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Stark and AKS Final Rules: Overview and Impact

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HCC Health Capital Consultants

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Regulatory Sprint

"…there is broad consensus throughout the health care industry regarding the urgent need for a movement away from legacy systems that pay for care on a FFS basis…"

"Identifying and addressing regulatory barriers to value-based care transformation is a critical step in this movement"

Goals of the Rules

Encourage Participation in Value-Based Arrangements

Clarify/Simplify Existing Stark/AKS Rules

Distinctions in Color

- Stark
- Anti-Kickback
- Both Stark and Anti-Kickback
- Important Stark/AKS Distinctions

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Snapshot of the Rules

- Effective January 19, 2021
  - January 1, 2022 for certain Stark changes applicable to group practices

Stark Law	Anti-Kickback	CMP Law
- 5 New exceptions - Almost every exception revised in some way - Significant revisions and new additions to definitions and special rules on compensation	- 7 New safe harbors - 4 Safe harbors significantly revised	- New exception to Remuneration

Stark Law Fundamental Terminology and Requirements Changes

Changes to "The Big Three"

- Many of the exceptions to the Stark Law require that one or more of the following requirements be met:
  - That the compensation arrangement be *commercially reasonable*
  - That the compensation methodology *not* be determined in a manner that takes into account the volume or value of referrals (or other business generated between the parties)
  - That the amount of compensation paid be *fair market value*
- CMS's reason for changing these definitions: "*to establish bright-line, objective regulations for each of these fundamental requirements…*"

Commercial Reasonableness

- **Historically** – No definition
- **Proposed Definition** – 2 alternative definitions
- **Finalized Definition** –
  - "*Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties*." [Emphasis added.]

Volume or Value of Referrals Standard

- **Historically** – No definition
- **Proposed Definition** –
  - 4 objective tests that define when compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties
  - 4 objective tests that define when fixed-rate compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties

Volume or Value of Referrals Standard

- **Finalized Definitions** –
  - Entity → Physician Test
    - The formula used to calculate the physician's compensation includes the physician's referrals (or other business generated) to the entity as a **variable**, **resulting in an increase or decrease** in the physician's compensation **that *positively correlates* with** the number or value of **the physician's referrals** (or other business generated) to the entity
    - Example: Compensation = (.50 x collections from personally performed services) + (.50 x collections from referred DHS) + (.50 x collections from non-DHS referrals)
  - Physician → Entity Test
    - The formula used to calculate the entity's compensation includes the physician's referrals (or other business generated) 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** (or other business generated) to the entity
    - Example: Medical Office Lease Compensation = $5,000/mo Base Rent – ($5 x diagnostic test [DHS] ordered & furnished in HOPD)
  - Fixed-rate compensation tests *not* finalized

Fair Market Value

- **Historically –**

"*the value in arm's-length transactions, consistent with the general market value....Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals*." [Emphasis added.]

Fair Market Value

- **Proposed Definitions –**

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)
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

Fair Market Value

- **Finalized Definitions –**

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)
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

- **Historically –**

  "*The price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.*" [Emphasis added.]

General Market Value

- **Proposed Definitions –**
  - **General:** "*The price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.*"
  - **Rental of Equipment or Office Space:** "*The price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement.*"

General Market Value

- **Finalized Definitions –**
  - **Assets**: "*the price that an asset would bring on the date of acquisition of the asset as the 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*." [Emphasis added.]
  - **Compensation**: "*the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other*." [Emphasis added.]
  - **Rental of Equipment or Office Space**: "*the price that rental property would bring at the time the parties enter into the rental arrangement as the 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*." [Emphasis added.]

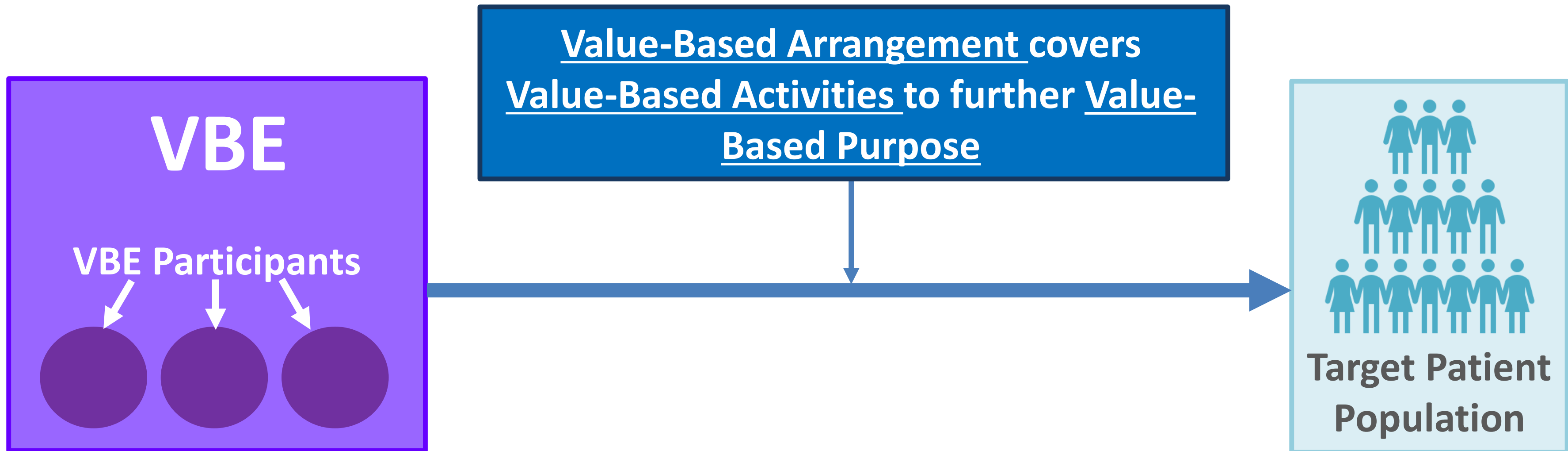
Fair Market Value vs. General Market Value

- CMS "*continue[s] to believe that the fair market value of a transaction–and particularly, compensation for physician services–may not always align with published valuation data compilations, such as salary surveys*."
- "*It is not CMS policy that salary surveys necessarily provide an accurate determination of fair market value in all cases…Consulting salary schedules or other hypothetical data is an appropriate starting point in the determination of fair market value, and in many cases, it may be all that is required*."
- "*[W]e agree that a hospital may find it necessary to pay a physician above what is in the salary schedule, especially where there is a compelling need for the physician's services. For example, in an area that has two interventional cardiologists but no cardiothoracic surgeon…a hospital may need to pay above the amount indicated at a particular percentile in a salary schedule to attract and employ a cardiothoracic surgeon*."
- "*We are uncertain why the commenters believe that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate. The commenters are incorrect that this is CMS policy*."

Revised Definitions
Key Takeaways

1. A Commercial Reasonableness Definition
2. Fair Market Value Effectively the Same
3. Treatment of the 75th Percentile

Value-Based Stark Exceptions and Anti-Kickback Safe Harbors



- **Value-Based Enterprise (VBE)**: two or more value-based participants collaborating to achieve value-based purpose, using a value-based arrangement and has an accountable body or person and governing document
- **Value-Based Participants**: individuals or entities engaged in value-based activity as part of a value-based enterprise – e.g. hospitals, physicians, digital health companies, SNFs, home health, etc. (OIG excludes some from safe harbor protection)
- **Value-Based Arrangement**: an arrangement for value-based activity by the value-based enterprise and/or its value-based participants
- **Value-Based Activity**: Providing an item or service, taking action, or refraining from an action, all in furtherance of a value-based purpose (does not include making a referral)
- **Value-Based Purpose**: coordinating and managing care; improving quality; appropriately controlling costs; transitioning from volume to value
- **Target Patient Population (TPP)**: an identified patient population selected by value-based enterprise or its value-based participants using “legitimate and verifiable criteria” set out in writing, in advance

Value-Based Enterprise

- "**Value-based enterprise**" – 2 or more "VBE participants:"
  - (1) Collaborate to achieve at least 1 "value-based purpose;"
  - (2) Party to a "value-based arrangement" with the other or at least one other "VBE participant" in the "VBE;"
  - (3) Accountable body or person responsible for financial and operational oversight of the "VBE;" and
  - (4) Governing document describing the "VBE" and how the "VBE participants" intend to achieve its "value-based purpose(s)"
- Distinct legal entity (e.g. ACO) or 2 Participants to Value-Based Arrangement

Value-Based Arrangement

- An arrangement for the provision of at least 1 value-based activity for a "TPP" to which the only parties are:
  - (1) a "VBE" and one or more of its "VBE participants;" or
  - (2) "VBE participants" in the same "VBE"
- At minimum – "**value-based arrangement**" must include an entity and a physician (otherwise Stark inapplicable)
- Value-based exceptions apply only to compensation arrangements
- AKS arrangements are not limited to physicians and entities performing or billing for DHS

Value-Based Activity

Value-based activity" means:

- provision of an item or service
- the taking of an action, or
- the refraining from taking an action,

– Must be **reasonably designed** to achieve at least **1** value-based purpose of the VBE

Value-Based Purpose

"**Value-based purpose**" means:

- coordinating and managing the care of "TPP;"
- improving the quality of care for "TPP;"
- reducing costs to or growth in expenditures of payors without reducing quality of care for "TPP;" or
- transitioning from health care delivery and payment based on volume to value/quality of care/cost control for "TPP"

Target Patient Population

- Selected by "VBE" or its "VBE participants" based on legitimate and verifiable criteria:
  - (1) In writing in advance of commencement of "value-based arrangement" &
  - (2) further the "VBE's" "value-based purpose(s)

Examples of Legitimate and Verifiable Criteria
Medical/Health Characteristics *(knee replacement patients)*
Geographic characteristics *(patients in county or zip code)*
Payor Status *(patients in particular health insurance plan/payor)*
Income
Age

Value-Based Exceptions and Safe Harbors

Stark	AKS
Full Financial Risk	Full Financial Risk
Meaningful Downside Risk to Physician	Substantial Downside Risk (to VBE)
Value-Based Arrangements	Care Coordination Arrangements
	Patient Engagement and Support
Indirect Value-Based Arrangements	
	Personal Services Arrangements
Group Practice (allocation of value-based reserve)	

Stark Anti-Kickback Both Stark and Anti-Kickback Important Stark/AKS Distinctions

New Value-Based Exceptions and Safe Harbors

Stark Exceptions	Anti-Kickback Safe Harbors
Full Financial Risk exception – value-based enterprise assumed full financial risk from payor for patient care for target patient population	**Full Financial Risk –** value-based enterprise financial responsible for all costs covered by payor for each patient in target patient population
Meaningful Downside Financial Risk exception – value-based arrangement where physician at downside risk for failure to achieve value-based purpose	**Substantial Downside Financial Risk –** value-based enterprise has assumed less than full downside financial risk for failure of VBE to achieve value-based purpose
Value-based arrangement exception – any value-based arrangement (satisfying certain requirements)	**Care Coordination Safe Harbor –** coordination arrangements to improve quality, health outcomes, and efficiency

Stark Anti-Kickback Both Stark and Anti-Kickback Important Stark/AKS Distinctions

Value-Based Arrangements (Stark Exceptions)

Element	Full Risk (VBE)	Meaningful Downside Risk (Physician)	Value-Based Arrangement
Remuneration for/from value-based activities	●	●	●
Must not limit medically necessary care	●	●	●
Not conditioned on referrals of unrelated business	●	●	●
Required referrals must include language for patient choice and professional judgment	●	●	●
6-year record retention	●	●	●
Writing Requirement		● (no signature req.)	● (signed by parties)
Compensation methodology set in advance		●	●
Commercial Reasonableness			●
Outcome measures (if any) set in advance and modifications in writing			●
Monitoring			●

Full Financial Risk Exception and Safe Harbor

- "VBE" must be ***financially responsible*** (or contractually obligated to be financially responsible within 12 months following the start of value-based arrangement)
  - **prospective basis**
  - **cost of all patient care items and services**
  - **"TPP"**
  - **specified period of time**

- Examples: ***capitation payments*** or ***global budget payment*** (other approaches to full financial risk **not** prohibited)
- Remuneration must be for/result from **value-based activities**

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Full Financial Risk Exception and Safe Harbor

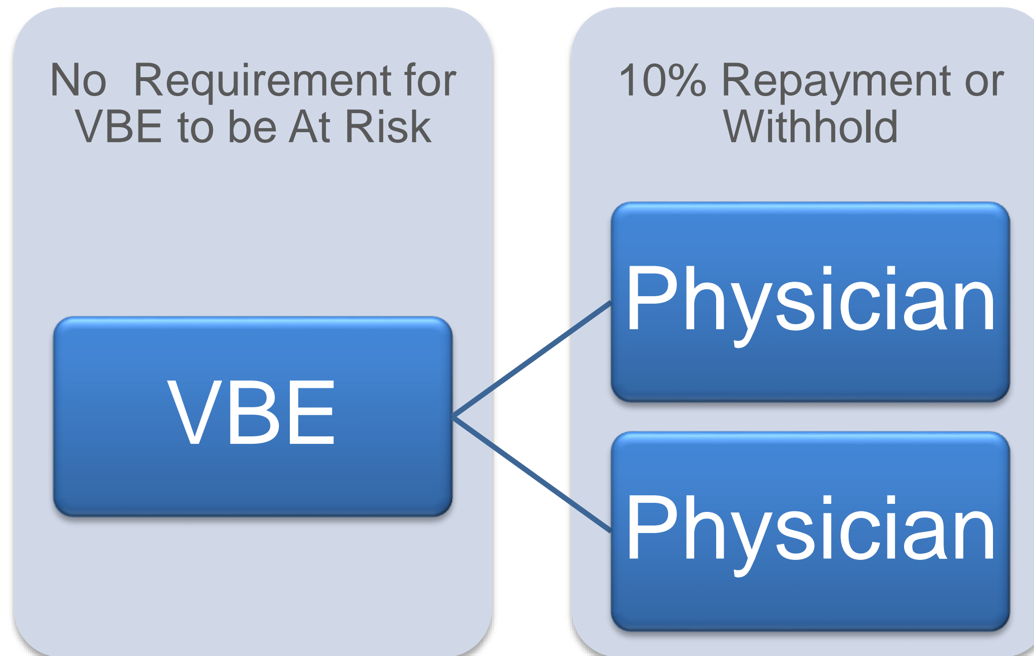
Other requirements:

- Does not reduce or limit medically necessary items or services (whether in the "target patient population" or not)
- Is not conditioned on referrals outside the value-based arrangement: (patients not part of "target patient population" or business not covered under the "value-based arrangement")
- Referrals inside the value-based arrangement meet certain criteria (Stark only): if conditioned on the physician's referrals to a particular provider, value-based arrangement complies with both requirements
  1. must be set out in writing and signed by the parties; and
  2. may not apply if patient expresses a preference for a different provider; patient's insurer determines the provider; or referral is not in the patient's best medical interests in the physician's judgment
- Records (methodology and amount of remuneration) maintained for at least 6 years

Stark Anti-Kickback Both Stark and Anti-Kickback Important Stark/AKS Distinctions

Meaningful Downside Financial Risk Exception

- "**Meaningful downside financial risk**" - physician responsible to repay or forgo at least ***10 percent*** of total value of the remuneration the physician receives under the "value-based arrangement"
  - 10 % of *value* of the remuneration (captures in-kind remuneration)



Meaningful Downside Financial Risk Exception: Requirements

- Meaningful downside financial risk during entire duration of value-based arrangement
- Set forth in writing (the nature and extent of the physician's financial risk)
- Methodology set in advance (methodology to determine the amount of remuneration)
- Remuneration is for/results from value-based activities for patients in TPP
- Does not reduce or limit medically necessary items or services (whether in the "target patient population" or not)
- Not conditioned on referrals outside the value-based arrangement (patients who are not part of the "TPP" or business not covered under the "value-based arrangement")
- Records (methodology and amount of remuneration) maintained for 6 years

Meaningful Downside Financial Risk Exception: Requirements (continued)

- Referrals inside the "value-based arrangement" meet certain criteria:
  - If physician remuneration is conditioned on referrals to a particular provider, the "value-based arrangement" complies with both of the following conditions:
    - set out in writing and signed by the parties; and
    - patient preference for a different provider; patient's insurer determines the provider; or the referral is not in the patient's best medical interests in the physician's judgment (*then referral requirement does not apply*)

Substantial Downside Financial Risk Safe Harbor

§ 1001.952(ff) – "**Substantial downside financial risk**" is defined as:

- At *least 30%* of any losses for **ALL** items and services furnished to "target patient population;"
- At *least 20%* of any loss for defined clinical episode of care (across multiple care settings); **OR**
- Certain partial capitation payments

Substantial Downside Financial Risk Safe Harbor

- Remuneration provided by, or shared among, the "VBE" and "VBE participant:"
  - Is directly connected to one or more of the "VBE's" "value-based purposes;"
  - Is used predominantly to engage in "value-based activities" directly connected to the items and services for which the "VBE" has assumed substantial downside financial risk;
  - Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and
  - Is not exchanged or used for the purpose of marketing items or services furnished by the "VBE" or a "VBE participant" to patients or for patient recruitment activities.

Value-Based Arrangements Exception and Care Coordination Safe Harbor

- New exception for compensation arrangements that qualify as **value-based arrangements**, regardless of the level of risk undertaken by the VBE or any of its VBE participants [§ 411.357(aa)(3)]

- The value-based arrangement exception would permit both *monetary* and *nonmonetary* remuneration between the parties

  - **AKS Distinction** – AKS Care Coordination Safe Harbor is limited to protect only non-monetary (in-kind) remuneration

Stark **Anti-Kickback** **Both Stark and Anti-Kickback** **Important Stark/AKS Distinctions**

Value-Based Care Key Takeaways

1. AKS Safe Harbors and Stark Exceptions are Not Interchangeable
2. AKS Safe Harbors and Stark Exceptions are Broad and Flexible – Intended to Foster Innovation

Other New/Revised Exceptions and Safe Harbors

DHS Definition Changes

- Some Inpatient Hospital Services Removed from DHS Definition
- For services furnished to inpatients by a hospital, a service is not DHS if the furnishing of the service does not increase amount of Medicare payment to the hospital under any of the following PPS:
  - Acute Care Hospital Inpatient (IPPS)
  - Inpatient Rehabilitation Facility (IRF PPS)
  - Inpatient Psychiatric Facility (IFP PPS)
  - Long-Term Care Hospital (LTCH PPS)
- Outpatient services would remain DHS under the regulations

Limited Remuneration to Physician

- Protects remuneration from entity to physician for items or services **provided by the physician** that does not exceed an **aggregate of $5,000** (per year)
- Can't take into account V/V of referrals or other business generated and can't exceed FMV
- Commercially reasonable even if no referrals between parties
- Compensation for **lease or use of office space/premises or equipment** can't be determined using formula based on:
  - % of revenue from service in the office space or use of equipment; or
  - Per-unit of service rental charges
- Available even when parties fail to document arrangement in a contemporaneous writing

Limited Remuneration to Physician

- Unless payments can be attributed to individual physician and are passed through to that physician, payments to a group practice would be allocated and count against the annual aggregate limit for each physician owner within the group practice
  - E.g. $1,000 payment to a group practice could be treated as a $1,000 payment to each of the physician owners of the group practice for purposes of the aggregate limit.
- Unlike most exceptions under Stark, this special new limited exception is available even where the parties fail to document the arrangement in a contemporaneous writing.

Patient Choice and Directed Referrals

- Permits directed referrals if specific conditions are met to preserve patient choice, insurer's determinations, and protect medical judgment
- New condition – neither existence of a compensation arrangement or amount of compensation can be contingent on volume or value of referrals
- Directed referral requirement impermissible if compensation arrangement would be terminated if:
  - Physician failed to refer sufficient number of patients for DHS, **or**
  - Value of the physician's referrals of DHS failed to achieve the target established under the directed referral requirement
- May require percentage or ratio of referrals
- Would not "categorically prohibit" arrangement where physician paid different % of bonus pool based on % of physician's referrals in network

Personal Services and Management Contracts and Outcomes-Based Payments

Personal Services and Management Contracts

- Modification to existing Safe Harbor
- Set in advance requirement:
  - Aggregate compensation → changed to methodology for determining compensation
- Eliminate requirement that part-time arrangements have schedule set out in written agreement

Personal Services and Management Contracts and Outcomes-Based Payments

- **Outcomes-based Payment Arrangements** – Protects payments to improve patient or population health (through coordination of care or reduction in payor costs while improving quality)
- Outcome measure –
  - Selected based on clinical evidence and medical support
  - Benchmarks used to quantify improvements in quality and reduction in costs
- Outcomes-based payment –
  - For achieving outcome measure (reward) or failing to achieve (recoupment/reduction)
  - Cannot be based solely on internal cost savings, patient satisfaction, patient convenience
- Elements and Protections –
  - Methodology set in advance (FMV,CR,V/V), writing signed in advance or contemporaneous, no limit on patient choice, not less than 1-year, ongoing monitoring and assessment

Warranty

- Modification to existing Safe Harbor
- Protection for bundle of one or more items and related services if paid by same payor under same payment
- No protection for service-only arrangements
- Caps compensation under warranty at amount paid for item or bundle
- Excludes federal health care programs from reporting requirements for buyers
- Impermissible to condition warranty on exclusive use or minimum purchase of items or services
- Includes Warranty Definition

EHR Donation Safe Harbor/Exception

- Safe Harbor and Exception language not identical, but consistent
- Expressly permits replacement technology (removed requirement donor not provide equivalent technology)
- Retained 15% of cost share
  - Initial donation or replacement – must pay before receipt
  - Updates – need not pay in advance
- Retained limits on who can make donations
- Eliminated sunset date – establishing permanency

Cybersecurity Donation Safe Harbor/Exception

- Safe Harbor and Exception language not identical, but consistent
- Protects donation of cybersecurity technology and services
- Cybersecurity technology and services must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity
- Neither eligibility nor amount/nature of the donation may *directly* take into account the volume or value of referrals or other business generated
- Cannot condition donation on doing business with the donor (future referrals)
  - OIG Applicability – donor and recipient (and recipients' practice)
  - CMS Applicability – physician (and physician's practice

Cybersecurity Donation Safe Harbor/Exception (continued)

- No limit on who may donate
- No limit on value of donation – must be nonmonetary (technology and services)
- No cost sharing requirement
- Documented in writing

Transportation

- Modification to existing Safe Harbor
- Expands distance allowed for rural patients from 50→75 miles
- Removes any distance limitation at discharge (following inpatient admission or observation stay of at least 24 hours)
- Protects nonmedical transportation offered by "VBE participants" if such transportation has a direct connection to the coordination and management of care of the "TPP" and meets the other conditions of the safe harbor.
- Ride-sharing arrangements are permissible

Patient Engagement and Support

- Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency
- Remuneration does not include a patient engagement tool or support furnished by "VBE Participant" to patient in a "target patient population"
- Protects only in-kind remuneration
- Eligible entities to furnish, fund, or contribute support, do **not** include:
  - manufacturers, distributors, and wholesalers of pharmaceuticals;
  - pharmacy benefit managers;
  - laboratory companies;
  - pharmacies that primarily compound or dispense compounded drugs;
  - manufacturers of devices and medical supplies (unless the tool or support is digital health technology);
  - entities or individuals that sell or rent DMEPOS (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services);
  - medical device distributors and wholesalers; and
  - physician-owned medical device companies.

New Safe Harbor

- Also serves as exception from remuneration definition under CMP
- Protects incentive payment made by an ACO to assigned beneficiary who receives payment as part of ACO beneficiary incentive program
- Incentive payments only to assigned beneficiaries
- Payments must meet all requirements related to ACO Beneficiary Incentive Programs but no obligation to satisfy requirements outside the ACO Beneficiary Incentive Program
- Other CMS-sponsored incentive models may be covered under new safe harbor

New/Revised Exceptions Key Takeaways

1. Impact of Directed Referrals
2. Enhanced Focus on Technology
3. Increased Opportunities for Beneficiary Incentives

Questions & Answers

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