Physician Self-referral Law and Anti-kickback Statute Proposed Regulations: What You Need to Know

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Physician Self-referral Law and Anti-kickback Statute Proposed Regulations: What You Need to Know

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Today's Presentation

1. Policy Considerations: How did we get here?
2. Transition to Value-based Care Delivery and Payment
   - Proposed definitions
   - Proposed exceptions and safe harbors for value-based arrangements
   - Other related OIG and CMS proposals
3. Practitioner Commentary and Questions/Answers
4. Key Terminology Related to the Physician Self-referral Law
5. Proposals Involving Arrangements with Patients
6. Proposals Related to Cybersecurity and Electronic Health Records Arrangements
7. Other CMS and OIG Proposals of Note
8. Practitioner Commentary and Questions/Answers

Listeners are directed to CMS' and OIG's proposed rules for a complete description of the proposals.

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Policy Considerations

CMS' Burden Reduction and the Regulatory Sprint to Coordinated Care

CMS Burden Reduction Efforts

- Multiple requests for information in previous payment rules
- Recognized need to modernize and clarify the physician self-referral regulations

HHS' Regulatory Sprint to Coordinated Care

- Departmental Priority
  - Launched in 2018, with Requests for Information (RFI)
  - OIG received 359 public comments
  - CMS received approximately 375 public comments
- Encourage and improve:
  - Patients' ability to understand treatment plans and make empowered decisions
  - Providers' alignment on end-to-end treatment (*i.e.*, coordination among providers along the patient's full care journey)
  - Incentives for providers to coordinate, collaborate, and provide patients tools to be more involved in their own care
  - Information sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data
- Reduce regulatory barriers and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination

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Components of the Regulatory Sprint to Coordinated Care

- **OIG**: Federal anti-kickback statute and beneficiary inducements CMP
  - 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 (84 FR 55694)
  - Comments due December 31, 2019
- **CMS**: Physician self-referral law
  - Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (84 FR 55766)
  - Comments due December 31, 2019
- **SAMHSA**: 42 CFR Part 2 (substance use disorder information)
- **OCR**: Health Insurance Portability and Accountability Act of 1996

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OIG's Approach—Balancing Innovation with Protection Against Fraud and Abuse

- Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the healthcare industry.
- OIG's goal is to finalize safe harbors that protect arrangements that foster beneficial care coordination and promote value, while also protecting programs and beneficiaries against harms cause by fraud and abuse.
- For some arrangements, OIG believes it is appropriate for the anti-kickback statute, which is a criminal, intent-based statute, to serve as "backstop" protection for arrangements that might be protected by a less restrictive exception to the civil, strict liability physician self-referral law.

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Concerns Raised

- The physician self-referral law, anti-kickback statute, and beneficiary inducements CMP are perceived by some as barriers to innovative care coordination arrangements, which often are between or among those in a position to refer Medicare, Medicaid, and other Federal health care program beneficiaries and those seeking such business
- Care coordination often involves moving patients between providers who may have financial arrangements between them that relate to those patients (*e.g.*, an ACO shared savings arrangement)
- Questions have been raised about a variety of potential remuneration, such as—
  - Providing technology infrastructure
  - Sharing care coordinators
  - Data systems
  - Patient engagement arrangements
  - Outcomes-based payments
- Without clear exceptions and safe harbor protection, some stakeholders assert they are reluctant to innovate (and invest significant resources in new ways of delivering care) and point to heightened litigation risk
- Creating a level playing field for providers of different sizes and those serving underserved populations
- Expanding the private sector's ability to enter into arrangements like those in CMMI models, without having to be in a CMMI model

Transition to Value-Based Care Delivery and Payment

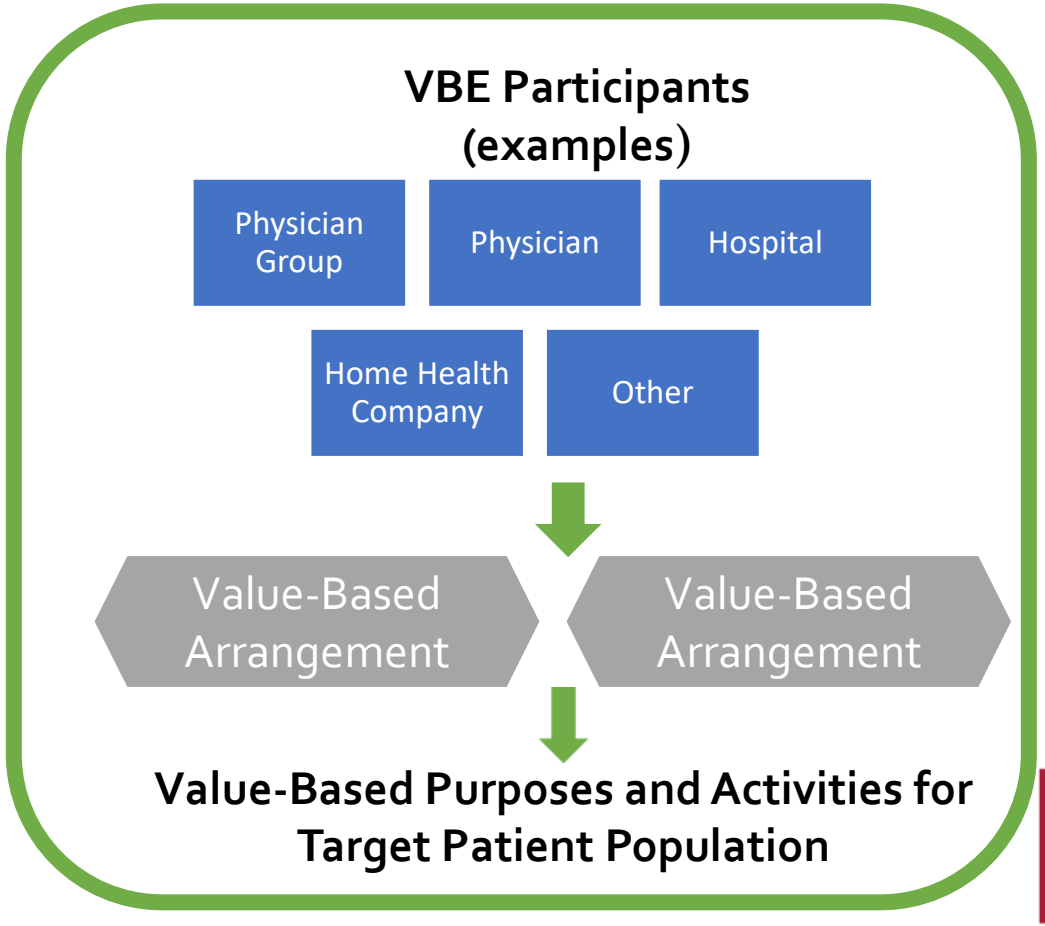
Proposed Definitions

Value-based Framework

Definitions

- Value-based enterprise (VBE)
- VBE participant
- Value-based purpose
- Value-based activities
- Value-based arrangement
- Target patient population

Illustrative Value-based Enterprise



Value-based Enterprise (VBE)

- 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 the 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)

- OIG and CMS proposed regulation text is aligned

VBE Participants

CMS Proposed Regulation Text

- Individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

OIG Proposed Regulation Text

- Individual or entity that engages in at least one value-based activity as part of a value-based enterprise.
- VBE participant does not include a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies; or a laboratory.

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VBE Participants

- Additional proposals included in preamble
- Other alternative is to exclude value-based arrangements involving one or more of these entities from protection of the proposed exceptions or safe harbors
- CMS preamble proposals align with OIG proposed regulation text, but represent only one alternative to addressing stated program integrity concerns regarding pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories.
- OIG's preamble also proposed to exclude pharmacies (including compounding pharmacies), pharmacy benefits managers, wholesalers, and distributors, and the subset of health technology companies that are device manufacturers

Value-based Purpose

- 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 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

- OIG and CMS proposed regulation text is aligned

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Coordination and Management of Care

CMS

- No proposed definition for this term

OIG

- The deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population.
- Several of OIG's proposed safe harbors require that the remuneration has a direct connection to the coordination and management of care for the target patient population.

Value-based Activities

- 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
  - The refraining from taking an action
- The making of a referral is not a value-based activity.

- OIG and CMS proposed regulation text is aligned (aside from formatting)

Value-based Arrangement

- An arrangement for the provision of at least one value-based activity for a target patient population between or among—
  - The value-based enterprise and one or more of its VBE participants; or
  - VBE participants in the same value-based enterprise

- OIG and CMS proposed regulation text is aligned

Target Patient Population

- An identified patient population selected by the value-based enterprise 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)

- OIG and CMS proposed regulation text is aligned

Defined Terms—Foundation to Protection

- CMS and OIG propose definitions for key terms that are used consistently in several proposed exceptions and safe harbors.
- The proposed defined terms are intended to work in conjunction with one another to describe the universe of value-based arrangements potentially eligible for proposed safe harbor protection and of individuals and entities that can engage in protected arrangements, provided all requirements of an applicable exception are satisfied or conditions of a specific safe harbor are squarely met.

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Proposed Exceptions and Safe Harbors for Value-based Arrangements

Proposed Exceptions and Safe Harbors for Value-based Arrangements

CMS

- NEW
  - Full financial risk
  - Meaningful downside financial risk to the physician
  - Value-based arrangements
  - Indirect value-based arrangements
- REVISED
  - Group practice rules (distribution of profits directly attributable to a physician's participation in a value-based enterprise)

OIG

- NEW
  - Full financial risk
  - Substantial downside financial risk (to the value-based enterprise)
  - Care coordination arrangements to improve quality, health outcomes, and efficiency
  - Patient engagement and support (discussed later in presentation)
- REVISED
  - Personal services and management contracts and outcomes-based payment arrangements

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Full Financial Risk (to the Value-based Enterprise)

CMS: Proposed § 411.357(aa)(1)

OIG: Proposed § 1001.952(gg)

Full Financial Risk

CMS

- “Full financial risk” means that value-based enterprise is financially responsible 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.
- “Prospective basis” means that the value-based enterprise 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 in the target patient population.

OIG

- “Full financial risk” means that the value-based enterprise is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor.

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CMS Proposed § 411.357(aa)(1)

- The value-based enterprise is at full financial risk during the entire duration of the value-based arrangement.
  - "Pre-participation" timeframe up to 6 months permissible: Value-based enterprise is contractually obligated to be at full financial risk within the 6 months following the commencement of the value-based arrangement and for the entire duration of the value-based arrangement.
- The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
- If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

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OIG Proposed § 1001.952(gg)

A proposed safe harbor for the exchange of payments or anything of value between an VBE and a VBE participant pursuant to a value-based arrangement if all the proposed standards are met. Some proposed standards include:

- The VBE (directly or through a VBE participant acting on behalf of 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 target patient population and contains terms evidencing that the VBE is at full financial risk for that population for a period of at least 1 year.
- The remuneration exchanged between the VBE and a VBE participant is used primarily to engage in the value-based activities and 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 target patient population).
- The renumeration does not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient.
- Neither the VBE nor VBE participant takes into account the volume or value of, or condition the remuneration on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
- The VBE provides or arranges for an operational utilization review program and a quality assurance program that protects against underutilization and specifies patient goals, including measurable outcomes, where appropriate.
- The value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities.

Meaningful Downside Financial Risk to the Physician

CMS: Proposed § 411.357(aa)(2)

Meaningful Downside Financial Risk to the Physician

- The physician—
  - Is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or
  - 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 covered by the applicable payor for each patient in the target patient population for a specified period of time.
    - Comments requested on the minimum appropriate for a “defined set of patient care items and services.”

CMS Proposed § 411.357(aa)(2)

- The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.
- A description of the nature and extent of the physician's downside financial risk is set forth in writing.
- The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.
- The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
- If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

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Value-based Arrangements with Substantial Downside Financial Risk

OIG: Proposed § 1001.952(ff)

Proposed Definition—Substantial Downside Financial Risk

Substantial downside financial risk means risk, for the entire term of the value-based arrangement, in the form of:

(A) Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;

(B) A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;

(C) A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, 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

(D) A 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 percent of the total expected fee-for-service payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangement.

OIG Proposed § 1001.952(ff)

A proposed safe harbor for the exchange of payments or anything of value between a VBE and a VBE participant pursuant to a value-based arrangement if all the proposed standards are met. Some proposed standards include:

- The VBE (directly or through a VBE participant acting on the VBE's behalf) has assumed (or is contractually obligated to assume in the next 6 months) substantial downside financial risk from a payor for providing or arranging for the provision of items and services for a target patient population.
- Under the value-based arrangement, the VBE participant meaningfully shares in the VBE's substantial downside financial risk for providing or arranging for the provision of items and services for the target patient population. A VBE participant meaningfully shares in the VBE's substantial downside financial risk if the value-based arrangement provides that the VBE participant is subject to risk under one of the three specified methodologies.
- The remuneration provided by, or shared among, the VBE and VBE participant is used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk and 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 target patient population.

OIG Proposed § 1001.952(ff) (continued)

- The remuneration does not induce VBE participants to reduce or limit medically necessary items or services furnished to any patient.
- The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
- The value-based arrangement does not place any limitation on VBE participants' ability to make decisions in the best interest of their patients or direct or restrict referrals to a particular provider, practitioner, or supplier if certain specified circumstances exist.
- The value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities.
- There is a signed writing that includes specified information.

Value-based Arrangements/Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency

CMS: Proposed § 411.357(aa)(3)

OIG: Proposed § 1001.952(ee)

CMS Proposed § 411.357(aa)(3)

- The arrangement is set forth in writing and signed by the parties. The writing includes a description of—
  - The value-based activities to be undertaken under the arrangement.
  - How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise.
  - The target patient population for the arrangement.
  - The type or nature of the remuneration.
  - The methodology used to determine the remuneration.
  - The performance or quality standards against which the recipient will be measured, if any.
- The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.
- The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

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CMS Proposed § 411.357(aa)(3)

- The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
- If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of § 411.354(d)(4)(iv).
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

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OIG Proposed § 1001.952(ee)

A proposed safe harbor for the exchange of anything of value pursuant to a value-based arrangement if all of the standards are met. Some proposed standards include:

- The value-based arrangement is directly connected to the coordination and management of care of the target patient population.
- The VBE participants establish one or more specific evidence-based, valid outcome measures against which the recipient will be measured and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population.
- The remuneration exchanged:
  - (i) Is in-kind;
  - (ii) Is used primarily to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population;
  - (iii) Does not induce VBE participants to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient; and
  - (iv) Is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the applicable VBE.

OIG Proposed § 1001.952(ee) (continued)

- The value-based arrangement is commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE.
- There is a signed writing in advance that includes specified information.
- The offeror of the remuneration does not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the target patient population business not covered under the value-based arrangement.
- The recipient pays at least 15 percent of the offeror's cost for the in-kind remuneration. If a one-time cost, the recipient makes such contribution in advance of receiving the in-kind remuneration. If an ongoing cost, the recipient makes such contribution at reasonable, regular intervals.
- The value-based arrangement does not place any limitation on VBE participants' ability to make decisions in the best interest of their patients or does not direct or restrict referrals to a particular provider, practitioner, or supplier if specified circumstances exist.

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OIG Proposed § 1001.952(ee) (continued)

- The value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities
- The VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person monitors and assesses, and reports such monitoring and assessment to the VBE's accountable body or responsible person as applicable, no less frequently than annually or at least once during the term of the value-based arrangement for arrangements with terms of less than 1 year:
  - (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 terminate the arrangement within 60 days if the VBE's accountable body or responsible person determines that the value-based arrangement is unlikely to further the coordination and management of care for the target patient population, has resulted in material deficiencies in quality of care; or is unlikely to achieve the evidence-based, valid outcome measure(s).

CMS-sponsored Model Arrangements and CMS-sponsored Model Patient Incentives

OIG: Proposed § 1001.952(ii)

OIG Proposed § 1001.952(ii)

A proposed new safe harbor for certain remuneration provided in connection with a CMS-sponsored model (as defined in the proposed rule), which should reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models. Under the proposal, CMS would determine that the safe harbor is available and the CMS-sponsored model parties or participant must satisfy programmatic requirements as may be imposed by CMS in connection with the use of the safe harbor.

For remuneration between or among CMS-sponsored model parties under a CMS-sponsored model arrangement, the proposed conditions include:

- The CMS-sponsored model parties reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model;
- The exchange of value does not induce CMS-sponsored model parties or other providers or suppliers to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient; and
- The CMS-sponsored model parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the CMS-sponsored model.

For CMS-sponsored model patient incentives (as defined in the proposed rule), the proposed conditions include:

- The CMS-sponsored model participant reasonably determines that the CMS-sponsored model patient incentive will advance one or more goals of the CMS-sponsored model; and
- The CMS-sponsored model patient incentive has a direct connection to the patient's healthcare.

Personal Services and Management Contracts and Outcomes-based Payment Arrangements

OIG: Proposed amendments to § 1001.952(d)

Proposed Revisions to § 1001.952(d)(1)

- Proposed modifications to the existing safe harbor for personal services and management contracts (§ 1001.952(d)) to add flexibility with respect to outcomes-based payments and part-time arrangements.

(d) *Personal services and management contracts and outcomes-based payment arrangements*.

(1) As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following ~~seven~~ standards are met:

(i) The agency agreement is set out in writing and signed by the parties.

(ii) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

~~(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.~~

(iii) The term of the agreement is ~~for~~ not less than ~~one~~ 1 year.

~~(5) The aggregate~~ (iv) The methodology for determining the compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

(v) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vi) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Proposed Revisions to § 1001.952(d)(2)

- The proposed modifications to § 1001.952(d)(2) would protect any outcomes-based payment that satisfies the conditions of the safe harbor. The proposed conditions include:
- The outcomes-based payment is made between or among parties that are collaborating to:
  - Measurably improve (or maintain improvement in) quality of patient care; or
  - Appropriately and materially reduce costs to, or growth in expenditures of, payors while improving, or maintaining the improved, quality of care for patients.
- To receive an outcomes-based payment, the agent satisfies one or more specific evidence-based, valid outcome measures that are
  - Related to:
    - (1) measurably improving, or maintaining the improved, quality of patient care;
    - (2) appropriately and materially reducing costs to, or growth in expenditures of, payors while improving, or maintaining the improved quality of care for patients; or
    - (3) both; AND
  - Selected based upon clinical evidence or credible medical support.

Proposed Revisions to § 1001.952(d)(2) (continued)

- The methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement is: set in advance; commercially reasonable; consistent with fair market value; and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a Federal health care program.
- The agreement neither limits any party's ability to make decisions in their patients' best interest nor induces any party to reduce or limit medically necessary items or services.
- For each outcome measure under the agreement, the parties:
  - Regularly monitor and assess the agent's performance, including the impact of the outcomes-based payment arrangement on patient quality of care; and
  - Periodically rebase during the term of the agreement, to the extent applicable.
- The principal has policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.

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Indirect Value-based Arrangements

CMS: Proposed § 411.354(d)(4)(ii) and preamble proposals

Indirect Value-based Arrangements

- Defining an “indirect value-based arrangement”
- Considerations—
  - Apply existing exception for indirect compensation arrangements at § 411.357(p)
  - Apply proposed exceptions for value-based arrangements
  - Establish a separate exception for arrangements that qualify as “indirect value-based arrangements”

Transition to Value-based Care Delivery and Payment

Practitioner Commentary and Q&A

Key Terminology Related to the Physician Self-referral Law

CMS: Proposed §§ 411.351 and 411.354(d)(5) and (6)

Key Terminology ("The Big 3")

- Compensation arrangements that are commercially reasonable
- Compensation that is fair market value
- The "volume or value standard"
  - Compensation that is not determined in any manner that takes into account the volume or value of referrals
  - Compensation that is not determined in any manner that takes into account the volume or value of other business generated by the physician for the entity

Commercially Reasonable

- Two alternative proposed definitions
  - The particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. (84 FR 55790 and proposed regulation text)
  - The arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty. (84 FR 55790)

- An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.
  - Proposed under both alternatives (85 FR 55791 and proposed regulation text)

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Fair Market Value

- Section 1877(h)(3) of the Act defines “fair market value” to mean the value in arm’s-length transactions, consistent with the general market value, and with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted 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.

Fair Market Value

- *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
- 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

Fair Market Value

General	Rental of Equipment	Rental of Office Space
The value in an arm's-length transaction—	The value in an arm's-length transaction—	The value in an arm's-length transaction—
• With like parties and under like circumstances	• With like parties and under like circumstances	• With like parties and under like circumstances
• Of like assets or services	• Of rental property for general commercial purposes (not taking into account its intended use)	• 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
• Consistent with the general market value of the subject transaction	• Consistent with the general market value of the subject transaction	• Consistent with the general market value of the subject transaction

General Market Value

General	Rental of Equipment or Office Space
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.	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.

The Volume or Value Standard

- Special rules proposed at § 411.354(d)(5) and (6)
  - Definition unworkable due to varying ways to reference the volume or value standards in the statutory and regulatory provisions
- Separate standards for compensation *to* a physician or immediate family member of a physician (§ 411.354(d)(5)) and *from* a physician or immediate family member of a physician (§ 411.354(d)(6))
- Proposals describe the universe of compensation methodologies that are considered to take into account the volume or value of referrals or other business generated

  Proposals are not deeming provisions that permit specific compensation methodologies
- Clarifies interpretation of varying "other business generated" language to mean the other business generated *by* the physician *for* the entity
- These special rules apply only for purposes of the physician self-referral law.

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Compensation to the Physician (or the Immediate Family Member of the Physician)

- Compensation from an entity furnishing designated health services to a physician takes into account the volume or value of referrals only if—
  - The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or
  - There is a predetermined, direct correlation between the physician's *prior* referrals to the entity and the *prospective* rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.
    - If prior referrals were X, then compensation for the duration of the current arrangement is Y.
- A positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

Compensation to the Physician (or the Immediate Family Member of the Physician)

- Compensation from an entity furnishing designated health services to a physician takes into account the volume or value of other business generated only if—
  - The formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity; or
  - There is a predetermined, direct correlation between the other business *previously* generated by the physician for the entity and the *prospective* rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.
    - If other business previously generated was X, then compensation for the duration of the current arrangement is Y.
- A positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

Compensation from the Physician (or the Immediate Family Member of the Physician)

- Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if—
  - The formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity; or
  - There is a predetermined, direct correlation between the physician's *prior* referrals to the entity and the *prospective* rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.
    - If prior referrals were X, then compensation for the duration of the current arrangement is Y.
- A negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

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Compensation from the Physician (or the Immediate Family Member of the Physician)

- Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if—
  - The formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity; or
  - There is a predetermined, direct correlation between the other business *previously* generated by physician for the entity and the *prospective* rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.
    - If other business previously generated was X, then compensation for the duration of the current arrangement is Y.
- A negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

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Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency

OIG: Proposed § 1001.952(hh)

OIG Proposed § 1001.952(hh)

A proposed new safe harbor for certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency. Some proposed conditions include:

- The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis does not exceed $500 unless such patient engagement tools and supports are furnished to patients based on a good faith, individualized determination of the patient's financial need.
- The patient engagement tool or support is furnished directly to the patient by a VBE participant.
- No individual or entity outside of the applicable VBE funds or otherwise contributes to the provision of the patient engagement tool or support.

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OIG Proposed § 1001.952(hh) (continued)

- The patient engagement tool or support:
  - Is an in-kind preventive item, good, or service, or an in-kind item, good, or service;
  - That has a direct connection to the coordination and management of care of the target patient population;
  - Does not include any gift card, cash, or cash equivalent;
  - Does not include any in-kind item, good, or service used for patient recruitment or marketing of items or services to patients;
  - Does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program;
  - Is recommended by the patient's licensed healthcare provider; and
  - Advances a clinical, health outcome, or safety goal.

Other Proposed Protections for Patient Arrangements

- **Local Transportation**. Proposed modifications to the existing safe harbor for local transportation (§ 1001.952(bb)) to expand and modify mileage limits for rural areas and for transportation for patients discharged from inpatient facilities.
- **Accountable Care Organization (ACO) Beneficiary Incentive Programs**. Codification of the statutory exception to the definition of "remuneration" related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (§ 1001.952(kk)).
- **Telehealth Technologies for In-Home Dialysis**. A proposed amendment to the definition of "remuneration" in the CMP rules at 42 C.F.R. § 1003.110 interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patients.

Proposals Related to Cybersecurity Technology and Services and Electronic Health Records (EHR) Items and Services

CMS: Proposed § 411.357(bb) and proposed modifications to § 411.357(w)

OIG: Proposed § 1001.952(jj) and proposed modifications to § 1001.952(y)

Proposed Exception and Safe Harbor for Cybersecurity Technology and Services

CMS

- Nonmonetary remuneration (consisting of certain types of technology and services), if—
  - The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity;
  - Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties;
  - Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor; and
  - The arrangement is documented in writing.

OIG

- Nonmonetary remuneration (consisting of certain types of technology and services), if—
  - The technology and services are necessary and used predominantly to implement and maintain effective cybersecurity;
  - The donor does not—
    - Directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated; or
    - Condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals;
  - Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor;
  - The arrangement is set forth in a writing that: (i) is signed by the parties; and (ii) describes the technology and services being provided and the amount of the recipient's contribution, if any; and
  - The donor does not shift the costs of the technology or services to any Federal health care program.

CMS and OIG: "Technology" means any software or other types of information technology other than hardware.

Proposed Revisions to Exception and Safe Harbor for EHR Items and Services

- Propose to expressly permit donation of cybersecurity software and services necessary and used predominately to protect electronic health records.
- Proposed to make exception/safe harbor permanent by removing December 31, 2021 sunset provision.
- Propose to align EHR exception/safe harbor with the 21st Century Cures Act
  - Revise "deeming provision" for interoperability: software is deemed to be interoperable if, on the date it is provided to the recipient, it "is certified by a certifying body authorized by the National Coordinator for Health Information Technology…."
  - Revise "data lock-in" provision to prohibit the donor (or anyone acting on the donor's behalf) from engaging in a practice constituting information blocking, as defined in the Public Health Services Act.
  - Revise definitions of "electronic health record" and "interoperable."
- Other considerations and proposals
  - Eliminate the 15 percent contribution requirement for some or all recipients.
  - Permit donation of certain replacement EHR technology.

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Limited Remuneration to a Physician

CMS: Proposed § 411.357(z)

Proposed Exception for Limited Remuneration to a Physician (§ 411.357(z))

- Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of $3,500 per calendar year, as adjusted for inflation, if—
  - The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician;
  - The compensation does not exceed the fair market value of the items or services;
  - The arrangement is commercially reasonable; and
  - Arrangements for the rental or use of office space or equipment do not violate the prohibitions on per-click and percentage-based compensation formulas.
- $3,500 limit is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30.

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Proposed Modifications to Warranties Safe Harbor

OIG: Proposed modifications to § 1001.952(g)

Proposed Revisions to § 1001.952(g)

- OIG proposes to modify the warranties safe harbor to:
  - Protect warranties for one or more items and related services upon certain conditions;
  - Exclude beneficiaries from the reporting requirements applicable to buyers; and
  - Define “warranty” directly and not by reference to 15 U.S.C. § 2301(6).

Select CMS Proposals to Revise Existing Definitions, Exceptions, and Special Rules

CMS: Existing § 411.351, § 411.354(e), and § 411.357(l)

Proposed Revision to the Definition of "Designated Health Service"

- Current definition: Designated health services include, among other things, inpatient and outpatient services.
- Proposed revision: For services furnished to inpatients by a hospital, a service is not a designated health service 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 the Acute Care Hospital Inpatient Prospective Payment System (IPPS).
- Example: After an inpatient has been admitted to a hospital under an established diagnosis-related group (DRG), the patient's attending physician requests a consultation with a specialist who was not responsible for the patient's admission, and the specialist orders an X-ray. By the time the specialist orders the X-ray, the rate of Medicare reimbursement under the IPPS has already been established by the DRG (diagnostic imaging is bundled into the payment for the inpatient admission), and, unless the X-ray results in an outlier payment, the hospital will not receive any additional payment for the service over and above the payment rate established by the DRG. Moreover, insofar as the provision of the X-ray does not affect the rate of payment, the physician has no financial incentive to over-prescribe the service. As illustrated here, we do not believe that the X-ray is a designated health service that is payable, in whole or part, by Medicare (84 FR 55805).

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Proposed Special Rule on Writing and Signature Requirements (§ 411.354(e)(3))

- In the case of any requirement for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—
  - The compensation arrangement between the entity and the referring physician fully complies with an applicable exception except with respect to the writing or signature requirement of the exception; and
  - The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception.
- Preamble statement of longstanding policy: An electronic signature that is legally valid under Federal or State law is sufficient to satisfy the signature requirement of various exceptions in CMS' physician self-referral regulations (84 FR 55815).

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Proposed Revisions to Exception for Fair Market Value Compensation (§ 411.357(l))

- Current regulation: Exception for fair market value compensation is not available for arrangements for the lease of office space.
- Proposal: Exception could be used for rental of office space, including short-term arrangements for the rental of office space of less than 1 year.
  - Parties would be permitted to enter into only one arrangement for the rental of the same office space during the course of a year.
  - Parties would be able to renew the arrangement on the same terms and conditions any number of times, provided that the terms of the arrangement and the compensation for the same office space do not change.
- Per-click and percentage-based compensation rules would apply to arrangements for the rental of office space and the use of office space (and continue to apply to arrangements for the rental of equipment).

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Any questions?

Practitioner Commentary and Q&A

Thank you

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