



Move to Value Virtual Summit

An update on the evolution of Medicare fraud
and abuse waivers

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Stark Law and Anti-Kickback Statute (AKS) Final Rules

Executive Overview

Establishes new Stark Law exceptions and AKS safe harbors for **value-based arrangements**:

- Assuming **more financial risk** associated with **greater flexibilities** and **fewer requirements**



- Not limited to CMS-sponsored models
- Existing Fraud and Abuse waivers remain in place
- May streamline development of waivers for future models

Provides **greater clarity** around fundamental Stark Law terms and requirements:



- ✓ commercial reasonableness
- ✓ fair market value
- ✓ volume or value standard



Makes **EHR exception and safe harbor permanent**

New protections for **donation of cybersecurity technology**

Modernizes exceptions and safe harbors to **align with changes in Health IT policies**



Still **need legislative action** to align with movement to value-based care and to codify policies in statute



Developed in conjunction with HHS' Regulatory Sprint to Coordinated Care

Focused on removing potential regulatory barriers to care coordination and value-based care by reforming four key health care laws/regulations:

1. **Physician self-referral law (Stark Law)**
2. **Federal anti-kickback statute (AKS)**
3. Health Insurance Portability and Accountability Act (HIPAA)
4. 42 CFR Part 2 related to substance use disorder treatment



Background on Stark Law and Anti-kickback Statute

- **Physician Self-Referral Law (Stark Law)** – prohibits **physicians** from referring **Medicare patients** to entities with which the physician (or immediate family member) has a financial relationship. Also prohibits **entities** from submitting claims from prohibited referrals.
 - Applicable to certain services (or designated health services, DHS)
 - Strict liability – do not need to prove intent
 - Violators subject to civil penalties
 - Certain aspects of the law also apply to Medicaid
 - Statutory exceptions; Secretary also has authority to create regulatory exceptions for financial relationships that do not pose a risk to the program or patients
 - Overseen by CMS
- **Anti-kickback statute (AKS)** – prohibits the knowing and willful payment of remuneration to induce or reward patient referrals or generation of business of **any items/service** payable by a **Federal healthcare program**.
 - Remuneration includes anything of value (cash, non-monetary items, rental space, etc.)
 - Violators subject to criminal and civil penalties (fines, prison term, CMPs)
 - Intent must be proven
 - Must squarely fit into a safe harbor for arrangement to be protected
 - Overseen by HHS Office of Inspector General (OIG)

- Released Nov. 20, 2020 and published in Federal Register on Dec. 2, 2020
 - Policies are generally effective Jan. 19, 2021 (exception of a couple policies)

Goals of the Stark and AKS Rules:

- Remove barriers to innovation and reduce provider burden while facilitating regulatory compliance;
- Align wherever feasible OIG's AKS and CMS's Stark Law reforms;
- Ensure Medicare program integrity; and
- Contain sufficient flexibility to remain relevant over time as health care patterns evolve.



Value-based arrangement exceptions and safe harbors

CMS and OIG finalize similar **value-based terms** for the exceptions and safe harbors

Value-based Purpose

Must meet at least one of the following core goals:

- (1) Coordinating and managing the care of a **target patient population**;
- (2) Improving the quality of care for a **target patient population**;
- (3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a **target patient population**; or
- (4) Transitioning from health care 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**.

Finalized as proposed.

Value-based Activity

Any of the following that is reasonably designed to achieve at least one **value-based purpose** of the **VBE**:

- (1) provision of an item or service;
- (2) taking of an action; or
- (3) refraining from taking an action.

Does not include making a referral (*OIG only*)

CMS' and OIG's definitions differ. CMS did not finalize its proposal to explicitly state that making a referral is not a value-based activity.

Coordination and Management of Care (*OIG Only*)

Deliberate organization of patient care activities and sharing of information between two or more **VBE participants**, one or more **VBE participants** and the **VBE**, or one or more **VBE participants** and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the **target patient population**.

Modified to clarify (1) the parties engaged in care coordination and management, (2) that efforts to improve efficiency can be part of coordination and management of care, and (3) that efforts must be designed to achieve stated goals.

OIG's and CMS' definitions of **VBE Participant** differ slightly

OIG Definition: An **individual** or entity that engages in at least one **value-based activity** as part of a **VBE**, **other than a patient acting in their capacity as a patient**

- Adds language to clarify that patients do not qualify as VBE participants.
- Did not finalize proposal to exclude certain entities (e.g., pharmaceutical and device manufacturers) from definition. Instead, OIG finalized policy making certain entities ineligible for value-based safe-harbors

CMS Definition: A **person** or entity that engages in at least one **value-based activity** as part of a **VBE**.

Replaces “individual” with “person,” noting its widely used and refers to both natural and non-natural persons.

Value-based Enterprise (VBE)

Two or more **VBE participants** who are:

- (1) Collaborating to achieve at least one **value-based purpose**;
- (2) Each of which is a party to a **value-based arrangement** with the other or at least one other **VBE participant** in the **VBE**;
- (3) That have an accountable body or person responsible for financial and operational oversight of the **VBE**; and
- (4) That have a governing document that describes the **VBE** and how the **VBE participants** intend to achieve its **value-based purpose(s)**.

Finalized as proposed. CMS clarified that VBE participants can be added to VBE after start of arrangement but each addition must be analyzed separately for compliance

Value-based arrangement

An arrangement for the provision of at least one **value-based activity** for a **target patient population** to which the only parties are:

- (1) The **VBE** and one or more of its **VBE participants**; or
- (2) **VBE participants** in the same **VBE**.

- Finalizes minor modifications to clarify only applicable to the VBE and its participants or VBE participants in the same VBE.
- CMS clarifies does not cover compensation arrangements between payor and physician
- The OIG did not finalize language that would have limited protection for entities under common ownership.

Target Patient Population

An identified patient population selected by a **VBE** or its **VBE participants** based on legitimate and verifiable criteria that are set in writing in advance of commencing the **value-based arrangement** and further the **VBE's value-based purpose(s)**.

CMS finalized as proposed. The OIG modified proposed definition to align with CMS.

Overview of value-based arrangement exceptions

- The CMS Stark Law Rule creates **three new self-referral exceptions** for value-based arrangements:
 - **Value-based arrangements**
 - **Meaningful downside financial risk**
 - **Full financial risk**
- The OIG AKS Rule establishes **three new safe harbors** for value-based arrangements:
 - **Care coordination arrangements**
 - **Substantial downside financial risk**
 - **Full financial risk**
- Both rules define specific conditions that arrangements must meet for remunerations to be excepted as a financial relationship under Stark Law or protected under a Safe Harbor:
 - In general, greater flexibilities as parties assume greater downside financial risk
 - Several conditions must be met by all three of the exceptions or safe harbors



Conditions required for all Stark Law value-based arrangements

The following conditions **must be met by all three of the exceptions**:

- Remuneration is not conditioned on referrals outside the target population or businesses not covered under the arrangement
- Remuneration is not an inducement to reduce or limit medically necessary items/services
- If remuneration to physician is conditioned on referrals, the value-based arrangement must satisfy both of the following requirements:
 - Document requirement to make referrals (signed and in writing)
 - Requirement to make referrals does not apply if the patient prefers a different provider, the patient's insurer does not cover the provider, or the referral is not in the patient's best medical interest.
- Must maintain records of the methodology to determine remuneration for at least 6 years and make available to Secretary upon request
- Does not include requirements around volume or value of referrals or fair market value of the remuneration



Conditions required for all AKS value-based arrangements

The following conditions must be met by all **three of the safe harbors**:

- Value-based arrangement cannot induce VBE or VBE participants to furnish medically unnecessary services or reduce/limit medically necessary services
- Arrangement established in writing in advance of, or concurrent with start of, value-based arrangement and any material changes – specifies min. requirements
- Cannot take into account volume or value of or condition remuneration on referrals outside the target population or businesses not covered under the arrangement
- Does not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest
- Remuneration cannot be exchanged or used for marketing items/services by VBE or VBE participants to patients or for patient recruitment
- Cannot limit medical decision-making or patient freedom of choice
- Must maintain records and materials sufficient to establish compliance with safe harbor for at least 6 years and make available to Secretary upon request

Did not finalize following conditions:

- Disallowing exchanged remuneration from being funded by entity outside of VBE
- Requirement for VBEs to submit data to the OIG identifying VBE, participants, and arrangements
- Prohibition on cost-shifting to federal programs

Stark Law: Full Financial Risk Exception

- VBE has assumed **full financial risk** during the entire duration of the arrangement
- *Pre-participation protections:* Would protect value-based arrangements in the **12 months** leading up to VBE assuming full financial risk.
 - Had proposed pre-risk period of 6 months; finalized proposal emulates MSSP preparticipation waiver
- Full financial risk arrangements must meet following conditions to be eligible for the exception:
 - Remuneration results from a value-based activity undertaken by the recipient as part of the arrangement
 - Requirements that must be met by all value-based exceptions

Full financial risk: VBE is financially responsible on prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target population for a specified period of time

Clarified several policies including:

- ✓ Technology or infrastructure already possessed by recipient does not count as in-kind remuneration.
- ✓ Does not prohibit prospectively-defined shared savings or other incentive payments conditioned on quality performance, and payments to offset shared losses above a prospectively-defined level.
- ✓ Remuneration related to covered patients could be used for the benefit of non-covered patients.



AKS: Value-Based Arrangements With Full Financial Risk

- Protects remuneration in arrangements where VBE assumes **full financial risk** from a payor for a target patient population – two options for assuming risk:
 - Payor is VBE Participant and VBE has assumed risk from payor through value-based arrangement – remuneration between payor and VBE protected
 - Payor is not part of VBE; VBE can assume risk from payor through written contract, which is not part of value-based arrangement – safe harbor does not protect remuneration between payor and VBE
- Certain entities are ineligible for safe harbor
- Protects monetary and in-kind remuneration between VBE and VBE participants
 - Not between VBE participants and not with downstream contractors
- Certain conditions must be met for remuneration to be protected:
 - Remuneration must be connected to one or more value-based purposes
 - Did not finalize requirement that one of purposes must be coordination and management of care
 - Must arrange for quality assurance program for services furnished to target patient population
 - Did not finalize requirement to have operational utilization review program
 - Requirements that must be met by all value-based safe harbors
- *Pre-participation protections*: Protects value-based arrangements in the 12 months leading up to VBE assuming full financial risk
 - Had proposed pre-risk period of 6 months

Full financial risk: VBE is at risk on a prospective basis for the cost of all items and services covered by applicable payor target patient population for at least one year.

Modified to require VBE to be **at risk** on prospective basis – proposed language had required VBE to be prospectively paid.

Did not finalize the following requirements:

- Value-based arrangement be for a term of one-year
- Remuneration be used primarily to engage in set value-based activities

Stark Law: Meaningful Downside Financial Risk

- Physician is at **meaningful downside financial risk** for failure to achieve value-based purpose during entire duration of the arrangement.
- Protects remunerations paid to or from the physician
- Remuneration (monetary and/or non-monetary) is protected if the value-based arrangement satisfies the following conditions:
 - Remuneration results from a value-based activity undertaken by the recipient as part of the arrangement
 - Documentation of the nature and extent of the physician’s financial risk
 - Methodology for remuneration set in advance
 - Requirements that must be met by all value-based exceptions

Meaningful Downside Financial Risk: Physician is responsible to repay **or forgo** no less than **10%** of the **total** value of the remuneration the physician receives under the value-based arrangement.

- Finalized lower threshold – CMS had proposed no less than 25%
- Revised to allow physicians to “forgo” as option for structuring financial terms (e.g., withholds, repayment requirements)
- Revised to specify that percentage is applied to total value received under arrangement – including in-kind remuneration

Clarified several policies including:

- ✓ Exception focuses on value-based activities of individual physician – not designed to mirror OIG’s safe harbor
- ✓ Risk threshold relates to remuneration from an entity to a physician – not payments from payor for a physician’s services



AKS: Value-Based Arrangements With Substantial Downside Financial Risk

- Protection for arrangements where VBE assumes **substantial downside financial risk** for entire period of arrangement from a payor for services furnished to a target patient population
- Two options for VBE to assume substantial downside risk:
 - Payor is a VBE Participant and VBE has assumed risk from payor through value-based arrangement – remuneration between payor and VBE protected
 - Payor is not part of VBE; VBE can assume risk from payor through written contract, which is not part of value-based arrangement – safe harbor does not protect remuneration between payor and VBE
- VBE participants must **meaningfully share** in VBE's total risk

VBE would be at **Substantial Downside Financial Risk** if met one of the following methodologies:

- 1) Obligation to repay payor at least 30% of shared losses (*Shared Savings and Losses Method*) [proposed 40%]
- 2) Obligation to repay payor at least 20% of total losses for episodic or bundled payments (*Episodic Payment Method*)
- 3) Receive prospective, per-patient payment designed to produce material savings and paid on a monthly, quarterly, or annual basis for predefined set of items/services for target population (*VBE Partial Capitation Method*)

- Clarified calculation of methodologies
- Reduced risk threshold on Shared Savings Losses Method
- Revised VBE Partial Capitation Methodology
- Did not finalize population-based payment methodology

VBE participant would **Meaningfully Share** in risk if met one of the following methodologies:

- 1) Risk-sharing payment where participant is at two-sided risk for at least 5% (*Risk-Sharing Payment Method*) [proposed 8%]
- 2) Prospective, per-patient payments for predefined set of items/services furnished to target population (*Meaningful Share Partial Capitation Method*)

- Finalized lower threshold and clarified requires two-sided risk on Risk-Sharing Payment Methodology
- Revised Partial Capitation Methodology to be applicable to prospective per-patient payments
- Did not finalize method that would consider physicians to meaningfully share if qualified for Stark Law exception for meaningful downside risk



AKS: Value-Based Arrangements With Substantial Downside Financial Risk

- Protects monetary and in-kind remuneration between VBE and VBE participants
 - Does not protect arrangements downstream of VBE participant (e.g., arrangement between two VBE participants)
- Certain entities are ineligible for safe harbor
- Protected if the value-based arrangement satisfies the following conditions:
 - Remuneration used predominantly to engage in value-based activities
 - Remuneration exchanged pursuant to methodology for assumption of risk (i.e., substantial downside financial risk or meaningful share) do not need to meet this condition if all other conditions are met
 - Remuneration directly connected to at least one of the first three value-based purposes
 - Did not finalize requirement that one of purposes must be coordination and management of care
 - Requirements that must be met by all value-based safe harbors
- *Pre-participation protections*: Would protect value-based arrangements in the 6 months prior to VBE assuming substantial downside risk.
- Did not finalize commercial reasonableness requirement or monitoring standard

Stark Law: Value-Based Arrangement Exception

- Value-based arrangements **regardless of level of risk**
- Remuneration (monetary and/or non-monetary) would be protected if the value-based arrangement satisfies the following conditions:
 - Arrangement documented in writing and signed by parties -- CMS specifies what must be documented
 - **Outcome measures** are objective, measurable, and selected based on clinical evidence or credible medical support
 - Methodology for remuneration set in advance
 - Remuneration results from a value-based activity undertaken by the recipient as part of the arrangement
 - Requirements that must be met by all value-based exceptions
- Adds set of **mandatory monitoring requirements**
 - Proposed rule had discussed implicit ongoing obligation to monitor for compliance and sought input – but did not proposal actual requirements.
 - Final rule specifies frequency of monitoring, what should be monitored, and “cure process” for non-compliance

Outcome measure:

Benchmark that quantifies –

- Improvements in or maintenance of the quality of patient care, or
- Reduction in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care

Changes must be made prospectively and in writing.

Revised proposal to require “performance or quality standards” to align with OIG’s requirement of “Outcome Measures”

- No requirement for downside risk
- Protects **“in-kind” remuneration** exchanged between a VBE and VBE participants or between VBE participants.
- Remuneration must be used predominantly to engage in value-based activities directly connected to **coordination and management of care**
 - Finalized condition that remuneration exchanged result in no more than incidental benefits to persons outside target patient population
 - Did not finalize separate requirement that arrangement be directly connected to coordination and management of care – duplicative
- Certain conditions must be satisfied for remuneration to be protected (*see next slide*)
- If accountable party/responsible person determines deficiencies in quality of care or arrangement is unlikely to further coordination and management of care – must terminate arrangement within 60 days or develop correction action plan to remedy within 120 days
- Certain entities are ineligible for participation – except in the case of Limited Technology Participants
- Does not include a “phase-in” period

Following conditions must be met for the arrangement to fit into the Safe Harbor -

- Requires one or more **legitimate outcome or process measures** (see sidebar)
- Must be commercially reasonable (definition not codified in regulation)
- Recipient must contribute at least 15% of cost or fair market value of remuneration
- Must monitor and assess certain aspects of the arrangement at least annually, including progress toward achieve measures.
- Requirements that must be met by all value-based safe harbors

Did not finalize several conditions and requirements, including:

- Fair market value requirement and restriction on remuneration tied to volume or value of referrals, including both business or patients that are part of arrangement
- Requirement that remuneration be provided directly from offeror to recipient

Required to establish one or more **legitimate outcome or process measures** that are reasonably anticipated to advance coordination and management of care for target patient population based on clinical evidence or credible medical/health science approach. (Broadened from proposed, which required evidence-based outcome measures)

Measure(s) must:

- include one or more benchmarks related to improving, or maintaining improvement, in the coordination and management of care for the target patient population;
- relate to the remuneration exchanged under the value-based arrangement; and
- not be based solely on patient satisfaction or patient convenience.

Must monitor and periodically assess – revise as necessary to ensure continues to advance coordination and management of care

- New safe harbor permits VBE participants to furnish **patient engagement tools and supports** to a patient in a target patient population of a value-based arrangement that the participant is party to:
 - Certain entities excluded; protection for Limited Technology Participants
 - Must be furnished directly to patient – either by VBE participant or eligible third-party agent
- Tools and supports must have a direct connection to the coordination and management of care of target population
- Protects in-kind, items, goods or services
 - Final rule does not specify categories of items, goods, or services
- Excludes: cash and cash equivalents
 - Did not finalize prohibition on gift cards – acknowledged that some gift cards could be considered in-kind
- Finalized several safeguards and conditions (*next slide*)



Patient Engagement and Support Safe Harbor Safeguards

- Annual limit of \$500 (adjusted annually for inflation)
 - Did not finalize exception for patients with demonstrated financial need
- Recommended by patient's licensed health care professional
 - Did not finalize written certification requirement
- Cannot be funded or contributed by persons outside the VBE and value-based arrangement
- May not result in medically unnecessary or inappropriate items or services being reimbursed by Federal health care program
- Must advance at least one of the specified goals: adherence to treatment or drug regimen or follow-up care plan; prevention or management of a disease condition; or ensuring patient safety
- Cannot be used to market other items or services reimbursable by Federal health care programs or for patient recruitment purposes
- Availability of tools and supports cannot take into account patient's insurance coverage
- Must maintain records sufficient to establish compliance with safe harbor for at least 6 years and make available to Secretary upon request

Did not finalize:

- Requirement to confirm tool or support is not duplicative of or substantially the same as tool or service patient already has
- Prohibition on cost-shifting to Federal health care programs
- Monitoring requirements
- Retrieval requirement
- Exclusion of tools or supports if offeror knew or should have known item or service would have been diverted or sold.
- Patient notification requirement

- New safe harbor that protects remuneration between parties allowed in **CMS-sponsored model arrangements** under AKS and the Beneficiary Inducement CMP
- Developed in response to stakeholder concerns about a patchwork of fraud and abuse waivers issued by CMS and OIG
- Applies to CMMI Models and the Medicare Shared Savings Program
- Protects remuneration and patient incentives covered under the model
- Parties may use the current waivers or may structure arrangements under the new safe harbor
- CMS determines scope and conditions for arrangements and incentives
 - E.g., parties could include drug and DMEPOS manufacturers, labs

Safeguards and conditions include:

- No inducements to furnish medically unnecessary services or reduce medically necessary services
- No inducements for referrals or other business generated outside model
- Record retention requirements
- Must satisfy CMS program requirements
- Patient incentives have direct connection to patient's health care – unless participation documentation specifies different standard
- Oversight by CMS and OIG
- Protection while parties operating under the model – clarifies duration in final rule:
 - On or after start of model (e.g., start of performance period 1) and no later than six months after final payment determination by CMS

- Bipartisan Budget Act of 2018 modified the MSSP ACO program
- Allows certain two-sided ACOs to operate beneficiary incentive programs without violating the beneficiary inducement CMP law
- OIG codifies the rule:
 - Does not impose additional safeguards
 - Clarifies the incentives may only be provided to assigned beneficiaries

Interaction with existing APM waivers

- Value-based arrangement exceptions and safe harbors are not limited to CMS-sponsored models
- New exceptions and safe harbors do not impact model-specific or program-specific waivers – will remain in place
- Existing waivers or the new exceptions/safe harbors can be used whenever the respective requirements are met
- May streamline development of waivers for future value-based models
 - May eliminate need for future waivers for CMS-sponsored models



Congressional action is needed to reform Stark Law and AKS

- Rules are still constrained within the confines of a statutory framework that was designed to address vulnerabilities in a fee-for-service system
- Potential areas for reform:
 - Remove strict liability provisions for Stark Law
 - Revise Secretary's authority to establish regulatory exceptions
 - Currently limited to only financial relationships that pose no risk of program or patient abuse
 - Establish broad exceptions and safe harbors to protect value-based arrangements that are inclusive of all participants
 - Simplify and align definitions across Stark and AKS value-based frameworks
 - Reduce civil monetary penalties for providers participating in value-based arrangements.

- APM Participants –
 - Potential greater flexibility in structure and composition of APM entities to be more specific to goals of APM
 - For example, operation of a separate ACO and CIN may become more attractive
 - Greater alignment between activities in Medicare APM and other contractual arrangements
- Non-APM Participants –
 - the differences between the Stark and AKS value-based care rules mean that organizations will likely continue to find themselves in a compliance “grey zone” where an arrangement satisfies a Stark Law exception—because it must—but is unable to meet an AKS safe harbor because the safe harbor is too restrictive.*

* = <https://www.mwe.com/insights/hhs-finalizes-sweeping-changes-to-stark-law-anti-kickback-statute-regulations/>

Potential Implications- Portfolio Review of Physician Incentives

Attributes	Physician Alignment Models											
	Practice Acquisition	Employment Contract Re-design	Management Services Organization (MSO)	Joint Ventures	Gainsharing	Bundled Payments	Co-Management	Employee Health Plan Shared Savings	Hospital Quality & Efficiency Program	CIN/ACO	Organizational Model Alignment	Value-based Payment Models (no risk → full risk)
Payment Model Type	Traditional FFS	Transitional	Traditional FFS	Variable	Traditional FFS	Value-based Care	Transitional	Value-based Care	Value-based Care	Value-based Care	Value-based Care	Value-based Care
Physician Targets	All	All (Employed / Foundation)	All	All	Surgical Specialists	Medical & Surgical Specialists	Medical & Surgical Specialists	PCPs	Medical & Surgical Specialists	All	All	All
Independent MD Engagement	Low	Low	High	High	High	Variable	High	High	High	High	Moderate	High
System Quality Impact	Low	Moderate	Low	Low	Low	Moderate	High	Moderate	High	High	Moderate	High
System Financial Impact	Variable	Low	Low	Moderate	High	Moderate	Moderate	Moderate	High	Moderate	Low	High

The spectrum of incentives to engage physicians must be carefully weighed and considered when establishing an effective strategy to address both local and market considerations

1. Develop internal inventory of incentives available to all provider types (PCP, medical specialists, proceduralists, hospital-based, etc.) to identify current gaps in physician engagement and performance
2. Assess downside financial risk as a percentage of total value-based covered lives / revenue potential
3. Evaluate potential for investment in virtual health / patient activation technology
4. Consider development of internal physician incentive models (EHP, HQEP, co-management) to enhance provider engagement

Questions?



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