LIFE SCIENCES & HEALTHCARE

2020 Legal and Regulatory Updates

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Agenda

- The World Changed in 2020
- Spotlight on New Stark and AKS Rules
- OIG Special Fraud Alert
- Updated Compliance Program Guidance

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The World Changed in 2020

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Transformation of Healthcare in 2020

Pre-Pandemic	Current Situation
Limited, stable amount of telehealth offerings	Significant, rapid expansion of telehealth services
Evolving but relatively stable laws and regulations	Avalanche of regulatory and sub-regulatory changes
Limited number of staff working remotely	Shift toward teleworking when possible
Relatively stable supply chain needs	Rapid increase in demand for certain supply chain items
Established controls for contracting with third-party vendors	Emergency situation accelerating engagement of new vendors and contractors

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Telehealth Expansion

Telehealth expanded exponentially in 2020.

- Between mid-March and mid-October 2020, **over 24.5 million out of 63 million (over one-third)** beneficiaries and enrollees have received a Medicare telemedicine service during the PHE.
- Before the public health emergency, **only 15,000 fee-for-service beneficiaries** each week received a Medicare telemedicine service. In April 2020, that number increased to **nearly 1.3 million** Medicare beneficiaries receiving telehealth services on a weekly basis.
- CMS added **144 telehealth services** covered by Medicare during the PHE.

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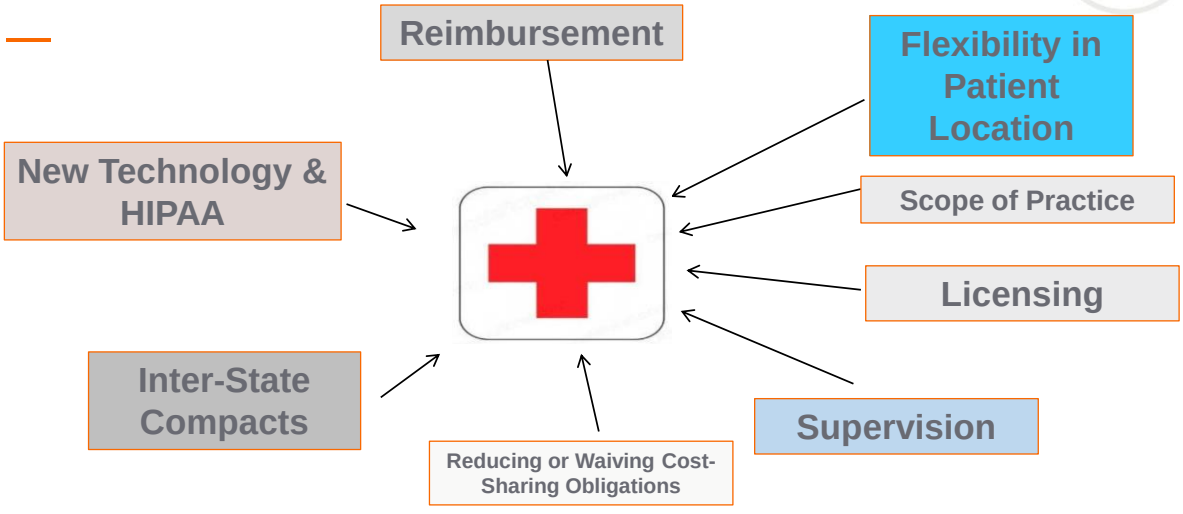
Telehealth Policy Changes



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Telehealth Waivers

- CMS has waived some statutory (SSA § 1834(m)) and regulatory (42 C.F.R. § 410.78) requirements for telehealth.
  - Waiver authorizes use of telephones that have audio and visual capabilities
  - For "good faith" provision of telehealth, no penalties imposed for noncompliance with HIPAA Privacy Rules
- Statutory Waivers:
  - § 1135: Waiver of telehealth "originating site" restrictions
  - § 3703: Secretary can waive 3-year established patient requirement
  - § 3704: Permits FQHCs and RHCs to be "distant sites" during a PHE
  - § 3706: May use telehealth for face-to-face hospice recertification during PHE
  - § 3707: Encourages home health telehealth services during a PHE
  - § 3212: Expands telehealth grants
  - § 3701: Preferential tax treatment for HD plans offering telehealth with no co-pays

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Hospital Without Walls Initiative

In March 2020, CMS announced its Hospital Without Walls Initiative, which provides broad regulatory flexibility that allows hospitals to provide services in locations beyond their existing walls, including patients' homes

- Must comply with all applicable, non-waived CoPs
- The location must is consistent with a state's emergency preparedness or pandemic response plan and comply with state licensing requirements

In November 2020, CMS expanded this effort and announced additional flexibilities:

- Acute Hospital Care At Home Program
- Ambulatory Surgical Center Flexibility
- Medicare Telehealth Expansion

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Acute Hospital Care At Home Program

Overview of the Acute Hospital Care At Home Program:

- Provides eligible hospitals with regulatory flexibilities to treat eligible patients in their homes.
  - Program is for beneficiaries who require acute inpatient admission to a hospital and require at least daily rounding by a physician and a medical team to monitor their care needs on an ongoing basis.
- CMS is accepting waiver requests to waive sections of the Hospital Conditions of Participation that require nursing services to be provided on the premises 24 hours a day, 7 days a week, and the immediate availability of a registered nurse for care of any patient.
- Hospitals that participate will be required to have appropriate screening protocols in place to assess medical and non-medical factors, including working utilities, assessment of physical barriers, and screenings for domestic violence concerns.
- Medicare beneficiaries will be admitted only from emergency departments and inpatient hospital beds, and an in-person evaluation by a physician will be required prior to starting care at home.
- A registered nurse must evaluate each patient once daily, either in person or remotely, and there must be two in-person visits per day by either registered nurses or mobile integrated health paramedics, based on the patient's nursing plan and hospital policies.

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Stark and AKS – A New Frontier

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The Stark Law – Purpose of Revisions

"This final rule addresses any undue regulatory impact and burden of the physician self-referral law… [it] modernizes and clarifies the regulations that interpret the Medicare physician self-referral law. Following an extensive review of policies that originated in the context of a health care delivery and payment system that operates based on the volume of services, and to support the innovation necessary for a health care delivery and payment system that pays for value, we are establishing new, permanent exceptions to the physician self-referral law for value-based arrangements and definitions for terminology integral to such a system. This final rule also includes clarifying provisions and guidance intended to reduce unnecessary regulatory burden on physicians and other health care providers and suppliers, while reinforcing the physician self-referral law's goal of protecting against program and patient abuse"

— CMS

The AKS Law – Purpose of Revisions

"The Secretary of HHS (the Secretary) has identified transforming the U.S. health care system to one that pays for value as a top priority. Unlike the traditional fee-for-service (FFS) payment system, which rewards providers for the volume of care delivered, a value-driven health care system is one that pays for health and outcomes. Delivering better value from the health care system will require the transformation of established practices and enhanced collaboration among providers and other individuals and entities. The purpose of this rulemaking is to finalize modifications to existing safe harbors to the Federal anti-kickback statute and finalize the addition of new safe harbors and a new exception to the civil monetary penalty provision prohibiting inducements to beneficiaries, "Beneficiary Inducements CMP," to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care."

— OIG

Certain Key Changes to Both Stark and AKS

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Incorporation of Value-Based Concepts

Value-Based Enterprise (VBE)

Two or more "*VBE participants*" —

1. Collaborating to achieve at least one "*value-based purpose;*"
2. Are parties to the "*value-based arrangement*" with the other or another VBE participant;
3. Have an accountable body or person responsible for financial and operational oversight of the "*VBE*"; and
4. Have a governing document that describes the *VBE* and how the "*VBE participants*" intend to achieve its "*value-based purposes*."

Definitions

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Overview: Value-Based Concepts (II)

Value-Based Purpose

CMS finalized its proposed definition of "value-based purpose:"

Doing any of the following:

1. Coordinating and managing care of a "*target patient population*;"
2. Improving quality of care for a "*target patient population*;"
3. Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a "*target patient population*;" or
4. Transitioning from payment mechanisms based on volume to payment mechanisms based on the quality of care and cost controls for a "*target patient population*."

Note: No substantive difference between OIG and CMS definitions.

Overview: Value-Based Concepts (III)

Value Based Arrangement

Proposed Rule: The proposed definition was finalized with one exception:

An arrangement for at least one "*value-based activity*" for a "*target patient population*" ~~*between or among*~~ ***to which the only parties are —***

1. The "*value-based enterprise*" and one or more of its "*VBE participants*;" or
2. The "*VBE participants*" *in the same "value-based enterprise."*

Reason for Change: To make clear that all parties to the value-based arrangement must be VBE participants in the same value-based enterprise.

Note 1: CMS did not finalize a proposal that would have limited "value based arrangements" to require care coordination and management to qualify for the definition.

Note 2: OIG's definition of this term is substantially the same as CMS's definition.

Overview: Value-Based Concepts (IV)

Value-Based Enterprise Participant (VBE participant)

An individual or entity that engages in at least one "*value-based activity*" as part of a "*value-based enterprise*."

Note: CMS did not adopt its proposal to exclude the following from the definition:

- pharmaceutical manufacturer;
- manufacturer, distributor, or supplier of DMEPOS; or
- a laboratory.

OIG did, however, adopted its proposal to exclude the following as "entities ineligible" for VBA Safe Harbor Protection:

1. Pharmaceutical Manufacturers, Wholesalers, and Distributors
2. Pharmacy Benefit Managers
3. Laboratory Companies
4. Medical Device Manufacturers, Distributors, and Wholesalers
5. DMEPOS Companies
6. Compounding Pharmacies

Value-Based Arrangements Subject to Detailed New Exceptions and Safe Harbors

Value-Based Arrangements Exceptions – Stark

1. Full Financial Risk
2. Meaningful Downside Financial Risk to the Physician
3. Value-Based Arrangements (Less Risk to the Physician)

Value-Based Arrangements Safe Harbors – AKS

1. Full Financial Risk
2. Substantial Downside Financial Risk
3. Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency (Less Risk)

Donations of Cybersecurity Technology and Services – Stark Exception and AKS Safe Harbor

Rules adopted substantially as proposed – biggest difference is that the final rules will protect donations of **hardware**.

Rules protect donations of technology and related services necessary and used predominantly to implement, maintain or reestablish cybersecurity ("**effective** cybersecurity" – AKS).

"Cybersecurity" means the process of protecting information by preventing, detecting and responding to cyberattacks.

"Technology" means any software or other types of information technology – the definition excluded hardware in the proposed rules but no longer does.

"Used **predominantly**" means that cybersecurity must be the core functionality.

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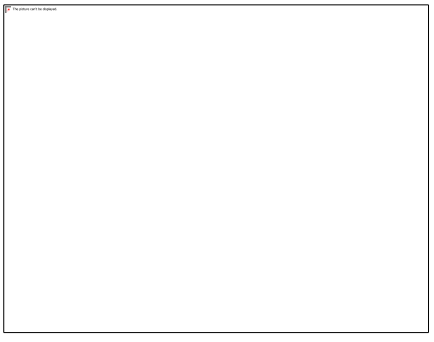
Donations of Cybersecurity Technology and Services

Rules protect donations of software, hardware, services and other types of cybersecurity technology:

- Software – cloud-based or locally installed.
- Patches and updates.
- Hardware.
- Application Programming Interface (API) technology.
- Infrastructure – not OK
  - High security doors or door locks
  - Upgraded wiring
  - Physical security systems.



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Donations of Cybersecurity Technology and Services

New rules protect a broad range of services:

- Services associated with developing, installing and updating cybersecurity software.
- Any kind of cybersecurity training.
- Business continuity and data recovery services.
- "Cybersecurity as a service" models that rely on a third party to manage, monitor or operate cybersecurity functions.
- Services associated with performance of risk assessments, vulnerability analysis or penetration testing.
- Services associated with sharing cybersecurity information.
- Provision of a full-time cybersecurity officer in a physician recipient's practice - possibly.
- Cybersecurity help desk services, but not general IT help desk services.

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Certain Additional Key Stark Revisions

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Compensation Exceptions: "The Big Three"

Compensation arrangement is **commercially reasonable**

Compensation is **fair market value**

Compensation is not determined in any manner that **takes into account the volume or value of referrals or other business generated** by the physician or between the parties

Recalibration: Define three distinct concepts

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Commercially Reasonable – Definition

Previously no codified definition

Now defined to mean "the particular arrangement furthers **a legitimate business purpose of the parties** and **is sensible**, considering the characteristics of the parties, including their size, scope, and specialty"

Notably, CMS specifically states that an arrangement may be commercially reasonable **even if it does not result in profit for one or more of the parties**. CMS notes further, however, that profitability is not completely irrelevant or always unrelated to the determination of CR.

So…what does this really mean?

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Commercially Reasonable – CMS Commentary

- A fact-specific analysis to be made by the particular parties to the arrangement
- Key question is "simply whether [it] makes sense as a means to accomplish the parties' goals"
- Not a question of valuation…*however,* compensation terms are "integral" part and "impact" ability to meet the parties' goals
- May be ok even if parties know in advance that it may result in losses, e.g:
  - *Community need*
  - *Timely access to healthcare services*
  - *Fulfillment of licensure or regulatory obligations (e.g., EMTALA)*
  - *Provision of charity care*
  - *Improvement of quality and health outcomes*

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The "Volume or Value" Standard – New Definition

Compensation from a DHS entity to a physician (or IFM) takes into account the volume or value of referrals or other business generated (OBG) only if –

The formula used to calculate the physician's (or IFM's) compensation includes the physician's referrals to (or OBG for) the DHS entity as a variable, resulting in an increase or decrease in the physician's (or IFM's) compensation that positively correlates with the number or value of the physician's referrals to (or OBG for) the DHS entity.

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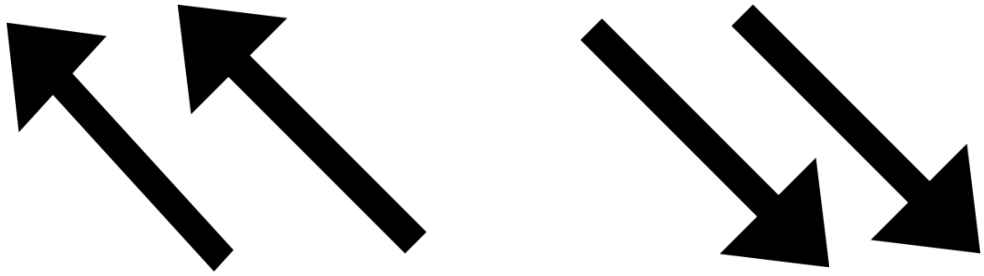
The "Volume or Value" Standard

A positive correlation between two variables exists when one variable increases as the other variable increases, or one variable decreases as the other variable decreases.



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The "Volume or Value" Standard

Compensation from a physician (or IFM) to a DHS entity takes into account the volume or value of referrals or other business generated (OBG) only if –

The formula used to calculate the entity's compensation includes the physician's referrals to (or OBG for) the DHS 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 (or OBG for) the DHS entity.

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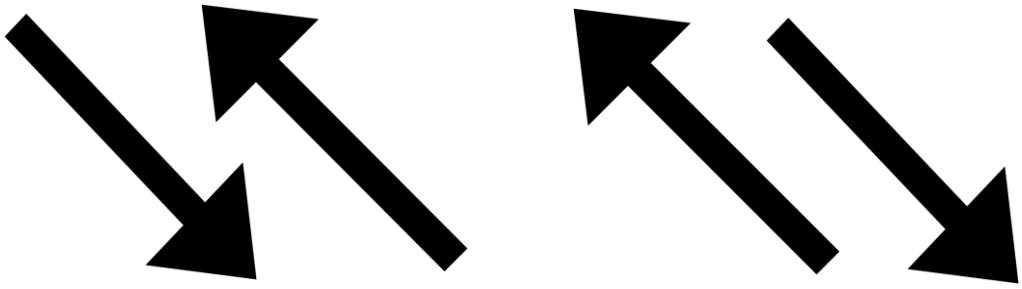
The "Volume or Value" Standard

A **negative correlation** between two variables exists when one variable decreases as the other variable increases, or one variable increases as the other variable decreases.



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Fair Market Value

"**Fair market value**" is defined:

- In general
- In the context of rental of equipment
- In the context of rental of office space

"**General market value**" is defined with respect to:

- Assets
- Compensation
- Rental of equipment or office space

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Fair Market Value – General

The general definition of "fair market value":

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

Note: CMS specifically notes that providers can deviate from FMV survey data based on facts and circumstances -- e.g., highly renown ortho surgeon may far exceed data suggesting $450K and family practitioner relocating to an area with low cost of living may be lower than $250K

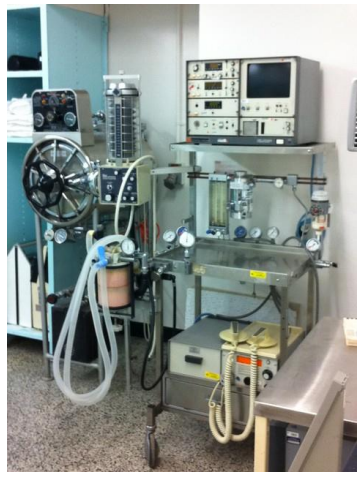
Fair Market Value – Rental of Equipment

"Fair Market Value" for **Rental of Equipment**:

The value in an arm's length transaction

of rental property for general commercial purposes (not taking into account its intended use),

consistent with general market value of the subject transaction.



Fair Market Value – Rental of Office Space

"Fair Market Value" for **Rental of Office Space:**

The value in an arm's length transaction

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 general market value of the subject transaction.

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Fair Market Value – General Market Value

General market value means:

The price that an **asset** would bring **on the date of acquisition** of the asset, as a result of *bona fide* bargaining between **a well-informed buyer and seller that are not otherwise in a position to generate business for each other.**

The **compensation** that would be paid **at the time the parties enter into the service arrangement,** as a result of *bona fide* bargaining between **well-informed parties that are not otherwise in a position to generate business for each other.**

The price that **rental property/equipment** would bring **at the time the parties enter into the rental arrangement,** as a result of *bona fide* bargaining between **a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.**

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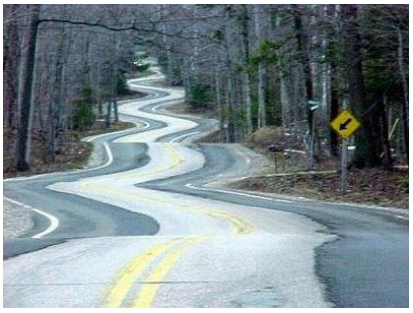
Indirect Compensation Arrangements: Definition

In a significant departure from the proposed rule, the final rule modifies the definition of an "indirect compensation arrangement" by changing the "aggregate compensation" standard to require that –

- The referring physician (or IFM) receives aggregate compensation that varies with the volume or value of referrals to (or OBG for) the DHS entity generated by the referring physician; and
- The individual unit of compensation received by the physician is (1) is not FMV for items/services actually provided; and (2) includes the physician's referrals to (or OBG for) the DHS entity as a variable, resulting in an increase or decrease in the physician's (or IFM's) compensation that positively correlates with the number or value of the physician's referrals to (or OBG for) the DHS entity.



Special Rule – Directed Referrals

New language specifies that neither **the existence of** nor **the amount of** compensation can be contingent on the **number** and **value** of referrals to the particular provider, practitioner, or supplier

- Practical import – entity cannot terminate the arrangement or change the compensation based on the number or value of referrals

However, the entity **can** require that a provider refer **a specified percentage or ratio of the physician's referrals** to that specific entity

- CMS states in commentary that, if a physician does not meet this percentage or ratio, the entity **can** terminate the arrangement

Percentage or Ratio Thresholds Permissible

> "We emphasize that §411.354(d)(4)(vi) does not prohibit directed referral requirements based on an established percentage—rather than the number or value—of a physician's referrals. Therefore, if the directed referral requirement in the commenter's example provided for termination of the compensation arrangement if the physician failed to refer 90 percent, for example, of his or her patients to a particular provider, practitioner, or supplier, it would not run afoul of the special rule at §411.354(d)(4) or jeopardize compliance with the requirement of the applicable exception.— EMPHASIS ADDED

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Directed Referrals – Applicability

Included as an element in the following exceptions:

- Employment
- AMCs
- Personal services
- Physician incentive plans
- Group practice with hospital
- FMV
- Indirect compensation
- Limited compensation (new)

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New Exception: Limited Remuneration to a Physician

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 $5,000 per CY, as adjusted for inflation, if—

- Comp is not determined in any manner that takes into account the v/v of referrals or other business generated by the physician;
- Comp does not exceed the FMV of the items/services;
- Arrangement is commercially reasonable; and
- Arrangements for the rental/use of office space/eqpt do not violate the prohibitions on per-unit of service ("per-click") and %-based comp formulas.

Benefits: No writing, signature, or set in advance required

§ 411.357(z)

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Certain Additional Key AKS Revisions

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Personal Services and Management Contracts Safe Harbor

Final amendments to the personal services and management contracts safe harbor include:

- Eliminates requirement that the agreement specify exactly the schedule of part-time intervals, their precise length, and the exact charge for the intervals.
- Removal of the requirement that the aggregate compensation over the term be set in advance in the agreement. Instead, the **methodology** for determining compensation paid over the term must be set in advance in the agreement; and
- Addition of provisions for outcomes-based payments (this safe harbor can be used to supplement the exception for in-kind remuneration paid under care coordination arrangements).

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The AKS Statute – Certain Key Additional Changes

- Create AKS safe harbor for patient engagement and support;
- Create a telehealth exception to the Beneficiary Inducement CMP;
- Revise the local transportation AKS safe harbor; and
- Revise the AKS safe harbor for warranties.

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OIG Special Fraud Alert

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OIG Fraud Alert on Speaker Programs

- OIG published its first Fraud Alert **in more than six years** on November 16, 2020 cautioning manufacturers and HCPs regarding speaker program activities.
- OIG categorizes speaker programs as "inherently risky" and expresses skepticism about their educational value, especially in-person programs.
- OIG offers a non-exhaustive list of program characteristics that pose higher risks of violating the AKS.

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Speaker Programs Facing Increased Scrutiny

"Suspect Characteristics" of Speaker Programs from OIG Special Fraud Alert

- Minimal substantive information
- Alcohol available or meal exceeds modest value
- Venue not conducive to learning
- Large number of programs sponsored
- No new medical/scientific information or new FDA-approved indication for a long period of time

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Speaker Programs Facing Increased Scrutiny

"Suspect Characteristics" of Speaker Programs from OIG Special Fraud Alert

- HCPs are repeat attendees or attendee after being a speaker on a similar topic
- Attendees have no legitimate business reason to attend
- Sales/Marketing business units influence speaker/attendee selection
- HCP speakers paid more than FMV
- HCP compensation takes into account value of past business generated by HCPs

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Updated Compliance Program Guidance

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DOJ Updated Compliance Guidance

Overview of the June 1, 2020 DOJ updated guidance:

- Continued focus on the three overarching questions, as clarified in 2019 guidance;
- Additional focus on each company's unique circumstances (how it has set up the compliance program and how it has evolved over time)
- Additional focus on company resources being committed to compliance (need adequate resources to function effectively)
- Greater need for data to drive compliance program efficacy (ensuring compliance personnel can access relevant data to monitor compliance)
- Engagement in periodic review process, including "lessons learned" from peers
- Proper management of third-party agents – initial vetting and monitoring

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DOJ: Core Questions Largely Remain the Same, With Added Nuance

U.S. Department of Justice
Criminal Division

Evaluation of Corporate Compliance Programs

(Updated June 2020)

1. "Is the corporation's compliance program well designed?"
2. "Is the program being applied earnestly and in good faith?" In other words, is the program adequately resourced and empowered to function effectively?
3. "Does the corporation's compliance program work" in practice?

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DOJ Guidance: Three Core Questions

1. ***Is the compliance program well designed?***

- **Risk Assessment** → ***designed to detect misconduct most likely to occur***
  - Risk management process
  - Risk-tailored resource allocation
  - Updates and revisions
  - Lessons learned (from itself and peers)

- **Policies and Procedures** → ***implement ethical norms to reduce risks***
  - Design and comprehensiveness
  - Accessibility
  - Responsibility of operational integration
  - Gatekeepers

- **Training and Communications** → ***program communicated to and understood by employees***
  - Risk-based training and form/content/effectiveness of training
  - Communications about misconduct
  - Availability of guidance

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DOJ Guidance: Three Core Questions

1. *Is the compliance program well designed?*

- **Confidential Reporting Structure and Investigation Process** → ***employees can anonymously or confidentially report allegations without fear of retaliation***
  - Effectiveness of reporting mechanisms
  - Properly scoped investigations by qualified personnel and investigation response
  - Resources and tracking of results
- **Third Party Management** → ***risk-based due diligence***
  - Risk-based and integrated processes and appropriate controls
  - Managed of relationships
  - Real actions and consequences (tracking)
- **Mergers and Acquisitions** → ***comprehensive due diligence of any acquisition targets***
  - Due diligence process
  - Integration in M&A process
  - Process connecting due diligence to implementation

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DOJ Guidance: Three Core Questions

2. *Is the program being applied earnestly and in good faith?*

- **Commitment by Senior & Middle Management** → ***create and foster culture of ethics and compliance***
  - Conduct at top
  - Shared commitment
  - Oversight
- **Autonomy & Resources** → ***ability to act with adequate authority and stature***
  - Structure and autonomy
  - Seniority and stature
  - Experience and qualifications
  - Funding and resources
  - Data resources and access to it
- **Incentives & Disciplinary Measures** → ***incentives for compliance and disincentives for non-compliance***
  - Human resources process
  - Consistent application
  - Incentive system

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DOJ Guidance: Three Core Questions

3. Does the program work in practice?

- **Continuous Improvement, Periodic Testing, & Review** → ***capacity to improve and evolve***
  - Internal audit and control testing
  - Evolving updates
  - Culture of compliance
- **Investigation of Misconduct** → ***timely and thorough investigations***
  - Properly scoped investigation by qualified personnel
  - Response to investigations (sharing and responding to findings)
- **Analysis & Remediation of Underlying Misconduct** → ***thoughtful root cause analysis and timely/appropriate remediation***
  - Root cause analysis
  - Prior weaknesses and prior indications
  - Payment systems (e.g., how misconduct funded and how to prevent)
  - Vendor management

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Questions?

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