



# Proposed Modifications to the Stark Law and the Anti-Kickback Statute

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

#### 42 CFR Parts 1001 and 1003

RIN 0936-AA10

#### Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

**AGENCY:** Office of Inspector General (OIG), Department of Health and Human Services (HHS).

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule is being issued by the Office of Inspector General (OIG) in conjunction with the Department of Health and Human Services' Regulatory Sprint to Coordinated Care. It proposes to add, on a prospective basis only after a final rule is issued, safe harbor protections under the Federal anti-kickback statute for certain coordinated care and associated value-based arrangements between or

recommendations, without unduly delaying any final rulemaking.

**ADDRESSES:** In commenting, please reference file code OIG-0936-AA10-P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. However, you may submit comments using one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-0936-AA10-P, Room 5521, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver your written comments by hand or courier before the close of the comment period to: Office of Inspector General, Department of Health

## I. Executive Summary

### A. Purpose and Need for Regulatory Action

The Secretary of Health and Human Services (the Secretary) has identified transforming our healthcare system to one that pays for value as one of the top priorities of the Department of Health and Human Services (the Department or HHS). Unlike the traditional fee-for-service (FFS) payment system, which rewards providers for the volume of care delivered, a value-driven healthcare system is one that pays for health and outcomes. Delivering better value from our healthcare system will require the transformation of established practices and enhanced collaboration among providers and other individuals and entities. The purpose of this proposed rule is to modify existing safe harbors to the anti-kickback statute and add new safe harbors and a new CMP law exception to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency.

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## Proposed Modifications to the Stark Law and the Anti-Kickback Statute

### Timeline

- Released October 9, 2019, published October 17, 2019. Comment deadline for 75 days following publication (December 31, 2019).
- HHS Deputy Secretary Eric Hargan “... a historic reform of how healthcare is regulated in America.”
- Significant opportunities for new arrangements, but current arrangements will need revision



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## HHS’s “Regulatory Sprint to Coordinated Care”

- Launched in 2018
- Goal of reducing regulatory burden and incentivizing coordinated care.
- Unnecessarily hinder innovative arrangements policymakers are hoping to see develop.
- Requests for information (RFIs) in June and August 2018.
- Stark/AKS, HIPAA, 42 CFR Part 2 (substance abuse)



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## Remember...

- CMS = Stark Law
- Stark Law = Exceptions
- OIG = Anti Kickback Statute (AKS)
- Anti Kickback Law = Safe Harbors



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## Brief Overview of Proposed Modifications

- The addition of value based entities safe harbors / exceptions for certain value-based arrangements.
- The addition of safe harbors for participants in CMS's alternative payment models;
- Proposed new safe harbor for donations of cyber security technology / Create a new exception for the donation of cybersecurity technology and services
- Modifications to electronic health records safe harbor / exception
- Modifications to the personal services safe harbors;
- Modifications to the local transportation safe harbor
- Provide additional guidance on "fair market value," "volume or value," and "commercial reasonableness."
- Create a new exception for arrangements were physicians receive limited remuneration for items or services that were actually provided by the physician.



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## Value Based Arrangements

### New Proposed Stark Exceptions and AKS Safe Harbors



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### Value Based - AKS Safe Harbors

- 1. Care Coordination Safe Harbor**
- 2. Value-Based Arrangements with Substantial Downside Financial Risk**
- 3. Value-Based Arrangements with Full Downside Financial Risk**



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## AKS and Stark Law Value-Based Definitional Framework

- Proposed Definitions:

- “Value-Based Activity (VBA)”-One of the following activities reasonably designed to achieve at least one Value Based Purpose and does not include the making of a referral.
  1. The provision of an item or service;
  2. The taking of an action; or
  3. The refrain from taking an action.
- “Value-based purpose”-One of the following for a target patient population (TPP)
  - Coordinating and managing the care;
  - Improving the quality of care;
  - Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care; or
  - transition from healthcare delivery and payment mechanisms based on the volume of items and services to a mechanism based on the quality of care and control of costs of care.



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- “Value-Based Enterprise (VBE)”-2 or more VBE participants
  1. collaborating to achieve at least one value-based purpose;
  2. Each of which is a party to a value-based arrangement with other or at least one other VBE participant;
  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 purposes.
    - Regulation excludes from participation in a VBE: pharmaceutical manufacturers; DME manufacturers, distributors, or manufacturers; and laboratories.
- “Target Patient Population (TPP)”- identified patient population selected by a VBE or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the VBE’s value-based purpose.



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- “Coordination and management of care” –the deliberate organization of patient care activities and sharing of information between two or more VBE participants and/or patients, tailored to improve health outcomes and achieve safer and more effective care.



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## Common Terms

- Prior to or at the time the arrangement begins, the arrangement is in writing, describes the value-based activities, describes the remuneration, and the outcome measures;
- The remuneration is primarily used to engage in the value-based activities, does not induce the participants to furnish medically unnecessary services or limit or reduce medically necessary services, and does not take into account or condition the arrangement on the volume or value of referrals or other business generated; and
- Does not unnecessarily direct or restrict referrals if (1) a patient has a preference; (2) the payor chooses another provider; or (3) would be contrary to law



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## Care Coordination Safe Harbor

- The proposed “care coordination safe harbor” would protect an value-based arrangement if the 12 requirements are met, including the following:
  - The VBE participants establish one or more specific evidence-based, valid outcome measures against which the recipient of the item or service will be measured and which are reasonably anticipated to advance the coordination and management of care;
  - Only in-kind, non-monetary remuneration, such as the provision of a care coordinator, and the party receiving the remuneration must reimburse the offeror for at least 15 percent of its costs;
  - The remuneration could not be funded by any individual or entity outside of the VBE



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## Care Coordination Safe Harbor (Cont.)

- The VBA is directly connected to coordination and management of care, does not restrict the ability of the participants to make decisions in the best interests of the patients, does not unreasonably direct or restrict referrals to particular providers;
- There is monitoring, assessment, and reporting program, requiring, at a minimum, annual reports of the results of the arrangement in achieving the VBP and any deficiencies;
- The VBA is terminated within 60 days if it does not further the value-based purpose or results in material deficiencies in the quality of care.



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## Care Coordination Safe Harbor (Cont.)

- OIG also discusses additional safeguards it is considering, including :
  - Imposing a fair market value requirement on any remuneration exchanged
  - Prohibiting VBE participants from determining the amount or nature of remuneration, or to whom they offer it, in a manner that takes into account the volume or value of other business generated.
  - Possible additional requirements specific to dialysis providers.
- The OIG proposed alternative regulatory structure (i.e. lieu of finalizing the safe harbors) that would rely on the revised personal services and management contracts safe harbor to create protection for value-based arrangements.



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## Substantial Downside Financial Risk

- This proposed safe harbor, would protect a value-based arrangement if the requirements are met:
  - The VBE has assumed “substantial downside financial risk” from a payor and the participant “meaningfully shares” in the VBE’s substantial financial downside risk;
  - The remuneration is
    - i. directly connected to one or more of the VBE’s value-based purposes, at least one of which must be the coordination and management of care for the target patient population; does not induce VBE participants to reduce or limit medically necessary items or services furnished to any patient;
    - ii. does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and
    - iii. is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the VBE;



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## Substantial Downside Financial Risk (Cont.)

- “Substantial downside financial risk” means for the entire term of the arrangement, there is:
  - i. Shared savings with a repayment obligation to the payor of at least 40 % of any shared losses;
  - ii. A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 % of any total loss;
  - iii. A prospectively paid population-based payment for a defined subset of the total cost of care of a TPP, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; or
  - iv. Partial capitated payment from the payor for a set of items and services for the target patient population, where such capitated payment reflects a discount equal to at least 60 % of the total expected fee-for-service payments based on historical expenditures.



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## Substantial Downside Financial Risk (Cont.)

- “Meaningfully share” means there is:
  - i. a risk sharing agreement for which the participant is at risk for 8% of the risk of the VBE;
  - ii. there is a partial or full capitation payment or similar payment methodology; or
  - iii. if the participant is a physician, a payment that meets the requirements of a VBA under the Stark law exceptions.



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## Full Financial Risk

- This safe harbor would protect cash payments and in-kind remuneration between a VBE and a VBE participant when the VBE has assumed “full financial risk,”
- “Full financial risk” means the VBE is financially responsible for the costs of all items and services and is prospectively paid by the payor.



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## Full Financial Risk (Cont.)

This proposed safe harbor would protect a value-based arrangement, if the requirements are met, including:

- The VBE has assumed (or is contractually obligated to assume in the next 6 months) full financial risk from a payor and has a signed writing with the payor that specifies the TPP and contains terms evidencing that the VBE is at full financial risk for that population for a period of at least 1 year.
- The VBE participant does not claim payment in any form directly or indirectly from a payor for items or services.



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## Full Financial Risk (Cont.)

The remuneration:

- (i) Is used primarily to engage in the value-based activities;
- (ii) Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the TPP;
- (iii) Does not induce a reduction or limit medically necessary items or services furnished to any patient;
- (iv) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and
- (v) Is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the VBE.



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## Full Financial Risk (Cont.)

- Only applies to remuneration between a VBE at full financial risk and a VBE participant pursuant to a value-based arrangement.
- Would not protect remuneration between VBE participants that are part of the same VBE, or remuneration between a VBE participant and another contracted provider or vendor.



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## Value Based Stark Exceptions

New Value Based Stark Exceptions are designed to parallel the AKS Safe Harbors and include:

1. Full Financial
2. Meaningful Downside Financial Risk to the Physician
3. Value-Based Arrangements without Financial Risk
4. Indirect Compensation Arrangements to Which the Value-Based Exceptions Are Applicable



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## Stark Value-Based Framework Distinctions

“Value-based participants” substantially the same as AKS, except it does not exclude pharmaceutical manufacturers; DME manufacturers, distributors, or suppliers; or laboratories.

Unlike AKS, CMS does not define “coordination and management of care.”

“Full financial risk” means the value-based enterprise is financially responsible (or is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.



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## Stark Value-Based Framework Distinctions

“Prospective basis” means the VBE has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients.

“Meaningful downside financial risk” means (1) the physician is responsible to pay the entity no less than 25% of the value of the remuneration or (2) is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services.

- Replaces the substantial downside financial risk requirement under the AKS proposed Safe Harbor.

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### Full Financial Risk Exception

Conditions are substantially similar to AKS safe harbor:

1. The VBE is at full financial risk;
2. The remuneration is for or results in value-based activities;
3. The remuneration is not an inducement to reduce or limit medically necessary items or services;
4. The remuneration is not conditioned on referrals to a particular supplier or provider;
5. Records are maintained for 6 years.



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## Meaningful Downside Risk

1. The physician is at meaningful downside financial risk for failure to achieve the value-based purpose;
2. The risk is set forth in writing;
3. The methodology used to determine the remuneration is set in advance;
4. The remuneration is for or results from value-based activities;
5. The remuneration is not conditioned on referrals;
6. The remuneration is not an inducement to reduce or limit medically necessary items or services.



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## Value-Based Arrangements Exception (42 CFR

411.357(aa)(3))

- Proposed exception for value based arrangements where neither party, including the physician, has taken on financial risk:
  1. The arrangement is in writing, signed by the parties, and describes the arrangement, the value-based activities and purposes, the remuneration, and the performance metrics;
  2. The performance metrics are objective and measurable and changes to them must only be prospective;
  3. The methodology to calculate the remuneration is set in advance, if for or results in value-based activities, is not an inducement to reduce or limit medically necessary services or items, and is not conditioned on referrals;
  4. Records must be maintained for 6 years.



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## Indirect Compensation Arrangements which are Applicable to the Value-Based Exceptions

### CMS Proposes 2 Options:

1) In an indirect compensation arrangement exists and the remuneration paid to the physician qualifies under a value-based arrangement, then the value-based exceptions would be available to protect the arrangement.



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## Indirect Compensation Arrangements which are Applicable to the Value-Based Exceptions

2) If between the physician and the entity, there exists an unbroken chain of any number (but not fewer than one) of persons (including but not limited to natural persons, corporations, and municipal organizations) that have financial relationships (as defined at § 411.354(a)) between them (that is, each person in the unbroken chain is linked to the preceding person by either an ownership or investment interest or a compensation arrangement); (2) the financial relationship between the physician and the person with which he or she is directly linked is a value-based arrangement; and (3) the entity has actual knowledge of the value-based arrangement in subparagraph (2).



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## CMS's Concerns with New Exceptions

- CMS cites its continuing concerns that value-based payment models may pose risks, such as stinting on care, “cherry-picking,” “lemon-dropping,” and manipulating or falsifying data used to verify outcomes.



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## Other Considerations for Value Based Enterprises

### Monitoring Expectations



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## Monitoring Expectations

- Monitoring – One of the Elements of an Effective Compliance & Ethics Program under the US Sentencing Guidelines
  - Note 2019 DOJ Criminal Division Guidance and June, 2020 Update
- *“We expect that, as a prudent business practice, parties would monitor their arrangements to determine whether they are operating as intended and serving their intended purposes, **regardless of whether the arrangements are value-based**, and have in place mechanisms to address identified deficiencies, as appropriate. **In fact, there is an implicit ongoing obligation for an entity to monitor its financial relationship with a physician for compliance with an applicable exception.**”*
- **Adoption of a monitoring requirement into the Stark Law?**



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## Value Based Enterprises (VBEs)

- The network of individuals and entities that collaborate together to achieve one or more value-based purposes (2 or more)
- Examples: 2 independent physician practices; 2 or more hospital systems; ACO
- Each participant must be party to a value based arrangement
- Each VBE must have an Accountable Body



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## VBEs– Accountable Body

- “gatekeeper” to the VBE – Governing Body, an Entity or a Person
- Process and criteria to ensure that VBE Participants have a legitimate role in the VBE - not participants in name only
- Operational / financial oversight
- Identify program integrity issues and to initiate action to address them, as necessary and appropriate



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## VBEs– Accountable Body (cont.)

No programmatic oversight like CMS sponsored models. Therefore, considering whether:

- the VBE or its participants **should be required to have a compliance program** ... and whether the accountable body or person should have responsibility for the compliance program.
- **explicitly agree to cooperate with its oversight efforts (e.g., by requiring the inclusion of a statement to this effect in the applicable written agreement )**
- Oversight related to utilization of items and services, cost, quality of care, patient experience, adoption of technology, and the quality, integrity, privacy, and security of data related to the arrangement (such as outcomes, quality, and payment data)
- Whether VBEs should be required to implement reporting requirements for their VBE participants
- Whether VBEs should be required to implement mechanisms for obtaining access to, and verifying, VBE participant data concerning performance under any value-based arrangement
- **Whether to impose a standard requiring either independence or a duty of loyalty as a criterion**



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## VBEs – Continuous Monitoring

- **No less frequently than annually- monitor and assess (i) The coordination and management of care for the target population in the value-based arrangement, (ii) any deficiencies in the delivery of quality care under the value-based arrangement, and (iii) progress toward achieving the evidence-based, valid outcome measure(s) in the value-based arrangement.**

**The parties must terminate the arrangement within 60 days of such a determination or lose safe harbor protection** if determine the arrangement is (i) unlikely to achieve the evidence-based, valid outcome measure(s) or further the coordination and management of care for the target patient population or (ii) has resulted in material deficiencies in quality of care



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## Additional Proposed AKS Safe Harbor Revisions



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## Personal Services Safe Harbor

Would modify the existing personal services safe harbor

- Eliminates the requirement that the aggregate compensation must be set in advance, so long as the methodology to determine the aggregate compensation is set in advance.
  - Must still represent fair market value and not take into account the volume or value of referrals or other business generated.
- Removes the requirement to specify the schedule of a part-time or periodic contractor.



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## Patient Engagement and Support Safe Harbor

Allows a patient engagement or support tool furnished by a VBE to a patient if:

- The tool is furnished directly to the patient by a VBE participant.
- No individual or entity outside of the VBE funds or otherwise contributes to the provision of the tool.
- The tool:
  - (i) Is an in-kind preventive item, good, or service, or an in-kind item, good, or service such as health-related technology;
  - (ii) That has a direct connection to coordination and management of care;
  - (iii) Does not include any gift card, cash, or cash equivalent;
  - (iv) Does not include any in-kind item, good, or service used for patient recruitment or marketing of items or services to patients;
  - (v) Does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program;



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## Patient Engagement and Support Safe Harbor

- (vi) Is recommended by the patient's licensed healthcare provider; and
- (vii) advances one or more of the following goals:
  - (A) Adherence to a treatment regimen determined by the patient's licensed healthcare provider.
  - (B) Adherence to a drug regimen determined by the patient's licensed healthcare provider.
  - (C) Adherence to a follow-up care plan established by the patient's licensed healthcare provider.
  - (D) Management of a disease or condition as directed by the patient's licensed healthcare provider.
  - (E) Improvement in measurable evidence-based health outcomes for the patient or for the target patient population.
  - (F) Ensuring patient safety.



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## CMS-Sponsored Model Arrangements Safe Harbor

Remuneration exchanged between parties under a CMS-Sponsored Model Arrangement, 42 CFR 1001.952(ii)(1), would be protected if the requirements are met, including:

- The parties reasonably determine that the arrangement will advance one or more goals of a CMS-sponsored Model;
- The exchange does not induce the recipient to furnish medically unnecessary services or reduce or limit medically necessary services.
- The parties do not offer, pay, solicit, or receive remuneration in return for referrals or other business;
- The terms of the arrangement is set forth in a writing.



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## CMS-Sponsored Model Patient Incentives Safe Harbor

- Remuneration in the form of a CMS-sponsored patient incentive would be protected if the requirements are met, including:
  - The patient incentive will advance 1 or more of the goals of the CMS sponsored model;
  - The patient incentive has a direct connection to the patient's healthcare;



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## Outcomes Based Payment Safe Harbor (42 CFR

1001.952(d)(2))

Would protect remuneration in a personal services arrangement for outcome based measurements.

- Paid between parties collaborating to (1) measureable improve the quality of care; (2) materially reduce costs or growth in expenditures or improvements in quality of care; or (3) both;
- The outcome measurements must be based on clinical evidence or credible medical support;
- There are policies and procedures to measure effectiveness.
- Does not apply to measurements designed solely for internal cost savings.
- Does not apply to pharmaceutical manufacturers; DME manufacturers, distributors, or manufacturers; and laboratories.



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## CMS Proposed Modifications to Terminology

- Proposed modifications to the Big 3:
  - Commercially reasonable
  - Volume or value
  - Fair market value



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## Commercial Reasonableness

- Proposing to define “commercially reasonable” for the first time.
- Clarifying that “commercial reasonableness” is not a valuation issue. An arrangement can be commercially reasonable even if it is not profitable.
- Seeking further comments on the proposed definitions.
- Proposing two possible definitions:
  1. A particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements; or
  2. A particular arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable entity of similar scope and specialty.



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## Volume or Value of Referrals and Other Business

- Compensation will be considered to take into account the volume or value of referrals if:
  - Compensation to a physician includes the referrals as a variable and results in an increase or decrease in compensation that positively correlates with the number or value of the referrals.
  - Compensation from a physician to an entity increases or decreases in a way that negatively correlates to referrals. Essentially, more referrals = less compensation.



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## Fair Market Value

Three proposed definitions:

1. General. The value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction.
2. Rental of equipment. With respect to the rental of equipment, the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.



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## Fair Market Value

3. Rental of office space. With respect to the rental of office space, the value in an arm's-length transaction, with like parties and under like circumstances, 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.



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## General FMV

CMS is proposing to modify the phrase General Market Value to mean:

1. General. The price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.
2. Rental of equipment or office space. The price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement.



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## Group Practice Modifications

- Physicians may be paid a share of profits that are indirectly related to the volume or value of the physician's referrals.
- Physicians in a group practice may be paid a productivity bonus based on services personally performed or performed "incident to" the physician's services that is indirectly related to the volume or value of referrals:
  - Must be calculated in a reasonable and verifiable manner, based off of one of the following:
    - The total patient encounters or wRVUs personally performed;
    - Services that are not DHS and would not be considered DHS if payable by Medicare;
    - Revenues derived from DHS are less than 5% of the total revenue of the group and would constitute less than 5% of the total compensation paid to the physician from the group.



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## Other AKS Safe Harbor and Stark Exception Revisions



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## New Exception for Limited Remuneration to a Physician

- **New Exception for Limited Remuneration to a Physician.** CMS proposes a new exception to protect compensation not exceeding an aggregate of \$3,500 per calendar year if certain conditions are met.
- Avoid liability for non-abusive conduct
- Save CMS resources in resolving self-disclosures related to arrangements that do not pose risks to federal health care programs.



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## Temporary Non-compliance

- **Temporary Non-Compliance.** The special rule on parties being permitted to execute writings within 90 days
- CMS proposes to expand the 90-day grace period for certain writing requirements.
- What if the compensation arrangement is not in writing but constitutes an enforceable contract under applicable state law?



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## Period of Disallowance

- **Period of Disallowance.** CMS proposes to delete the goal posts for when an entity would know the period of disallowance has ended.



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## Proposed Modifications to the Transportation Safe Harbor

- **Local Transportation.** OIG proposes to expand and modify mileage limits applicable to rural areas and for transportation related to patients discharged from inpatient facilities.
- Would expand the limit for rural transportation services from 50 miles to 75 miles.
- Seeking comment on whether to eliminate distance requirements for patients discharged from an inpatient admission, regardless of whether it was urban or rural.
- Seeking comment on whether to permit transportation to another facility or for certain non-medical services that would affect health outcomes (such as nutrition or housing).



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## Electronic Health Records Items and Services



- Rules currently allow for donation of EHR Items and Services (15% cost share) upon meeting all conditions
- **Proposal on Deemed Interoperability Requirement** If Software is certified by a certifying body VS. Software is certified on the date it is provided
- Modifications to align with the Information Blocking Provision and related exceptions under the 21<sup>st</sup> Century Cures Act.
  - A health care provider **or Health plan** engages in a practice of information blocking if such a provider “knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information



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## Electronic Health Records Items and Services (cont.)



- Cybersecurity – clarify this is included (but duplicative of the proposed Cybersecurity exception/safe harbor)
- Sunset provision – Currently set to expire 12/31/21; Proposal to eliminate the sunset provision
- Cost – sharing: No proposal at this time, but seeking comment on whether to eliminate or modify
- Replacement Technology
- Expanded Donors



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## New Opportunities for Cybersecurity Technology (42 CFR 1001.952(jj))

### New Stark Law Exception and AKS Safe Harbor for Cybersecurity Technology and Related Services.

- Nonmonetary (no payment of a ransom amount)
- Cybersecurity: the process of protecting information by preventing, detecting, and responding to cyberattacks.
- Technology: “any software or other types of information technology, other than hardware
- Proposal for No Contribution
- Proposal for no restrictions on categories of donors or donees



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## Cybersecurity Technology (cont.)

Conditions:

- The technology is necessary and used to implement and maintain effective cybersecurity; ??
- The donor does not take into account or condition the donation on the volume or value of referrals or other business generated;
- The recipient does not condition referrals on receiving the technology;
- The arrangement is set out in writing, signed by the parties, and describes the technology being donated.



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## Cybersecurity - Examples

- **malware prevention software,**
- **software security measures to protect endpoints that allow for network access control,**
- **business continuity software that mitigates the effect of cyberattacks,**
- **data protection and encryption,**
- **email traffic filtering.**



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## Cybersecurity - Examples

- Services associated with developing, installing, and updating cybersecurity software;
- Cybersecurity training services;
- Cybersecurity services for business continuity and data recovery services to ensure the recipient's operations can continue during and after a cyberattack;
- performing a cybersecurity risk assessment or analysis, vulnerability analysis, or penetration test; or
- any services associated with sharing information about known cyber threats, and assisting recipients responding to threats or attacks on their systems.



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## Telehealth for In-Home Dialysis

**Telehealth for In-Home Dialysis.** OIG proposes to interpret and incorporate the Bipartisan Budget Act of 2018 statutory exception for furnishing telehealth technologies to certain in-home dialysis patients.

- To exclude from the definition of remuneration, telehealth technologies to a patient with end stage renal disease if:
  - The provider or facility is currently providing in-home dialysis, telehealth visits, or other end stage renal care;
  - The technology is not offered as part of an advertisement or solicitation;
  - The technologies contribute substantially to the provision of care; and
  - The provider or facility does not bill a Federal health care program, other payor, or other individuals for the technology



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## Future Regulatory Direction

- OIG states in proposed rule preamble that and final safe harbor would apply only apply prospectively and give not retrospective protection.



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