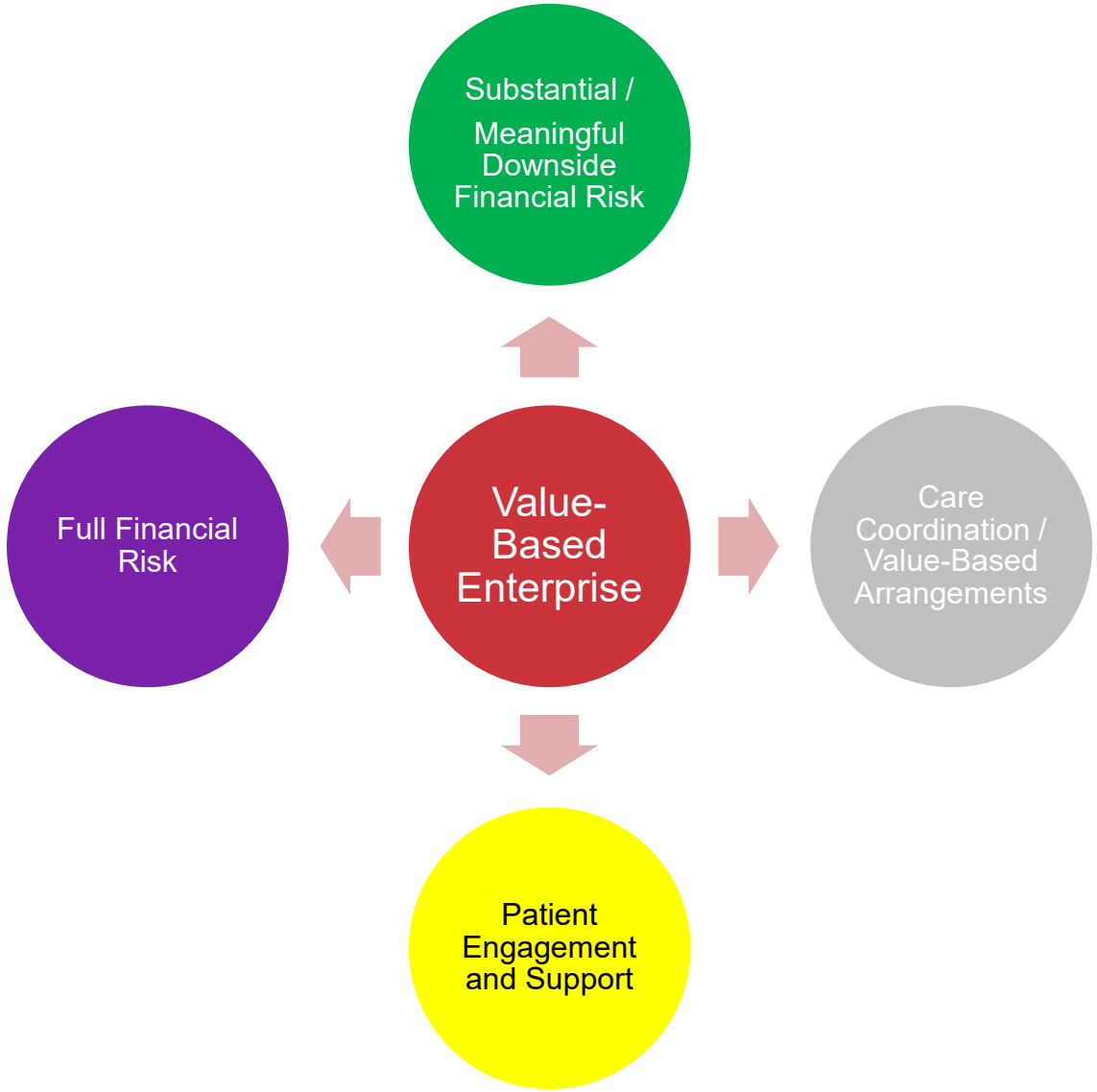
Value-Based Framework



Key Definitions for Value-Based Arrangements

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Value-Based Arrangements (VBAs)

- VBAs and the “Value-Based Framework” are the cornerstone of several new AKS safe harbors and Stark exceptions
- Each of these safe harbors and exceptions has its own criteria, and protects “remuneration” (AKS) or “compensation arrangements” (Stark) under various different conditions
- Although the VBA-related safe harbors and exceptions are different, several foundational concepts define:
  - the structure and organizational requirements of a VBA
  - the purpose of the VBA
  - the function of the VBA

Value-Based Enterprise (VBE)

- *Value-based enterprise* or *VBE* means two or more VBE participants:
  - Collaborating to achieve at least one value-based purpose;
  - Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise
  - That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and
  - That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).
- **AKS and Stark definitions identical**

Value-Based Enterprise (VBE)

- **Takeaways:**
  - Need not be a separate legal entity
  - To be protected under safe harbors, an entity must be in the VBE – downstream relationships with entities outside VBE not protected
  - No compliance program required
  - No fiduciary duties of accountable body or person to the VBE
  - Flexibility on VBE governing document – can be the VBA or payor contract

VBE Participants

AKS	Stark
An individual or entity	A person or entity
Engages in at least one value-based activity	Engages in at least one value-based activity
As part of a VBE	As part of a VBE
Other than a patient acting in their capacity as a patient	-

VBE Participants: Who is Excluded from Safe Harbors?

Entity	No Risk	Substantial Risk	Full Risk	Patient Engagement
Pharma manufacturer/wholesaler/distributor	X	X	X	X
Device manufacturer/wholesaler/distributor (other than limited technology participant)	X	X	X	✓ Allowed only if for digital health technology
Laboratory	X	X	X	X
Compounding pharmacy	X	X	X	X
Pharmacy benefit manager	X	X	X	X
DMEPOS supplier (other than limited technology participant)	X	X	X	X
Limited technology participant	✓	X	X	X

Note: no entities/persons excluded from protection under Stark regulations

Value-Based Activity

- *Value-based activity* means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:
  - The provision of an item or service;
  - The taking of an action; or
  - The refraining from taking an action.
  - Does not include the making of a referral **(AKS only)**
- **AKS and Stark definition identical except for express exclusion of making a referral from definition of value-based activity in AKS**

Value-Based Arrangement

- *Value-based arrangement* means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are:
  - The value-based enterprise and one or more of its VBE participants; or
  - VBE participants in the same value-based enterprise.
- **AKS and Stark definition identical**
- **Takeaways:**
  - Includes commercial and governmental arrangements
  - Can include arrangements among entities under common ownership

Target Patient Population

- *Target patient population* means an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that:
  - Are set out in writing in advance of the commencement of the value-based arrangement; and
  - Further the value-based enterprise's value-based purpose(s).
- **AKS and Stark definitions identical**
- **Takeaways:**
  - Payors need not be involved in defining the TPP
  - Legitimate criteria can be based on geography, disease state, social determinants of health (e.g. income and age criteria)
  - TPP can be the entire population served by a VBE participant

Value-Based Purpose

- *Value-based purpose* means:
  - Coordinating and managing the care of a target patient population;
  - Improving the quality of care for a target patient population;
  - Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
  - Transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.
- **AKS and Stark definitions identical**

Value-Based Purpose

- **Takeaways:**
  - Value-based purpose for transitioning from FFS to value-based care is a permissible purpose for the Full Financial Risk safe harbor
    - Allows Full Financial Risk VBEs to use 12 months leading up to assuming risk to build infrastructure of the VBE – like an ACO pre-participation waiver
  - Value-based purposes do not prohibit goals of internal cost savings for the VBE, but to meet definition of a purpose supporting safe harbor protection, savings must inure to benefit of payors

Value-Based Arrangement Safe Harbors & Exceptions

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Congratulations! You have built a VBE. Now what?

Applications of the VBE/VBA Framework

- **No financial risk:** Care Coordination Arrangements (42 CFR 1001.952(ee)); Value-Based Arrangements (42 CFR 411.357(aa)(3))
- **Substantial/meaningful downside financial risk:** Substantial Downside Financial Risk (42 CFR 1001.952(ff)); Meaningful Downside Financial Risk to the Physician (42 CFR 411.357(aa)(2))
- **Full financial risk:** Full Financial Risk (42 CFR 1001.952(gg); 42 CFR 411.357(aa)(1))
- **Patient Engagement and Support:** 42 CFR 1001.952(hh) (AKS only)
- In general, more flexibility and fewer requirements for VBAs under which greater financial risk assumed

The Three Core VBA Safe Harbors/Exceptions

Element	No Risk	Substantial Risk	Full Risk
Writing and Signature	Yes	**AKS:** yes; **Stark:** only if remuneration conditioned on required referrals and writing to describe physician risk	**AKS:** yes; **Stark:** only if remuneration conditioned on required referrals and writing to describe physician risk
Fair Market Value	**AKS:** Sort of; **Stark:** No	No	No
Commercial Reasonableness	Yes	No	No
In-Kind Remuneration	Yes	Yes	Yes
Cash Remuneration	**AKS:** no; **Stark:** yes	Yes	Yes
Contribution by Recipient	**AKS:** 15% of cost or FMV; **Stark:** No	No	No
Directed Referrals	Allowed with carve-outs	Allowed with carve-outs	**AKS:** Allowed with QA program; **Stark:** Allowed with carve-outs
Value-Based Purpose	Must include coordinating and managing care	Must include at least one of: coordinating care, reducing costs, improving quality	Any/all value-based purposes allowed

VBA Exception / Care Coordination Arrangements (No Financial Risk)

Element	AKS	Stark
Parties	VBE to VBE participant, or between VBE participants ***(not ineligible entities)***	VBE or VBE participant to physician who is VBE participant
Writing/Signature	Arrangement is in writing and signed by parties	***Signature only required if remuneration conditioned on referrals***
Contents of Writing	• Value-based purposes of the value-based activities • Value-based activities • ***Term of VBA*** • TPP • Description of remuneration • ***Offeror's cost or FMV of remuneration*** • ***Percentage contributed by recipient and frequency of contribution*** • Outcome measures against which recipient of remuneration is assessed	• Value-based activities • How value-based activities further value-based purposes • TPP • Type or nature of remuneration • Methodology to determine remuneration • Outcome measures against which recipient of remuneration is assessed ***(if any)***
Outcome Measures	• Legitimate outcome measures based on clinical evidence or credible medical support • ***Reasonable anticipation of advancing coordination and management of care of TPP*** • ***Monitored, periodically reassessed, revised*** • ***One or more benchmark tied to coordination and management of care of TPP*** • ***Relate to remuneration exchanged under the VBA***	• Objective, measurable, based on clinical evidence or credible medical support • Changes to outcome measures made prospectively and in writing

VBA Exception / Care Coordination Arrangements (No Financial Risk) - Continued

Element	AKS	Stark
Commercial Reasonableness	Arrangement must be commercially reasonable	Same as AKS
Remuneration	• In-kind • Set in advance • Not take into account volume or value of non-TPP patient referrals or business outside of the VBA	• ***Any form of remuneration*** • Set in advance • Not take into account volume or value of non-TPP patient referrals or business outside of the VBA
Purposes/Uses of Remuneration	• Predominantly to engage in value-based activities that are directly connected to coordination and management of care of TPP • No more than incidental benefit to non-TPP patients • Not used more than incidentally for recipient's billing or financial management services • Not used for marketing or patient recruitment • Remuneration not likely to be diverted or resold	***Remuneration is for or results from value-based activities***
Contribution	• ***Recipient pays at least 15% of offeror's cost or FMV of in-kind remuneration***	No contribution requirement
Patient Choice / Referrals	• Does not limit VBE participant ability to make decisions in best interest of patient • Does not direct/restrict referrals if patient has different preference, payor dictates otherwise, or contrary to Medicare or Medicaid law	***If remuneration to physician conditioned on referrals to a particular provider, then signature required*** and patient choice/referral protections the same as AKS safe harbor

VBA Exception / Care Coordination Arrangements (No Financial Risk) - Continued

Element	AKS	Stark
Quality of Care Protection	Does not induce furnishing medically unnecessary items or services or reduce or limit medically necessary items or services	Does not reduce or limit medically necessary items or services
Limited Technology Participants	LTP remuneration not conditioned on exclusive or minimum use of LTP products or services	-
Monitoring and Assessment	• At least annual monitoring • Coordination and management TPP care • Deficiencies in quality • Progress on outcome measures • If material deficiencies in quality or unlikely to further coordination and management of TPP care, agreement must be terminated within 120 days or plan of correction completed within 120 days to remedy deficiencies (termination in 120 days if not remedied)	• At least annual monitoring • ***Whether value-based activities have been furnished*** • ***Whether continuation will further value-based purposes*** • Progress on outcome measures • ***If value-based activities ineffective***, agreement must be terminated within ***30 days or ineffective activities modified within 90 days (termination if not modified in 90 days)***
Records	Keep records for 6 years to establish compliance with safe harbor	Same as AKS

Substantial Downside Risk / Meaningful Downside Financial Risk

Element	AKS	Stark
Parties	VBE to VBE participant ***(not ineligible entities)*** ***Note: does not include between VBE participants***	VBE or VBE participant to physician who is VBE participant
Writing/Signature	Arrangement is in writing and signed by parties	***Signature only required if remuneration conditioned on referrals***
Contents of Writing	• Evidence of substantial downside risk assumed by VBE within next six months and VBE participants' meaningful share • Value-based purposes of the value-based activities • Value-based activities, TPP • Description of remuneration	• Description of physician's meaningful downside financial risk
Substantial/Meaningful Downside Risk	• VBE, directly or through VBE participant (other than payor) enters into a written contract to assume substantial downside risk within the next 6 months from a payor for a period of at least 1 year • VBE assumes "substantial downside financial risk" • VBE participants assume "meaningful share" of the VBE"s substantial downside financial risk	• ***Physician is at meaningful downside financial risk for failure of VBE to achieve value-based purposes***

Substantial Downside Risk / Meaningful Downside Financial Risk (Continued)

Element	AKS	Stark
Substantial/Meaningful Downside Risk (Con't)	• Substantial downside financial risk: at least 30% of losses on payor's cost of care; 20% of financial risk on episode of care; partial capitation payment. • Meaningful share: two-sided risk for at least 5% of VBE's losses/savings; partial capitated payment	• ***Meaningful downside financial risk: responsible to repay or forgo no less than 10% of the total value of the remuneration the physician receives under the VBA***
Remuneration	• Directly connected to one or more value-based purposes other than transitioning to value-based care • Does not protect investment/ownership interests • Not take into account volume or value of non-TPP patient referrals or business outside of the VBA	• Set in advance • Not take into account volume or value of non-TPP patient referrals or business outside of the VBA
Purposes/Uses of Remuneration	• Predominantly to engage in value-based activities that are directly connected to items/services for which VBE has assumed risk • Not used for marketing or patient recruitment	***Remuneration is for or results from value-based activities***

Substantial Downside Risk / Meaningful Downside Financial Risk (Continued)

Element	AKS	Stark
Patient Choice / Referrals	• Does not limit VBE participant ability to make decisions in best interest of patient • Does not direct/restrict referrals if patient has different preference, payor dictates otherwise, or contrary to Medicare or Medicaid law	***If remuneration to physician conditioned on referrals to a particular provider, then signature required*** and patient choice/referral protections the same as AKS safe harbor
Quality of Care Protection	Does not induce reducing or limit medically necessary items or services	Same as AKS
Records	Keep records for 6 years to establish compliance with safe harbor	Same as AKS

Full Financial Risk

Element	AKS	Stark
Parties	VBE to VBE participant ***(not ineligible entities)*** ***Note: does not include between VBE participants***	VBE or VBE participant to physician who is VBE participant
Writing/Signature	Arrangement is in writing and signed by parties	***Signature only required if remuneration conditioned on referrals***
Contents of Writing	• All material terms • Value-based activities • Term	***Writing only required if remuneration conditioned on referrals***
Full Financial Risk	• VBE, directly or through VBE participant (other than payor) enters into a written contract to assume full financial risk within the next 12 months from a payor • "Full financial risk" means responsibility on a prospective basis for all items and services covered by the payor ***for a term of at least 1 year***	• VBE enters into a contract to assume full financial risk within the next 12 months from a payor • "Full financial risk" means responsibility on a prospective basis for all items and services covered by the payor ***for a specified period of time***

Full Financial Risk (Continued)

Element	AKS	Stark
Claims for Payment to Payor	VBE participant does not submit claims for payment to payor for items or services covered under the full risk arrangement between the VBE and the payor	-
Remuneration	• Directly connected to one or more value-based purposes • Does not protect investment/ownership interests • Not take into account volume or value of non-TPP patient referrals or business outside of the VBA	Not take into account volume or value of non-TPP patient referrals or business outside of the VBA
Purposes/Uses of Remuneration	• Not used for marketing or patient recruitment	***Remuneration is for or results from value-based activities***
Patient Choice / Referrals and Quality of Care Protection	• VBE provides or arranges for a QA program that protects against underutilization and assess quality of care • Does not induce reducing or limit medically necessary items or services	• ***If remuneration to physician conditioned on referrals to a particular provider, then signature required*** and patient choice/referral protections the same as AKS safe harbor • Does not induce reducing or limit medically necessary items or services
Records	Keep records for 6 years to establish compliance with safe harbor	Same as AKS

Patient Engagement and Support Safe Harbor

- AKS only – serves as exception to CMP beneficiary anti-inducement provision by operation of law
- Protects "patient engagement tool[s] and support[s]" provided by eligible VBE participants to patients in TPP if:
  - Furnished directly by VBE participant or its eligible agent
  - In-kind / no cash or cash equivalent
  - Directly connected to coordination and management of TPP care
  - Does not result in medically unnecessary services/items
  - Recommended by patient's licensed health care professional
  - Advances goals of: adherence to treatment regimen, drug regiment, or care plan, or prevention or management of a disease or condition (all as directed/recommended by patient's licensed health care professional)
  - Aggregate retail value cap of $500 (per VBE participant/patient combination)
  - Not funded by ineligible entities or VBE participants not party to the VBA
  - Not used for marketing or patient recruitment purposes
  - Not determined based on and does not take into account patient insurance status

Patient Engagement and Support

Other patient engagement provisions in final OIG rule:

- **Local Patient Transportation Safe Harbor Revisions**
  - Increase rural transportation mileage limit from 50 to 75 miles
  - No mileage limit on inpatient discharge to patient residence
  - Ridesharing acceptable mode of transportation (e.g., Uber, Lyft)

- **Telehealth technologies provided to ESRD patients receiving home dialysis**
  - CMP exception (not AKS)
  - No cap on value of telehealth technologies

CMS-Sponsored Models

- **AKS: Remuneration among CMS-Sponsored Model parties and to patients covered by model protected by safe harbor if:**
  - CMS designates model as eligible for safe harbor protection
  - CMS specifically identifies arrangements and patient incentives protected under the specific model
  - Core fraud and abuse protections (set forth in safe harbor) are met
    - Remuneration does not induce medically unnecessary services or limit medically necessary care
    - No inducement for business outside the model
    - Written, signed agreement describing terms
  - Programmatic requirements of the model are met (e.g. in CMS participation agreements, other guidance relevant to model)
- **Stark: No Separate Exception for CMS-Sponsored Models**

  "We carefully evaluated our final exceptions against the existing CMS-sponsored models, programs, and other initiatives, and are confident that at least one of the new exceptions at § 411.357(aa) is applicable to the types of compensation arrangements contemplated under each model, program, or initiative. . .Thus, it is not necessary to establish an exception specific to arrangements undertaken pursuant to a CMS-sponsored model . . ."

Fundamental Terminology & Other Significant Changes

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Stark Law Fundamental Terminology Changes

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The Big Three:
Fair Market Value Definition Tightened

- CMS revises regulatory definition to more closely align with statutory definition and to clarify that FMV is separate and distinct from the volume or value or other business generated standards
- FMV means, in general, the value in an arm's-length transaction, consistent with the general market value of the subject transaction
  - For equipment rentals, FMV is to be determined without taking into account the intended use of equipment
  - For office space leases, FMV is to be determined without taking into account the intended use of property, and without adjustment to reflect additional value attributable to the proximity or convenience to lessor where lessor is a potential referral source to lessee
- General market value is separately defined for assets, compensation, and rental of equipment or office space

The Big Three:
Fair Market Value Definition Tightened

- CMS emphasizes that FMV may not always align with salary surveys and other compilations of valuation data
  - While surveys may be an appropriate "starting point" and in many cases be "all that is required," each arrangement must be evaluated on its own
  - Commentary restates examples of "rock star" orthopedic surgeon and family medicine physician in LCOL area for whom national data may be inappropriate
  - Adds example of cardiothoracic surgeon in area with no such specialists
- CMS rejects commenters' requests for "safe harbors" that would deem compensation to be FMV if certain conditions are met
  - In doing so, CMS states that it is not CMS policy that compensation at or below 75th percentile is always appropriate, and that compensation above 75th percentile is suspect, if not presumed inappropriate

The Big Three:
Commercial Reasonableness Defined

- CMS now defines the term “commercially reasonable” to mean that the arrangement “furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty”
- Final rule also codifies in regulations the concept that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties

The Big Three:
Commercial Reasonableness Defined

- Key question is whether the arrangement makes sense as a means to accomplish the involved parties' goals
  - Made from perspective of particular parties
  - Not a judgment about the value of a transaction
- Commentary offers some ideas about "legitimate business purposes" for unprofitable transactions
  - Community need
  - Timely access to health care services
  - Fulfillment of licensure or regulatory requirements
  - Provision of charity care
  - Improvement of quality and health outcomes

The Big Three:
Volume or Value Standard Defined

- Final rule addresses the volume or value and other business generated standards through the creation of two sets of special rules to be codified at 411.354(d)
- Special rules define the entire “universe of circumstances” when compensation will be considered to take into account the volume or value of referrals or other business generated
- Any methodology that does not “fall squarely” within these circumstances will be permissible

The Big Three:
Volume or Value Standard Defined

- Compensation takes into account the volume or value or referrals or other business generated if the compensation formula includes referrals or other business generated as a variable, resulting in an increase or decrease in compensation that correlates with the number or value of referrals or other business generated
  - Requires translation of compensation terms into mathematical formula
  - Example: Entity pays physician 1/5th of bonus pool that is comprised of all collections from a set of services furnished by the entity, including those from DHS referred by physician
    - Physician compensation = (1/5 x value of physician's DHS referrals) + (1/5 x value of physician's other business generated by physician for entity) + (1/5 x value of services furnished by entity that were not referred or generated by physician)
    - Value of physician's referrals (and other business generated) is a variable

The Big Three:
Volume or Value Standard Defined

- CMS declines to adopt the proposed provisions regarding fixed rate compensation in the event there was a "predetermined, 'if X, then Y' correlation" between the volume or value of the physician's prior referrals (or other business previously generated) and the prospective rate of compensation
  - But incorporates concept into directed referral requirements
- Under final rule, there is effectively no longer a need for the existing "unit-based deeming provisions," but CMS keeps them to assist with historical reviews
- CMS reaffirms Phase I guidance about application of service-based exceptions in context of potential indirect compensation arrangements

The Big Three:
Volume or Value Standard Defined

- CMS reaffirms its Phase II position on physicians who are paid on personal productivity, but whose personal services are often accompanied by hospital services:
  - "An association between personally performed physician services and [DHS] furnished by an entity does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of a physician's referrals to the entity or the volume or value of other business generated by the physician for the entity"
  - "[A] physician may be compensated for his or her personally performed services using a unit-based compensation formula—even when the entity with which the physician has a … compensation arrangement bills for [DHS] that correspond to such personally performed services"
- CMS did not, however, codify its position in regulation text

On a Related Note:
Indirect Compensation Arrangement Definition

- Final rule simplifies definition of "indirect compensation arrangement"
  - Indirect compensation arrangement will exist if aggregate compensation to physician varies with the volume or value of referrals or other business generated by the physician for the DHS entity and the individual unit of compensation received by the physician either (1) is not fair market value or (2) is calculated using the physician's referrals to or other business generated for the DHS entity as a variable, resulting in an increase or decrease in compensation that positively correlates with the number or value of referrals or generation of other business for the entity
- Upshot: Fewer indirect compensation arrangements (but lingering question about meaning of "varies with")

On a Related Note:
Directed Referrals

- Final rule makes two substantive changes to the special rule under which physician referrals may be directed, in part because of changes made to the volume or value standard:
  - Incorporates compliance with special rule into several compensation exceptions (employment, personal services, FMV compensation)
  - Adds a new condition that neither the existence of the compensation nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider
    - But specifically permits directed referral requirements based on an established percentage—rather than the number or value—of referrals
- Also clarifies that it is the physician's compensation—not his or her "compensation arrangement"—that must be set in advance

Other Significant Stark Law Changes

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Group Practice Profit Share Clarifications:

No Service-Specific Pods, But VBE Allocations Permitted

- CMS clarifies that a group practice may not distribute profits from DHS on a service-by-service basis (e.g., profits from clinical laboratory tests to one subset of physicians, profits from diagnostic imaging services to another)
  - Profits from all DHS of the group, or any component of the group of at least five physicians, must be aggregated before distribution
  - But group practices may use different distribution methodologies to issue shares of overall DHS profits of each qualifying component, so long as distribution is not directly related to volume or value
- Group practices may distribute **directly** to a physician in group profits from DHS furnished by group that are derived from physician's participation in a value-based enterprise
- Delayed effective date: January 1, 2022

Designated Health Services Carve-out:

Inpatient Hospital Services Are Not DHS if They Don't Affect the DRG

- CMS proposed to revise definition of "designated health services" to clarify that a service provided by a hospital to an inpatient does not constitute a DHS payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under IPPS
  - Example: Physician with noncompliant financial arrangement with hospital orders an x-ray for a Medicare beneficiary who is an inpatient, but the x-ray does not affect the MS-DRG or otherwise impact the rate of payment, then the x-ray is not considered DHS
- Final rule adopts this policy and extends it to IRF PPS, IPF PPS, and LTCH PPS—but not to hospital services furnished to outpatients

Isolated Transactions Exception Clarified:

Exception Not Available for Multiple or Repeated Services Arrangements

- CMS confirms, through modifications to defined terms and to the regulatory exception, that the isolated transactions exception is **not** available to protect a single payment for multiple or repeated services, and that it is not available to retroactively cure noncompliance
  - May not use exception to protect an ordinary services arrangement that parties failed to document in writing or get signatures
  - Directs parties to consider use of special rule for writing and signature requirements as well as new exception for limited remuneration
- Parties may, however, rely on the exception to protect an isolated financial transaction that settles a *bona fide* dispute arising from an arrangement for multiple, repeated, or ongoing services

Policy for Correcting Administrative Errors:

Final Rule Confirms Ability to Resolve Unintentional Errors During Term, Adds Limited Grace Period for Ex Post Clean-up

- CMS affirms proposed rule guidance on the correction of unintended administrative errors or payment discrepancies during the course of an arrangement (e.g., invoicing the wrong amount due under a lease, paying the wrong amount under a services agreement due to typographic error)
  - But also affirms that failure to remedy known payment discrepancies can lead to a second financial relationship—gray area remains
- CMS codifies special rule at 411.353(h) that creates a 90-day grace period within which parties may reconcile payment discrepancies after the expiration or termination of a compensation arrangement
  - Permits claims submission and billing if reconciled within 90 days after expiration and termination, such that the entire amount of remuneration for items or services has been paid as required under the terms of arrangement

Writing and Signature Requirements:

Special Rules Clarify Grace Period, Compensation Modifications, Electronic Signatures

- CMS finalizes proposed special rule for writing and signature requirements
  - Writing requirement or signature requirement is deemed to be satisfied if:
    - Compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirement; and
    - Parties obtain the required writing or signature within 90 days of the date the arrangement failed to satisfy requirements of applicable exception
  - CMS reminds us the writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct of the parties

Writing and Signature Requirements:

Special Rules Clarify Grace Period, Compensation Modifications, Electronic Signatures

- Special rule for writing and signature requirements does not affect the requirement that compensation be set in advance
  - CMS clarifies that set in advance does not necessarily mean set out in writing before the furnishing of items or services, though the special rule at 411.354(d)(1)(i) describing when compensation is **deemed to be** set in advance does require as much
- CMS requires, however, that when compensation is **modified** during the course of an arrangement, it **must** be set forth in writing before the furnishing of items or services for which the modified compensation is to be paid—no 90-day grace period for amended compensation terms

Writing and Signature Requirements:

Special Rules Clarify Grace Period, Compensation Modifications, Electronic Signatures

- CMS also codifies its “longstanding policy” that an electronic signature that is legally valid under federal or state law is sufficient to satisfy the signature requirement
  - CMS declines to provide a general rule as to whether a sender’s typed or printed name on an email or letterhead would satisfy the requirement, but states that if an electronic signature under applicable federal or state law, then it would qualify as a signature for Stark Law purposes

Exception for Limited Remuneration to a Physician:

CMS Finalizes New Exception, Increases Annual Limit to $5,000

- CMS finalizes its proposal to add a new exception to protect limited remuneration to a physician for items or services provided by the physician even in the absence of documentation (and where the amount of or formula for calculating the remuneration is not set in advance) (411.357(z))
- Remuneration may not exceed $5,000 per calendar year (to be adjusted for inflation)
- Other familiar requirements:
  - Not in excess of FMV
  - Not be determined in a manner that takes into account volume or value of referrals or other business generated
  - Arrangement must be commercially reasonable

Decoupling Stark Law and AKS:

CMS Removes AKS Compliance Conditions from Stark Exceptions

- CMS finalizes proposal to remove requirement that arrangements not violate AKS (or federal or state laws governing billing or claims submission) from but one regulatory exception
  - Lone exception is the fair market value compensation exception (411.357(l)), because it can be used to protect arrangements that also could be protected by a statutory exception with additional safeguards (e.g., office space lease arrangements)
- Brings Stark closer to a strict liability standard, allows for greater certainty

Other Significant Stark Law Changes

Ownership and Investment Interest Exclusions Clarified

- CMS codifies exclusion of titular ownership, ESOP interests

FMV Compensation Exception Modified

- Exception expanded to cover office space and equipment leases, but retains AKS compliance requirement

Office Space and Equipment Lease Exceptions Modified

- Exclusive use requirement clarified; multiple lessees permitted to use space or equipment provided lessor is excluded

Other Significant Stark Law Changes

Exception for Remuneration Unrelated to DHS Unchanged

- CMS declines to finalize proposed expansion of exception, may revisit in future rulemaking

Exception for Payments by a Physician Expanded Slightly

- Exception broadened, but remains off limits where statutory exception (411.357(a) – (i)) applies

Remuneration Definition Limited Slightly

- CMS revises definition to not categorically exclude "surgical items, devices, or supplies," finalizes functional test

Other Significant Stark Law Changes

Physician Recruitment Exception Tweaked

- Physician practice signature requirement eliminated if no financial benefit to practice

Exception for Assistance to Compensate NPPs Clarified

- CMS clarifies key terms (“NPP patient care services”), timing considerations

Period of Disallowance Rules Scrapped

- CMS removes rules intended to establish bright-line, outside limits, citing stakeholder confusion

Other Significant AKS Changes

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Personal Services and Management Contracts Safe Harbor:

OIG Addresses Oft-Cited Issues, Adds Protection for Outcomes-Based Payments

- Final rule revises two of the most challenging conditions of safe harbor
  - Instead of requiring that the **aggregate compensation** over the term be set in advance, revised safe harbor requires only that the **methodology for determining compensation** be set in advance
  - Revised safe harbor removes cumbersome requirement that periodic, sporadic, or part-time service arrangements specify exactly the schedule of such intervals, their length, and the exact charge for intervals

Personal Services and Management Contracts Safe Harbor:

OIG Addresses Oft-Cited Issues, Adds Protection for Outcomes-Based Payments

- Final rule also significantly expands safe harbor to protect "outcomes-based payment arrangements"
  - Outcomes-based payments are payments that (1) reward recipient for achieving certain types of "legitimate outcome measures" or (2) recoup or reduce payment for failure to achieve such an outcome measure
  - Exclude payments that relate solely to achievement of internal cost savings for principal or on patient satisfaction or convenience measures
  - Exclude payments made directly or indirectly by certain actors (e.g., pharmaceutical manufacturer, PBM, laboratory company, compounding pharmacy, DMEPOS suppliers)
  - Subject to many familiar personal services safe harbor requirements as well as requirements in the care coordination arrangements safe harbor

Warranties Safe Harbor Expanded:

Final Rule Expands Protection for "Bundled" Warranties

- OIG finalizes modifications to warranties safe harbor as proposed
  - Expands safe harbor protection for "bundled" warranties
    - Final rule defines remuneration to not include payments or exchanges of value under a warranty provided by a manufacturer or supplier "of one or more items and services (provided the warranty covers at least one item) to the buyer … of the items and services"
  - OIG defines "warranty" directly in safe harbor, largely mirroring prior definition incorporated by cross-reference
    - Confirms potential application to warranty arrangements conditioned upon clinical outcomes guarantees but declines to provide examples

EHR & Cybersecurity Arrangements

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EHR Donation Safe Harbor & Exception Changes

- Final rules modify EHR donation safe harbor and exception in several important ways:
  - Eliminate sunset provisions; EHR donation regulations made permanent
  - Remove prohibition on providing EHR technology that is "equivalent" to technology already possessed by recipient (and expressly permit donation of replacement technology)
  - Extend protection to cybersecurity software and services that "protect" EHR
  - Remove existing information blocking provisions
  - Retain 15% minimum cost sharing obligation
    - But note that contribution for EHR **updates** received after initial donation (or replacement donation) need not be paid prior to donation (Stark exception requires that contribution be paid "at reasonable intervals")

New Cybersecurity Technology Safe Harbor & Exception

- Final rules add new safe harbor (1001.952(jj)) and exception (411.357(bb)) for cybersecurity technology and services
  - Protect donation of cybersecurity technology (including hardware) and related services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity
  - Neither eligibility for technology or services, nor the amount or nature of the technology or services, may be determined in a manner that directly takes into account volume or value of referrals or other business generated
  - May not condition donation on future referrals or business generation
  - Writing required (note differences between safe harbor and exception)
- What's not required?
  - No cost sharing requirement, no limit on value of donation, and no limit on who may donate

Contact Information

For additional resources, including an in-depth review of the final rules and additional insights on the practical implications for various stakeholders, visit **bradley.com/healthcare**.

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