Change Is the Only Constant: The 2021 Regulatory "Level Set" in the Sprint to Value-Based Care

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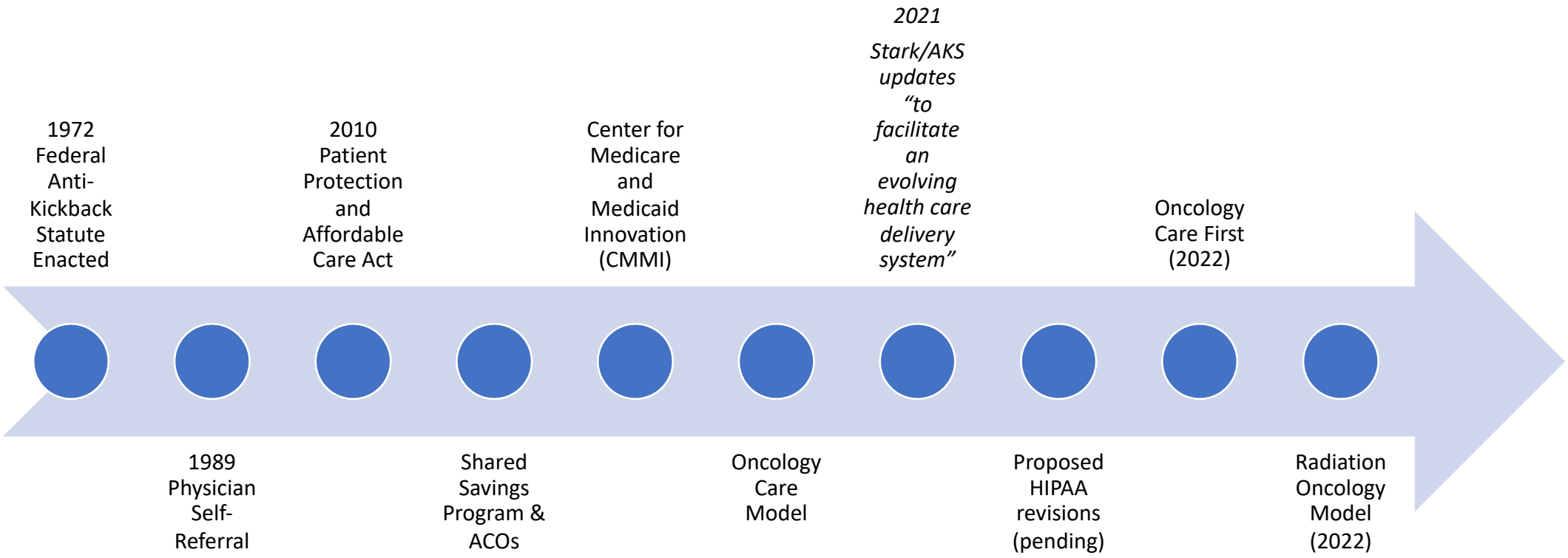
The Regulatory Sprint to Coordinated Care



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New Stark Exceptions and Anti-Kickback Safe Harbors

- Three new exceptions/safe harbors for value-based care arrangements and corresponding definitions
  - ✓Defined by characteristics of the arrangement and the level of financial risk undertaken by the parties
- Guidance on critical terms and concepts, including commercial reasonableness and fair market value
- Exception/safe harbor for electronic health records made permanent
- Two additional exceptions/safe harbors:
  - ✓Cybersecurity technology
  - ✓Limited remuneration to a physician
- AKS safe harbors for patient engagement, CMS-sponsored models
- Recalibrated scope and application of Stark regulations by revising several exceptions for compensation arrangements

The CMS and OIG VBE Exceptions and Safe Harbors Compared

The Centers for Medicare & Medicaid Services (CMS) finalizes 3 new exceptions

1. Value-based enterprise (VBE) assumes full financial risk
2. Physician assumes meaningful downside financial risk
3. VBE meets specified requirements regardless of financial risk level

Office of the Inspector General (OIG) finalizes 3 new anti-kickback statute (AKS) safe harbors

1. Full financial risk
2. Substantial downside financial risk
3. Care coordination arrangements

Value-Based Arrangements

CMS and OIG each finalized the following definitions (that are essentially identical from CMS to OIG)

- ✓Value-based enterprise (VBE)
- ✓VBE participant
- ✓Value-based arrangement
- ✓Value-based activity*
- ✓Value-based purpose
- ✓Target patient population

*OIG, but not CMS, includes within definition “does not include the making of a referral”

Stark Exceptions for Value-Based Arrangements

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The Stark Law: A Refresher

Under the Stark Law, in general, if a physician has a direct or indirect financial relationship with a designated health services (DHS) entity:

- ✓The physician may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare,
- ✓And the entity may not bill Medicare, an individual, or another payor for the DHS performed pursuant to the prohibited referral
  - "Designated health services" includes all inpatient and outpatient hospital services, lab, imaging, pharmacy, durable medical equipment, radiation therapy, physical therapy, occupational and speech therapy, parenteral and enteral drugs, nutrients, and supplies, prosthetics, orthodics, and home health services
- ✓…unless a specific exception applies

Stark is a strict liability/zero tolerance law

CMS Exceptions at a Glance…

Full Financial Risk

- VBE is at full financial risk (or is obligated to be at full risk within 12 months) for the entire duration of the value-based arrangement
- "Full financial risk" means that the VBE is financially responsible, on a prospective basis, for the cost of all patient care items and services for a payor/target population for a specified period of time

CMS Exceptions at a Glance…

Meaningful Downside Financial Risk

- Physician is at meaningful downside financial risk* for failure to achieve the value-based purpose(s)
- *Responsible to repay or forgo at least 10% of the total value of physician's remuneration
- In writing; methodology set in advance

CMS Exceptions at a Glance…

Value Based Arrangements

- Value-based activities are expected to further the value-based purpose(s) of the VBE
- In writing, including activities/purpose, target patient population, remuneration (type and methodology), outcome measures (if any)
- Monitoring required (at least annually)
- Must terminate (30 days) or amend (90 days) if value-based activity is ineffective in furthering the value-based purpose
- Commercially reasonable

Anti-Kickback Safe Harbors for Value-Based Arrangements

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The Anti-Kickback Statute: A Refresher

- ✓The Anti-Kickback Statute (AKS) prohibits knowing and willful offer or receipt of remuneration intended to induce or arrange for referrals of business paid for by Medicare/Medicaid programs

- ✓Any purpose test and problem of mixed motives
  - Violation does not require actual knowledge of AKS or specific intent
  - Claim for items or services resulting from AKS violation constitutes a false claim under the False Claims Act

- ✓*Arrangements are not necessarily unlawful because they do not fit in a safe harbor – would be reviewed based on the totality of their facts and circumstances, including the intent of the parties*

Requirements in all Three 3 Value-Based Anti-Kickback Safe Harbors

Safe harbor protection *not* available for certain entities:

- ✓ Pharmaceutical manufacturer, distributor, or wholesaler;
- ✓ Pharmacy benefit manager;
- ✓ Laboratory company;
- ✓ Compounding pharmacy;
- ✓ Manufacturer of a device or medical supply;*
- ✓ Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) providers;*
- ✓ Medical device distributor or wholesaler (that is not a manufacturer

**Protection for limited technology participants in care coordination arrangements safe harbor only*

Other protections introduced through the updates:

- ➢ New protection for outcomes-based payments, such as shared savings or performance bonus
- ➢ Safe harbor for CMS sponsored models

OIG Safe Harbors at a Glance…

Full Financial Risk

- VBE has assumed (or contracted to assume in the next 1 year) full financial risk from a payor
- "Full financial risk" means that the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the payor for each patient in the target patient population
- At least 1 year
- In writing; material terms included
- Quality assurance and protection against underutilization

OIG Safe Harbors at a Glance…

Substantial Downside Financial Risk

- VBE must assume (or be contractually obligated to assume within six months) "substantial downside financial risk" from a payor
- "substantial downside financial risk" defined based on specified risk-assumption thresholds
- VBE participant must "meaningfully share" (two-sided risk for at least 5% of the losses and savings) in the VBE's downside financial risk
- In writing; material terms specified

OIG Safe Harbors at a Glance…

Care Coordination Arrangements

- **Intended to protect in-kind remuneration exchanged among qualifying VBE participants with** value-based **arrangements**
- In-kind remuneration used predominantly to engage in *value-based activities* that are directly connected to the coordination and management of care for the *target patient population* and does not result in more than incidental benefits to persons outside of the target patient population
- Includes one or more legitimate outcome or process measures
- Recipient pays at least 15% of the offeror's cost for the remuneration
- Commercial reasonableness
- Monitoring and assessment required—60 days to terminate or develop 120-day corrective action plan if non-compliant
- In writing

Value-Based Arrangements: General Requirements (Stark & AKS)

- ✓ Remuneration for, or resulting from, value-based activities undertaken by the recipient for patients in the target patient population
- ✓ Tied to compensation, not ownership
- ✓ Exchange of remuneration must be between the VBE and a VBE participant—arrangements with downstream entities are not protected
- ✓ The remuneration is *not*…
  - An inducement to reduce or limit *medically necessary* items or services to any patient
  - Conditioned on referrals of patients who are *not* part of the target patient population or business not covered under the value-based arrangement
  - Tied to marketing or patient recruitment (AKS)
- ✓ Accountable body and governing document
- ✓ Six-year record retention requirement

Sample VBE Arrangements

Full Risk	• Capitation payments • Global budget payments • Percentage of premium arrangements • "Episode" based payments • Radiation Oncology Model (January 2022)
"Substantial" (Meaningful Downside) Risk	• Withholds, repayment requirements • Partial capitation • Bundled payments • Accountable care organizations (ACOs); shared savings models; other alternative payment models • Population-based payments • Incentive pay tied to meeting goals or outcome measures • Co-management (with downside risk)
Value Based Arrangements (Care Coordination)	• Clinical collaboration, care navigation • *Stark only* -- Co-management • *Stark only* -- Cash incentives to shape physician behavior, improve quality, reduce waste

Stark Law Practice Tip #1

"Period of Disallowance" provisions removed; New special rule for reconciliation

- ✓Period of disallowance (POD) provisions have been removed from Stark
- ✓CMS addresses administrative or operational errors or payment discrepancies during the course of the arrangement – allowing parties to *fix* them
- ✓90-day reconciliation period to fix discrepancies once arrangement ends
  - Once the 90-day period has ended, parties cannot retroactively "unring the bell" and cure previous non-compliance
- ✓Active monitoring encouraged

Stark Law Practice Tip #2

"Split pooling" not permitted for Group Practices (effective 1/1/2022)

- ✓"Group Practice" requirements permit distribution of designated health services (DHS) profits to groups of five or more physicians
- ✓"All the" inserted before "designated health services" at §411.352(i)(1)(ii)[1]
- ✓Implication is that the profits from all the DHS of any "pod of 5" must be aggregated before distribution
- ✓CMS clarifies its position that a group practice may not distribute profits from DHS on a service-by-service basis (so-called "split pooling")
- ✓Recognizing CMS policy is not fully and exactly depicted in current regs, CMS delays implementation to January 1, 2022

Stark Law Practice Tip #3
Mid-Term Amendments Permissible

- ✓In Phase III, CMS said that amending compensation terms of professional services agreements would run afoul of "set in advance" requirements
- ✓In 2009, CMS reversed position—amendments allowed if certain requirements met (including extending term from one year of amendment)
- ✓Final Rule codifies this position at §411.354(d)(1)(ii) but omits one-year requirement[2]
  - Modified compensation (or formula) must be determined before furnishing of items, services for which it is paid
  - Formula for modified compensation must be set forth in writing in sufficient detail so that it can be objectively verified—90-day extension for writing and signatures does not apply

Stark Law Practice Tip #4

Unlinking V/V from Referrals and Directed Referral Requirements

- ✓Prohibits making the existence of a compensation arrangement contingent on the number or value of the physician's referrals to a particular provider, practitioner, or supplier
- ✓However, CMS no longer believes that compensation predicated on making referrals of DHS should be evaluated for compliance with the volume/value (V/V) standard
- ✓Compliance with §411.354(d)(4) required for directed referrals:[2]
  - Set in advance, fair market value
  - In writing
  - Patient choice; insurance; patients' best medical interests (physician judgment)

Why are FMV, CR, and V/V Important?

- From CMS' "eye":[3]
  - Fair Market Value (FMV) = Did the calculation result in compensation that is fair market value for asset, item, service, or rental property?
  - Commercially Reasonable (CR) = Does the arrangement make sense as a means to accomplish the parties' goals?
  - V/V = How did the parties calculate the remuneration?

FMV Definition

- In general, the value in an arm's length transaction, consistent with the general market value of the subject transaction

- General market value means:
  - ***Assets*** – The 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*** – The compensation that would 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.
  - ***Rental of Equipment or Office Space*** – The 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.

Applications of New FMV Definition

- "General market value" is not "market value"
- "A hospital may not value a physician's services at a higher rate that a private equity investor or another physician practice…we recognize that reliance on similar transactions in the marketplace could simplify the process of determination FMV for purposes of the MD self-referral law, but adopting such a standard would allow parties to consider additional (or investment) value to certain types of entities, skewing the buyer-neutral fair market value"[3]
- Any commercially reasonable methodology may be used to establish FMV

CR Definition

- Commercially reasonable means "… *that the particular 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. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.*"[4]

Application of New CR Definition

- Determination of CR "is not one of valuation."
- Arrangements may appear to further legitimate business purposes but may not be CR
- What is "sensible"?
  - It is not good enough just to have a legitimate business purpose—execution/ongoing re-evaluation counts
  - Examples of legitimate business purposes
    - Addresses community need
    - Provides timely access to healthcare services
    - Fulfills licensure or regulatory obligations (i.e., Emergency Medical Treatment and Active Labor Act (EMTALA))
    - Provides charity care
    - Improves quality and health outcomes

Volume or Value Standard

- New “special rule” defining compensation methodologies that are considered to “take into account the volume or value of referrals or other business generated”
- Addresses compensation paid **to** a physician or immediate family member (IFM) of a physician by a designated health services (DHS) entity, and **from** a physician (or IFM) to a DHS entity
- CMS developed a two-part test to determine whether an arrangement meets the volume or value standard
  - Does a mathematical physician compensation formula exist that includes DHS referrals or other business generated as a variable?
  - If the answer to Question #1 is “Yes,” then does a physician’s compensation increase or decrease based on a positive or negative correlation with the physician’s referrals or other business generated?

Volume or Value Standard

- As an example, suppose there is an arrangement whereby a physician compensation formula is developed that pays a physician a certain percentage of a bonus pool that includes designated health services referred by the physician to an entity.
- CMS clarified that a unit-based (e.g., work relative value unit) compensation formula centered solely on a physician's personally performed services would meet the V/V standard.

FMV and CR Myths

- Myth #1: Benchmark data determines fair market value[5]
  - "It appears…that stakeholders may have been under the impression that it is CMS policy that reliance on salary surveys will result, in all cases, in a determination of fair market value"
  - "The FMV of a transaction…may not always align with published valuation data compilations, such a salary surveys"

FMV and CR Myths

- Myth #2: It is CMS policy that compensation set at or below the 75th percentile in a salary schedule is appropriate[5]
  - "We are uncertain why the commenters believe that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate. The commenters are incorrect that this is CMS policy."

FMV and CR Myths

- Myth #3: Arrangements cannot be commercially reasonable if they are not profitable[5]
  - CMS cites examples of non-profitable arrangements including those that meet community care, fulfill licensure/ regulatory obligations, and others
  - Profitability is still relevant – “We are not convinced that the profitability of an arrangement is completely irrelevant or always unrelated to the determination of CR”

Don’t Forget the Anti-kickback Statute

- Addresses key commercial reasonableness, fair market value, and other considerations in the context of seven safe harbors (three are value based).
- Specific to the Care Coordination Arrangements safe harbor (CCASH), multiple standards are required to be met
  - Establishment of one or more legitimate outcome or process measures
  - Arrangement must be CR
  - Only in-kind remuneration is protected
- Modified four existing safe harbors including the personal services and management contracts and outcomes-based payments

Key Takeaways

- ✓ With Value-Based Arrangements, the more risk, the more flexibility
- ✓ CMS and OIG made some important clarifications, and addressed many current questions, including related to FMV, CR, and V/V
- ✓ FMV and CR remain “facts and circumstances” specific, and FMV could fall above/below survey data based on qualitative and quantitative considerations
- ✓ While a bright line methodology for the V/V exists, the difficulty of ensuring compliance with this standard may leave many organizations looking to third party organizations to help with this subject
- ✓ Additional exceptions/safe harbors related to electronic health record and cybersecurity promoting use of technology to drive care, efficiency (not addressed here)
- ✓ Continued regulatory evolution to promote care coordination and value-based reimbursement not only expected, but ensured

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