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Welcome to PMI's Webinar Presentation:



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How Revisions to the Anti-Kickback Statute Impact Your Practice



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**How the New and Modified Anti-Kickback Safe Harbors
Impact Your Practice**

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Anti-Kickback Statute Basics

- **Pub. L. No. 92-603, §242(b), 86 Stat. 1329, 1419 (1972), "Social Security Act of 1972."** Evolution of the scienter and intent requirements under the Anti-Kickback Statute:

"(b) Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any—

"(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment,

or

"(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services,

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$10,000 or imprisoned for not more than one year, or both.

- **Pub. L. No. 96-499, §917, 94 Stat. 2625 (1980), "Omnibus Reconciliation Act of 1980."** This legislation amended the Social Security Act to require proof of **knowing** and **willful** conduct.

CRIMINAL STANDARDS FOR CERTAIN MEDICARE- AND MEDICAID-RELATED
CRIMES

SEC 917. Paragraphs (1) and (2) of section 1877(b) of the Social Security Act and of section 19090b) of such Act are each amended by inserting "knowingly and willfully" after "Whoever".

42 u s e 1395nn,
1396h.

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Anti-Kickback Statute Basics

- Pub. L. 111-148. 124 Stat. 759 (March 23, 2010), "*Patient Protection and Affordable Care Act*" (Affordable Care Act or ACA). Under the ACA, violations of the criminal AKS can also be pursued as a violation of the civil False Claims Act. Although the AKS continued to require that a person "knowingly" and "willfully" commit the crime, parties were no longer required to have actual knowledge that they were violating the Federal Anti-Kickback Statute in order for a violation to be shown. Nor were they required to have specific intent to violate the statute.

(2) REVISING THE INTENT REQUIREMENT.—Section 1128B of the Social Security Act (42 U.S.C. 1320a-7b), as amended by paragraph (1), is amended by adding at the end the following new subsection:

"(h) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."

- This means that a person does not have to know about the AKS in order to violate it. It also means that a person can violate the AKS without the government having to prove specific intent to violate the statute.

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Anti-Kickback Statute Basics

- "One Purpose Test" U.S. v. Greber (1985).
- Penalties under the Anti-Kickback Statute:
 - Felony.
 - 10 years in prison.
 - \$100,000 criminal fine.
 - Exclusion from Federal health benefits programs.
 - May be pursued as violations of the civil False Claims Act.
- DOJ prosecutors have aggressively prosecuted cases against health care providers and suppliers under the Federal Anti-kickback Statute.
 - ❖ **EDNY.** In this case, a Biller and two other clinic staff members paid patients in order to induce them to come to their clinic for medical services paid for by Medicare and Medicaid. All three plead guilty to committing a health care fraud scheme that caused \$55 million to be wrongfully billed to these government programs.

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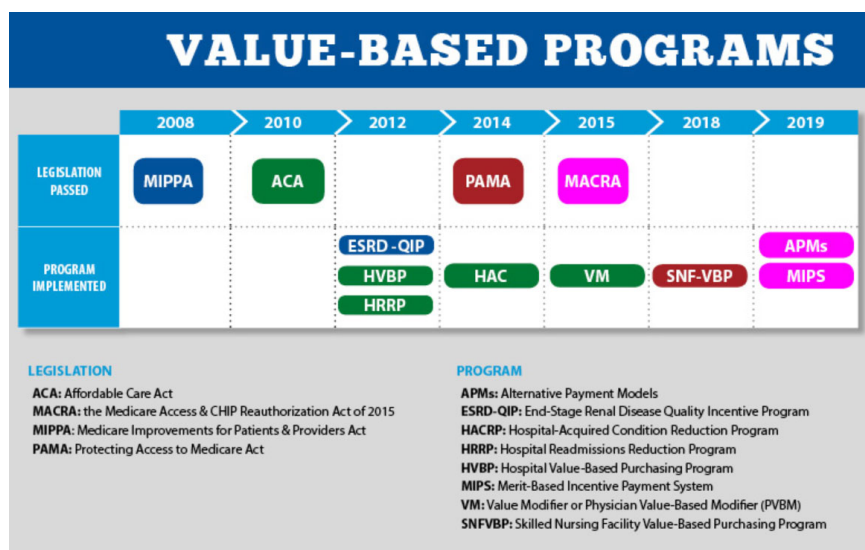
Anti-Kickback Statute Basics

- **Kickbacks / Disguised Kickbacks and Bribes**
 - ❖ Be especially careful before your practice or clinics enters into a **business arrangement** with a compounding pharmacy.
 - ❖ A continuing concern of the government involves **lease arrangements** with actual and / or potential referral sources.
 - ❖ Serving as a **medical director** to a hospice, home health agency, or nursing home to whom you make patient referrals.
 - ❖ Serving as a **consultant** to a pharmaceutical manufacturer, compounding pharmacy or durable medical equipment supplier whose products you prescribe.
 - ❖ While old school **"dine and dash"** approaches may be gone, bringing **lunch and other goodies** to a practice or office is still commonplace.
 - ❖ Participating in a **sham loan arrangement** with an entity to whom you make referrals or whose products you prescribe, order or recommend.
 - ❖ Acquiring or having a **financial interest** in an entity to whom you send referrals (especially if the referral is for DHS services).
 - ❖ Accepting **cash, gifts or other items of value** from a patient or other individual in exchange for a prescription for opioids or other controlled substances.
 - ❖ Accepting or soliciting any type of **remuneration (something of value)**, such as a **gift card, sporting event tickets** or **liquor**, from a pharmaceutical representative, compounding pharmacy or DME supplier whose products you order or prescribe (or could order or prescribe).

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The Long Road Towards Value-Based Care

- **Overview of CMS Value-Based Programs.** The shift to value-based care was triggered, in large part by the passage of the Affordable Care Act (ACA). The ACA introduced the Medicare Shared Savings Program and the CMS Innovation Center. Both of these programs really promoted the introduction of value-based care.



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Regulatory Sprint to Coordinated Care

- **2010.** The shift to value-based care was triggered, in large part by the passage of the Affordable Care Act (ACA). The ACA introduced the Medicare Shared Savings Program and the CMS Innovation Center. Both of these programs really promoted the introduction of value-based care.
- **2018.** The Department of Health and Human Services (HHS) launched what it calls a **"Regulatory Sprint to Coordinated Care" (Regulatory Sprint)**. The purpose of the Regulatory Sprint is to remove potential regulatory barriers to care coordination and value-based care created by four key Federal health care laws and associated regulations:

Anti-Kickback Statute

Physician Self-Referral Laws

Health Insurance Portability and Accountability Act Of 1996 (HIPAA)

Opioid and Substance Abuse Treatment Rules 42 CFR Part 2

- **Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations.** 84 Fed. Reg. 77492 (December 2, 2020).
- **Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements.** 85 Fed. Reg. 77684 (December 2, 2020).
- Despite the fact that CMS and the OIG worked closely together when crafting these latest rules, there are still significant, fundamental differences between how you have to analyze business arrangements with respect to Stark (a civil, strict-liability statute) and Anti-Kickback Statute (a criminal, intent-based statute) compliance.
- These differences can result in situations where a value-based business arrangement may meet the safe harbor / exception requirements of one statute but not the other.

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Overview of Recent Changes to the Anti-Kickback Statute New Safe Harbors and Statutory Exceptions

Value-Based Safe Harbors

- **42 CFR §1001.952(ee).** Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency.
- **42 CFR §1001.952(ff).** Value-Based Arrangements with Substantial Downside Financial Risk.
- **42 CFR §1001.952(gg).** Value-Based Arrangements with Full Financial Risk.

Additional New Safe Harbors

- **42 CFR §1001.952(hh).** Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency.
- **42 CFR §1001.952(ii).** CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives.
- **42 CFR §1001.952(jj).** Cybersecurity Technology and Related Services.
- **42 CFR §1001.952(kk).** ACO Beneficiary Incentive Program

New Statutory Exception to CMP Law

- **42 CFR §1003.110.** Telehealth for In-Home Dialysis.

With these Additions, There are Now 11 Statutory and 36 Regulatory Safe Harbors to the Federal Anti-Kickback Statute

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Overview of Recent Changes to the Anti-Kickback Statute Terminology Used in Value-Based Arrangements

The first three new safe harbors to the Anti-Kickback Statute are focused on **“Value-Based Arrangements.”** Before examining these three safe harbors, we need to look at some of the terminology adopted by the OIG in implementing these regulations.

- **“Value-Based Enterprise”** (1001.952(ee)(14)(viii)) is defined as two or more VBE participants:
 - Collaborating to achieve **at least one value-based purpose**;
 - Each of which is **a party to a value-based arrangement** with the other or at least one other VBE participant in the value-based enterprise;
 - That have **an accountable body or person** responsible for financial and operational oversight of the value-based enterprise; and
 - That have a **governing document** that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

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Overview of Recent Changes to the Anti-Kickback Statute Terminology Used in Value-Based Arrangements

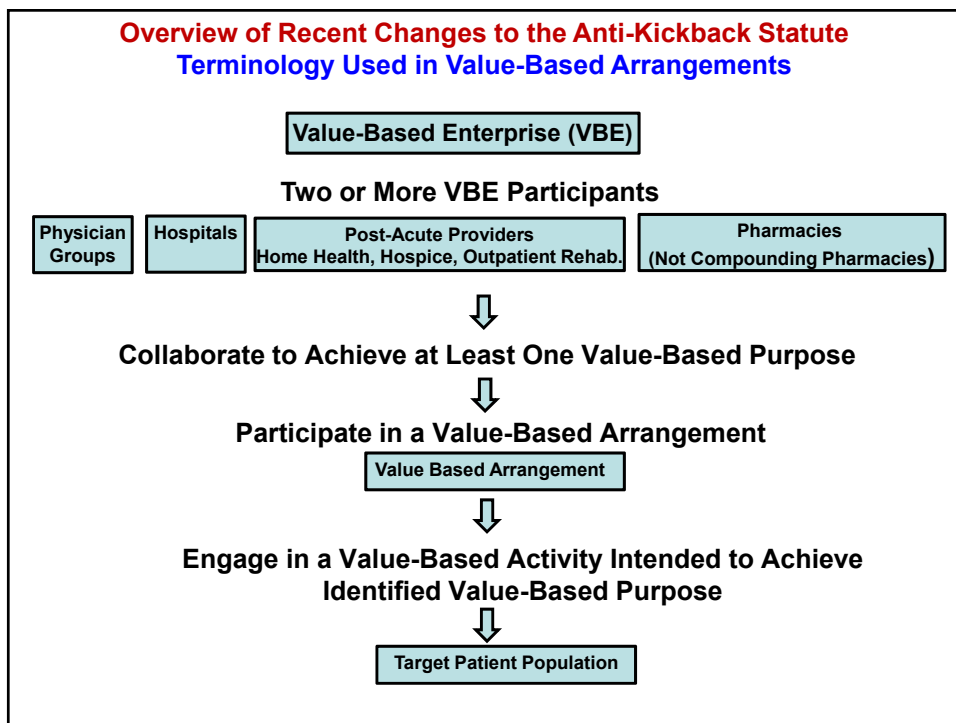
- **“Value Based Arrangement”** 1001.952(ee)(14)(vii) is an arrangement:
 - Between a **Value-Based Enterprise and its participants**; or
 - **Among VBE participants** in the same value-based enterprise;
 - For a **target patient population**.
- **“Value Based Participant”** 1001.952(ee)(14)(ix) means an individual or entity (except for a patient):
 - That engages in at least one value-based activity;
 - **Does not include**: Compounding Pharmacies, Pharmacy Benefit Managers, Pharmaceutical Manufacturers / Distributors / Wholesalers, Laboratory Companies, Physician-Owned Distributors (PODS);
 - There is a **limited pathway** for DMEPOS and Device Manufacturers to participate with respect to Digital Health Technologies.
- **“Value Based Purpose”** 1001.952(ee)(14)(x) means that with respect to a target patient population the Value Based Purpose is intended to:
 - **Coordinating and managing the care**;
 - **Improving the quality of care**;
 - **Appropriately reducing the costs** or growth in expenditures of payors; or
 - **Transitioning from health care delivery and payment mechanisms based on volume to mechanisms based on the quality of care** and control of costs of care.

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**Overview of Recent Changes to the Anti-Kickback Statute
Terminology Used in Value-Based Arrangements**

- **“Value Based Activity”** 1001.952(ee)(14)(vi) means any of the following activities, provided that the activity is reasonably designed to achieve at least one Value-Based Purpose of the Value-Based Enterprise:
 - The provision of an item or service;
 - The taking of an action; or
 - The refraining from taking an action; and
 - Does not include the making of a referral.
- **“Target Patient Population”** 1001.952(ee)(14)(vi) means
 - An identified patient population selected by the Value-Based Enterprise or its 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).

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Eligibility for the Value-Based Safe Harbors, the Patient Engagement and Support Safe Harbor, and the Personal Services and Management Contracts Safe Harbor for Outcomes-Based Payment					
Entity Type	Care Coordination Arrangements 42 C.F.R. § 1001.952(ee)	Substantial Downside Risk 42 C.F.R. § 1001.952(ff)	Full Financial Risk 42 C.F.R. § 1001.952(gg)	Patient Engagement and Support 42 C.F.R. § 1001.952(hh)	Outcomes-Based Payments 42 C.F.R. § 1001.952(d)(2)
Providers and Suppliers (e.g., hospitals, post-acute care providers, and physicians)	Eligible	Eligible	Eligible	Eligible	Eligible
Pharmacies Other Than Compounding Pharmacies	Eligible	Eligible	Eligible	Eligible	Eligible
Compounding Pharmacies (i.e., pharmacies that primarily compound drugs or primarily dispense compounded drugs)	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Manufacturer of a Device or Medical Supply (as defined in 42 C.F.R. § 1001.952(ee)(14)(iv))	Eligible, but only for in-kind remuneration that is digital health technology	Ineligible	Ineligible	Eligible, but only for tools and supports that are digital health technology	Ineligible
DMEPOS Suppliers (other than pharmacies or physicians, providers, or other entities that primarily furnish services)	Eligible, but only for in-kind remuneration that is digital health technology	Ineligible	Ineligible	Ineligible	Ineligible
Pharmacy-Benefit Managers	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Pharmaceutical Manufacturers, Distributors, Wholesalers	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Laboratory Companies	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Physician-Owned Distributors (PODs)	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Health Technology Companies Not Otherwise Covered by an Entity Type on This List	Eligible	Eligible	Eligible	Eligible	Eligible

*DISCLAIMER: This chart is current as of the date issued. It is an educational resource; it is not intended to create any rights, privileges, or benefits. Although every reasonable effort has been made to ensure the accuracy of this chart, the ultimate responsibility for complying with the Federal anti-kickback laws lies with the party or parties seeking compliance with such laws. We refer readers to the final rule published in the Federal Register for additional and official information.
<https://oig.hhs.gov/reports-and-publications/federal-register-notice/ineligible-entities-chart.pdf>

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Overview of Recent Changes to the Anti-Kickback Statute

Value-Based Arrangement #1

- **42 CFR § 1001.952(ee).** Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency.

Summary: This new safe harbor for care coordination arrangements protects in-kind remuneration between a VBE and a VBE participant, or between VBE participants, pursuant to a VBA, if the remuneration is used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. Additionally, it “does not result in more than incidental benefits to persons outside of the target patient population.”

Specifics:

- “Remuneration” does not include the exchange of anything of value between VBE and a VBE participant, or between VBE participants if certain requirements are met.
- The remuneration exchanged (1) Is in-kind; (2) Is used predominately to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population and does not result in more than incidental benefits to persons outside of the target population; (3) Is not exchanged or used more than incidentally for the recipient’s billing or financial management services; or (4) Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or VBE participant to patients or for patient recruitment activities.
- The value-based arrangement is commercially reasonable.
- Terms are set forth in writing, signed by the parties in advance or at the time of arrangement.
- Parties to the value-based arrangement establish legitimate outcome or process measures.
- The offeror of the remuneration does not take into account the volume or value of, or condition of the remuneration on (1) referrals of patients, or (2) business not covered by the arrangement.
- Recipient must pay 15% of the offeror’s cost or fmV for the remuneration.
- Maintain records for at least 6 years.

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Overview of Recent Changes to the Anti-Kickback Statute Value-Based Arrangement #2

- **42 CFR §1001.952(ff).** Value-Based Arrangements with Substantial Downside Financial Risk.

Summary: This new safe harbor protects monetary or in-kind remuneration between a VBE and a VBE participant if the VBE participant "meaningfully shares" in "substantial downside financial risk" (SDFR) the VBE assumes from a payer. The safe harbor includes methodologies to determine SDFR and meaningful share.

Specifics:

- Under this new safe harbor, the term "remuneration" does not include the exchange of payments or anything of value between a VBE and a VBE participant pursuant to a value-based arrangement if the standards in (ff)(1) through (8) are met.
- The remuneration cannot be exchanged by a specified list of parties listed in Section (ff)(1).
- The VBE has assumed through a written contract or value-based arrangement substantial downside risk from a payor for a period of at least 1 year.
- The VBE participant is at risk for a meaningful share of the VBE's substantial downside risk for providing or arranging for the provision of items or services for the target patient population. The remuneration provided or shared by the VBE and VBE participant is directly connected to one or more of the VBE's value-based purposes.
- The value-based arrangement is set forth in writing / signed by the parties in advance or at the time of the arrangement. It must specify the material terms. This includes the terms evidencing that the VBE is at substantial downside risk or will assume such risk in the next 6 months for the target population. It must also specify the manner in which the VBE participant is assuming risk.
- "Substantial downside financial risk" is expressly defined in the regulations.
- "Meaningful share" is also defined in the regulations.

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Overview of Recent Changes to the Anti-Kickback Statute Value-Based Arrangement #3

- **42 CFR §1001.952(gg).** Value-Based Arrangements with Full Financial Risk.

Summary: This new safe harbor only applies when a VBE (or a VBE participant on behalf of the VBE) agrees to accept FULL FINANCIAL RISK on a prospective basis for all payor-covered items and services for each patient in the target population for a period of at least a year. This safe harbor protects monetary or in-kind remuneration between a VBE and a VBE participant. This safe harbor is really for organizations that are going to accept capitation for target patient populations.

Specifics:

- Under this safe harbor, "remuneration" does not include the exchange of payments between the VBE and a VBE participant pursuant to a value-based arrangement if the requirements in (gg)(1) through (9) are met.
- The remuneration cannot be exchanged by a specified list of parties listed in Section (gg)(1).
- The VBE has assumed through a written contract or value-based arrangement FULL FINANCIAL RISK from a payor for a period of at least 1 year.
- The value-based arrangement is set forth in writing, is signed by the parties, and specifies all material terms, including the value-based activities and the term.
- The VBE participant does not claim payment in any form from the payor for items or services covered under the contract or value-based arrangement between the VBE and the payor.
- Remuneration provided or shared by the VBE and VBE participant is directly connected to one of the VBE's value-based purposes.
- The VBA does not induce the parties to reduce or limit medically necessary items or services.
- The offeror of the remuneration does not take into account the volume or value of, or condition remuneration on, referrals of patients who are not part of the target patient population or business not covered under the VBA.

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Overview of Recent Changes to the Anti-Kickback Statute Other New Safe Harbors

- **42 CFR § 1001.952(hh).** Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency.

Summary: This new safe harbor is meant to protect up to \$500 of annual, in-kind remuneration in the form of patient engagement tools and support.

Specifics:

- Under this new safe harbor, the term “remuneration” does not include a patient engagement tool or support furnished by a VBE participant to a patient in the target patient population of a value-based arrangement to which the VBE participant is a party if certain conditions are met.
- Engagement tool or support must be furnished directly to the patient or the patient’s caregiver through an “eligible agent” on the contributor’s behalf.
- Must be an in-kind item or service and not cash or cash equivalent.
- Not be funded or contributed by a VBE participant that is not a party to the applicable VBA.
- Have an aggregate retail value to a patient on an annual basis that does not exceed \$500, to be adjusted annually based on the Consumer Price Index.
- Not be used to support or market other FHCP-reimbursable items or services, or for patient recruitment purposes.
- Not have its availability determined in a manner that takes into account the type of insurance coverage of the patient.

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Overview of Recent Changes to the Anti-Kickback Statute Other New Safe Harbors

- **42 CFR § 1001.952(ii).** CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives

Summary: As CMS develops and defines Innovation Center models, it will set out the specific requirements that a party must meet to qualify for this safe harbor.

Specifics:

- Under this new safe harbor, the term “remuneration” does not include an exchange of anything of value between or among CMS-sponsored model parties under a CMS-sponsored model arrangement.
- As the OIG notes in the Final Rule “*The programmatic requirements that parties would have to satisfy to qualify for safe harbor protection would be set out in the CMS-sponsored model’s participation documentation or would be otherwise publicly available.*” 85 Fed. Reg. at 77812
- As the OIG further notes, “*CMS has broad authority to develop and define the Innovation Center models, what the models are testing, and the scope of participation in the models. It is important, therefore, that CMS affirmatively state that the safe harbor would be available for specific CMS-sponsored model arrangements and CMS-sponsored model patient incentives within a particular model or initiative.*” 85 Fed. Reg. at 77813.

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Overview of Recent Changes to the Anti-Kickback Statute Other New Safe Harbors

- **42 CFR § 1001.952(jj).** Cybersecurity Technology and Related Services

Summary: This new safe harbor is meant to cover certain donations of cybersecurity technology and services.

Specifics:

➤ Under this safe harbor, the term “remuneration” does not include nonmonetary remuneration (consisting of cybersecurity technology and services) that is necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity as long as 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 makes the receipt of technology or services a condition of doing business with the donor.

❑ A general description of the technology and services being provided and the amount of the recipient’s contribution, if any, are set forth in writing and signed by the parties.

❑ The donor does not shift the costs of the technology or services to any Federal health care program.

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Overview of Recent Changes to the Anti-Kickback Statute Other New Safe Harbors

- **42 CFR § 1001.952(kk).** ACO Beneficiary Incentive Program

Summary: Congress enacted the Patient Protection and Affordable Care Act (Pub. L. 111-148) on March 23, 2010. Section 3022 of the Affordable Care Act amended §1899 of the Social Security Act (the Act) and established the Shared Savings Program.

The 21st Century Cures Act amended the Act to require the Secretary of Health and Human Services to assign beneficiaries to Accountable Care Organizations (ACOs) participating in the Shared Savings Program based not only on their utilization of primary care services furnished by physicians, but also on their utilization of services furnished by Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs).

In addition, the Bipartisan Budget Act of 2018 (BBA of 2018) established additional tools and flexibilities for ACOs specifically in the areas of new beneficiary incentives, telehealth services, and choice of beneficiary assignment methodology.

Specifics:

➤ This new safe harbor is meant to codify the legislative changes discussed above. Under the new regulations, the term “remuneration” under the Anti-Kickback Statute does not include an incentive payment made by an ACO to an assigned beneficiary under a beneficiary incentive program established under §1899(m) of the Social Security Act (the Shared Savings Program), as amended by Congress from time to time, if the incentive payment is made in accordance with the requirements found in such subsection.

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Overview of Recent Changes to the Anti-Kickback Statute Modifications to Existing Safe Harbors

- **42 CFR § 1001.952(d).** Personal Services and Management Contracts and Outcomes Based Payment Regulations.
Summary: Prior to the issuance of the Final Rule, in order for personal services and management contracts to qualify for coverage under the safe harbor, *aggregate compensation* had to be set in advance. This made it difficult for indeterminate hourly compensation and per diem business arrangements to qualify for coverage. Under the modified Final Rule, only the *methodology* for determining compensation has to be set in advance. A number of other restrictions remain in place under the modified Final Rule.
Specifics:
 - “Remuneration” does not include payments made by a principal to an agent as compensation for the services of the agent as long as the following standards are met:
 - An agency agreement must be in writing and signed by the parties.
 - The agency agreement covers all of the services the agent provides to the principal for the term of the contract *and* specifies the services to be provided by the agent.
 - The term of the agreement is for not less than a year.
 - The methodology for determining the compensation paid to the agent is:
 - Set in advance, and
 - Consistent with fair market value in arm’s length transaction, and
 - Is not determined in a manner that takes into account the value or volume of any referrals or business otherwise generated between the parties for which payment is made by Medicare, Medicaid or another Federal health care program.
 - The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates State or Federal law.
 - The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish commercially reasonable business purpose of the services.

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Overview of Recent Changes to the Anti-Kickback Statute Modifications to Existing Safe Harbors

- **42 CFR § 1001.952(d).** Personal Services and Management Contracts and Outcomes Based Payment Regulations. *Continued:*
Summary: Under the Final Rule, the safe harbor has been expanded to include “outcomes-based payment arrangements” that meet certain criteria.
Specifics:
 - “Remuneration” does not include outcome-based payments if certain requirements are met:
 - To receive an outcomes-based payment, an achieves one or more legitimate outcome measures that:
 - Are selected based on clinical evidence or credible medical support; and
 - Have benchmarks that are used to quantify (1) Improvements in, or the maintenance of improvements in, the quality of patient care; (2) A material reduction in costs to or growth in expenditures of payors while maintaining or improving quality of care for patients; or (3) Both.
 - Is not determined in a manner that takes into account the value or volume of any referrals or business otherwise generated between the parties for which payment is made by Medicare, Medicaid or another Federal health care program.
 - The methodology for determining aggregate compensation must be set in advance, commercially reasonable, consistent with fair market value and not determined in a manner that takes into account value or volume of referrals of business.
 - Must describe arrangement, be in writing, signed in advance or at that time.
 - Term must be for not less than 1 year.
 - Can’t involve counseling or otherwise violate State or Federal law.
 - Outcome measures must be regularly monitored and assessed.

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Overview of Recent Changes to the Anti-Kickback Statute Modifications to Existing Safe Harbors

- **42 CFR § 1001.952(g). Warranties.**

Summary: The Final Rule revises the safe harbor to protect, for the first time, warranties covering services. However, it is important to note that the modified safe harbor does not protect warranties that warranty only services.

Specifics:

- The term “warranty” is now defined at **42 CFR § 1001.952(g)(7)**. You no longer have to cross-reference a different statute.
- The modified safe harbor is expanded to protect warranties covering a bundle of items or a bundle of items and services. This revision protects, for the first time, warranties covering services, although the safe harbor does not provide protection to warranties that warranty only services.
- The revised safe harbor is intended to offer greater flexibility to buyers and sellers to enter into innovative arrangements that warranty the value of an entire bundle of items or that include bundled items and services.

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Overview of Recent Changes to the Anti-Kickback Statute Modifications to Existing Safe Harbors

- **42 CFR § 1001.952(bb). Local Transportation**

Summary: The Final Rule modifies the existing safe harbor for local transportation of beneficiaries and expands the mileage limits for rural areas up to 75 miles.

Specifics:

- Under the modified version of this safe harbor, “remuneration” does not include free or discounted local transportation made by an eligible entity to a Federal health care program participant as long as:
 - The service are set forth in a policy that is applied uniformly and consistently.
 - Is not determined in a manner related to past or anticipated value or volume of Federal health care program business.
 - The free or discounted local transportation services do not include air, luxury or ambulance-level transportation
 - The eligible entity does not publicly market the free or discounted local transportation;
 - No marketing of health care items or services occurs during the course of the transportation by drivers;
 - Drivers and other arranging for the transportation are not paid on a per-beneficiary-transported basis;
 - An eligibly entity only makes free or discounted transportation available to individuals who are qualify as an “established patient” of the eligible entity;
 - The transportation is provided within an eligible entity’s local area (25-mile radius) or if the area qualifies as a rural area (75-mile radius).

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Overview of Recent Changes to the Anti-Kickback Statute Modifications to Existing Safe Harbors

- **42 CFR § 1001.952(y).** Electronic Health Records Items and Services

Summary: The modified version of this safe harbor eliminates the sunset provision and make the safe harbor permanent. It also clarified that cybersecurity software and services fit within the safe harbor as long as they are used predominantly to protect health records and also meet the other safe harbor requirements.

Specifics:

- “Remuneration” does not include certain non-monetary remuneration (consisting of items and services in the form of software or information technology and training services, including cybersecurity software and services), that are necessary and used predominantly to create, maintain, transmit, receive or protect electronic medical records.
- ❑ Neither the eligibility of a recipient for EHR items or services nor the amount of EHR items or services can be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties.
- ❑ The software is interoperable at the time it is provided to the recipient (and is certified by a certifying body authorized).
- ❑ The sunset provision has been removed. This safe harbor is now permanent
- ❑ The “no equivalent technology” requirement has been eliminated, allowing for protection of donations of replacement technology
- ❑ The recipient must pay 15% of the donor’s cost for the EHR items or services before receiving the EHR items or services.
- ❑ Expanded the list of “protected donors” allowing entities such as parent companies of hospitals, health systems and ACOs as permissible donors.

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Overview of Recent Changes to the Anti-Kickback Statute New Statutory Exception to CMP Law

- **42 CFR §1003.110.** Telehealth for In-Home Dialysis
(This is intended to align with the statutory exception at 1128A(i)(6)(J) of the Social Security Act)

Summary: As part of the Budget Act of 2018, Congress established a statutory exception to the Beneficiary Inducements CMP. In the Final Rule, OIG has codified this statutory exception and amended the definition of remuneration in the CMP law to protect the provision of telehealth technologies by a provider of services, physician, or renal dialysis facility to an individual with end-stage renal disease who is receiving in-home dialysis paid for by Medicare Part B. “Telehealth technologies” is defined broadly to mean “hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention, or ongoing care management.” It does not reference any specific type of technology, cite a limit on the type of communication, or a requirement that the telehealth services be paid for by Medicare Part B. As such, OIG noted that all technologies would be protected (including telephones, facsimile machines, and electronic mail systems), as long as all conditions of the exception are met.

Specifics:

- Under this statutory exception, the term “remuneration” does not include:
 - ❑ The provision of telehealth technologies are permitted is they are furnished an individual with end-stage renal disease by a provider of services, physician or the renal dialysis facility providing the in-home dialysis, telehealth services or other end-stage renal disease care to the individual.
 - ❑ The telehealth technologies are not offered as part of any advertisement or solicitation; and
 - ❑ The telehealth technologies are provided for the purpose of [furnishing](#) telehealth services related to the individual's end-stage renal disease.

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QUESTIONS

This outline is provided as general information only. It does not constitute legal advice and should not be used as a substitute for seeking legal counsel. Michael Cook and Robert Liles are attorneys with Liles Parker. The Firm represents physicians and other health care providers nationwide. We have offices in:

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