Value-Based Amendments to the Stark Law and the Medicare Anti-Kickback Statute

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Overview

- Background of Stark Law and Medicare Anti-Kickback Statute (AKS)
- Background of and Impetus for Current Amendments to Stark Law and Medicare Anti-Kickback Statute
- Modifications to Existing Stark Regulations
  - Modifications to Existing Definitions and Exceptions
  - New Exceptions (excluding VBE Exceptions and Cybersecurity Exception)
- Modifications to Existing AKS Safe Harbors
- Focus on New Value-Based Enterprise Exceptions/Safe Harbors
- Focus on New Cybersecurity Exception/Safe Harbor
- Modifications to EHR Donation Exception/Safe Harbor

Background

General Overview

- Stark and AKS were each created to combat concerns that financial arrangements between healthcare providers would drive healthcare decision making resulting in higher healthcare costs and lower healthcare quality
- Each law addresses this concern from a different vantage point and uses different tools to do so; the Stark Law is a “strict liability” statute and AKS enforcement is intent based
- Unlike basic healthcare fraud laws, which focus on activities normally identified as fraudulent (e.g., false statements), Stark and AKS dissect common business arrangements between healthcare providers to determine whether one healthcare provider is paying the other healthcare provider (directly or indirectly) in exchange for patient referrals or other types of healthcare business

Background of Stark Law

- Stark is newer of two laws (1991)
- Stark is a civil law, a reimbursement law and strict liability
- Primary sources of guidance for Stark are regulatory text, advisory opinions and cases (the statute is found at 42 U.S.C. §1395nn)
- The Centers for Medicare and Medicaid Services (“CMS”) primarily enforce Stark

Stark Basic Prohibition – Five Factors (Simplified)

- Physician and DHS Provider (“Entity”);
- Referral by Physician to Entity;
- Service or Item Referred is a “designated health service” (“DHS”);
- DHS Referred is payable by Medicare (and probably Medicaid); and
- Physician (or an immediate family member) has a Financial Relationship with Entity.

Note: All of these terms have fixed statutory and/or regulatory definitions

Stark Exceptions

- If Stark applies to a financial relationship between a physician (or immediate family member) and a DHS provider, the financial relationship does not violate Stark if the financial relationship fits into an Exception
- Stark Exception fall into three (3) categories:
  - Exceptions applicable to Ownership/Investment Interests
  - Exceptions applicable to Compensation Arrangements
  - Exceptions applicable to Ownership/Investment Interests and/or Compensation Arrangements involving Certain Types of Services
- Stark Exceptions are like recipes in a cookbook; the more complicated the recipe, the greater the likelihood of failure

Background of AKS

- AKS (enacted in 1972) is a criminal statute
- Primary sources of guidance for AKS are regulatory text, advisory opinions and cases (the statute is found at 42 U.S.C. § 1320a-7b)
- The Office of Inspector General ("OIG") of the US Department of Health & Human Services ("HHS") primarily enforces the AKS

AKS Basic Prohibition – Five Factors (Simplified)

- A health care provider, supplier, or vendor (referral recipient) and a referral source;
- A referral or recommendation by referral source to referral recipient;
- Payment by Medicare, Medicaid, or any other governmental health care program for referred service or item;
- A financial relationship of any type between the health care provider, supplier, or vendor and the referral source ("remuneration"); and
- Intent (the "One Purpose" test).

Note: None of these terms have a fixed statutory or regulatory definition. Instead, these terms are defined (so to speak) by advisory opinions and court decisions.

AKS Safe Harbors

- Given the “intent” factor of an AKS violation, it is difficult to know if a given financial relationship between a referral source and referral recipient violates AKS
- If a referral source and a referral recipient desire absolute certainty that their financial relationship does not violate AKS, they should make certain that the financial relationship fits into an AKS Safe Harbor
- AKS Safe Harbors do not fit into uniform or neat categories
- Like Stark Exceptions, AKS Safe Harbors are like recipes in a cookbook; the more complicated the recipe, the greater the likelihood of failure

Background of and Impetus for Current Stark and AKS Amendments

Background/Impetus

- In 2018, the U.S. Department of Health and Human Services initiated its Regulatory Sprint to Coordinated Care initiative with the goal of clearing regulatory hurdles to the growth of care coordination and value-based care
- As part of this process, CMS and OIG issued formal Requests for Information in 2018 seeking comments from the public that might inform their efforts to achieve these goals
- In response to these comments, on October 17, 2019 CMS and OIG issued Notices of Proposed Rulemaking proposing modifications to the existing Stark Regulations and the existing AKS Safe Harbors, as well as, new Stark Exceptions and new AKS Safe Harbors
- On December 2, 2020, CMS and OIG issued their Final Rules relating to the modifications to the Stark Regulations and the AKS Safe Harbors proposed in their October 17, 2019 Notices of Proposed Rulemaking effective January 19, 2021 (or not)

Modifications to Existing Stark Regulations

Overarching Theme

- Reduce provider self-reporting of non-abusive financial relationships which fail to meet one or more technical requirements of the Stark Law and its Exceptions
- Continues an initiative that began with the October 2015 amendments to the Stark Regulations
- Largely informed by lessons learned by CMS through the administration of the Stark Self-Disclosure Protocol (which went into effect in September of 2010)

Implementation Strategies

- Create clearer definitions of and distinctions between the three (3) pillars of most Stark Law Exceptions, i.e., “Commercially Reasonable,” “Volume or Value of Referrals or Other Business Generated,” and “Fair Market Value,” in order to create bright lines within the Stark Law and reduce the ability to blur these lines when seeking to enforce the Stark Law
- Reduce the rigidity of certain of the key technical requirements of many existing Stark Exceptions, i.e., the writing and signature requirements
- Provide additional means of protecting financial arrangements that fall short of one or more of the technical requirements of the existing Stark Exceptions

Modifications to Existing Definitions and Exceptions

Pillar 1 – Commercially Reasonable

First-Time 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."

Note: Until now, the term "commercially reasonable" was not defined in the Stark Law, despite the fact that it is an element of a number of the most commonly relied upon Exceptions, i.e., rental of office space, rental of equipment, bona fide employment, isolated transaction, fair market value, and indirect compensation

Pillar 1 – Commercially Reasonable

Key Takeaways:

- Commercial Reasonability is not a mathematical calculation nor does it require an appraiser or other valuation professional to determine
- Commercial Reasonability depends on the facts and circumstances of the financial relationship under consideration from the vantage point of the parties to the relationship (i.e., does the financial relationship represent a reasonable way for the parties to reach an appropriate goal of the parties (irrespective of referrals between the parties))
- The fact a financial relationship does not result in profit to one or more parties does not render that financial relationship commercially unreasonable, if the financial relationship accomplishes an otherwise appropriate goal

Pillar 2 – Volume and Value

New Definitions for Compensation to a Physician:

Compensation to a physician takes into account the "Volume or Value" of referrals or other business ***"only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity [or other business generated by the physician for the entity] as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity [or the physician's generation of other business for the entity]."***

Note: For purposes of this definition, a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

Pillar 2 – Volume or Value

New Definitions for Compensation from a Physician:

Compensation from a physician takes into account the "Volume or Value" of referrals or other business ***"only if the formula used to calculate the entity's compensation includes the physician's referrals to the entity [or other business generated by the physician for the entity] as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity [or the physician's generation of other business for the entity]."***

Note: For purposes of this definition, a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

Pillar 2 – Volume or Value

Key Takeaways:

- The new definitions supersede the prior per unit “deeming” rules, except as it relates to analyzing financial relationships during period prior to the promulgation of the new definitions
- The new definitions supersede any contrary reference in the Preamble commentary to previous iterations of or modifications to the Stark Regulations (i.e., “volume or value” is no longer linked to “fair market value” ala **Tuomey**)
- The new definitions do not apply to the following exceptions: medical staff incidental benefit, professional courtesy, community-wide health information systems, electronic prescribing items and services, electronic health records items and services and cybersecurity technology and related services

Pillar 2 – Volume or Value

Key Takeaways:

- CMS clarified that if a physician is paid based on personally performed professional services it does not mean that he/she is being paid based on the volume or value of referrals or other business generated simply because the professional services directly correlate with performance of facility or technical services by the DHS Entity (again repudiating one of the holding in **Tuomey**)

Pillar 2 – Volume or Value

Directed Referrals:

- Question: Does fixed compensation take into account the volume or value of referrals or other business simply because the physician is directed to refer patients to certain designated providers
- Original Answer: No, provided the requirement in set out in writing and signed by the parties and does not apply if contrary to patient preference, managed care requirements, or physician judgement
- Change: Amendment extended the application to the requirements on “directed referrals” to additional Exceptions and reflected a heightened focus by CMS on “directed referrals” overall

Pillar 3 – Fair Market Value

- **Technical modifications to definitions of "fair market value" and "general market value"**
- **Useful Insights** (in commentary in Preamble to Amendments):
  - Extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations, e.g., pay differentials for physicians in rural areas
  - CMS does not favor any specific method of valuation; all CMS requires is a method of valuation that is commercially reasonable and provides evidence that the compensation is comparable to what is ordinarily paid for the item of service in that location by parties in an arms-length transaction and not in a position to refer to one another
  - The fact that the compensation exceeds a certain percentile or other standard on a salary survey or other valuation compilation does not mean, as a matter of fact, that the compensation exceeds "fair market value"
  - Third-party appraisal/valuations of compensation are not need to prove that the compensation is "fair market value"

Other Modifications to Regulations

New Definition of "Indirect Compensation Arrangement"

- Encompasses new definition of "volume or value"
- Directly adds "fair market value" requirement
- Expected to decrease the number of compensation arrangements that qualify as "indirect compensation arrangements" and, as a result, the use of the "indirect compensation exception"

Other Modifications to Regulations

90 Day Grace Period for Both Signatures and Writings (When Requirement of Exception)

- Compensation arrangement still must meet other requirements of an Exception
- May not be used if compensation arrangement expires or is terminated prior to compensation arrangement being documented by a signed writing
- Compensation may not change during 90 day period as changes in compensation during the term of an arrangement must be in writing
- A writing can be a compilation of documents, not just a formal contract
- Signature includes any form of electronic signature valid under federal or state law

Other Modifications to Regulations

Set in Advance Requirement

- "Deeming" rules, as modified, still apply
- In order to meet the "deeming" rules, the method of calculating compensation must be set forth in writing before the items or services are provided
- A method of calculating compensation may be modified during the term of the arrangement and still meet the "set in advance" requirement, provided that the modification is set forth in writing before it goes into effect and only applies prospectively

Other Modifications to Regulations

Period of Disallowance

- Removed regulatory “safe harbor” tying end of period of disallowance to recovery of overpayment/collection of underpayment from physician
- Allows payment reconciliation during term of arrangement and for up to six (6) months after expiration or termination of arrangement without triggering Stark violation, if reconciliation is necessitated by inadvertent miscalculation of compensation

Other Modifications to Regulations

Isolated Transactions Exception

- Clarified that the Isolated Transactions Exception cannot be used to rectify an otherwise non-compliant arrangement with physicians
- Isolated Transactions Exception may, however, be used to resolve actual disputes with physicians

Other Modifications to Regulations

Fair Market Value Exception

- Now available for both space and equipment leases (which provides greater flexibility than space rental exception and equipment rental exception due to fact fair market value exception does not include exclusive use requirement)
- CMS clarified that renewals of short-term arrangements do not need to be written or signed

Other Modifications to Regulations

Payment by a Physicians Exception

- CMS clarified that this exception may be use for any compensation arrangement in which a physician is making a payment to a DHS entity (as opposed to receiving a payment for a DHS entity), except compensation arrangements involving rental of office space, rental of equipment, employment, personal services arrangements, physician recruitment, isolated transactions, arrangements with hospitals unrelated to DHS and group practice arrangements with hospitals

Other Modifications to Regulations

Group Practice Definition

- CMS clarified that for purposes of group practice's allocation of profits from DHS:
  - allocation must be based on "profits" of DHS, not "revenue" from DHS;
  - allocation must include all "profits" for DHS, not just "profits" from subset of DHS;
  - if group practice desires to allocate to "pods" of five (5) or more physicians, each physician may only be in one (1) "pod" (i.e., allocation based on multiple service-line specific "pods" with same physician participating in multiple "pods" no longer permissible
- Modifications do not go into effect until January 1, 2022

Other Modifications to Regulations

CMS De-Coupled Stark Exceptions from AKS

- Removed requirement of AKS compliance as a requirement of all Stark Exceptions, except the Fair Market Value Exception
- CMS acknowledge inconsistency of tying exceptions to a strict liability statute to compliance with an intent-based statute

New Exceptions (Excluding Value-Based Enterprise Exceptions and Cybersecurity Exception)

Limited Remuneration to a Physician Exception

Protects “remuneration” from a DHS entity to a physician for items and services, provided that the remuneration cannot exceed $5,000 per calendar year (adjusted annually for inflation) and the other requirements are met:

- the compensation does not take into account the volume or value of referrals or other business generated by the physician;
- the compensation does not exceed fair market value;
- the arrangement is commercially reasonable;
- if the arrangement covers the lease of office space or equipment, the compensation is not calculated based on a percentage of revenues or a per use basis

Note: This Exception does not require a writing, a signature, or that compensation be set in advance

Modifications to Existing AKS Safe Harbor

Personal Services and Management Contracts Safe Harbor

Major Modifications

- Eliminated requirement that if services are provided on a periodic, sporadic, or part-time basis, agreement must specify the exact schedule of intervals of work, their precise length and the exact charge per interval
- Eliminated requirement that aggregate compensation must be set in advance and now requires that method of determining compensation must be set in advance
- Now permits certain “outcome-based” compensation arrangements based on achieving quantifiable outcomes related to benchmarks selected based on clinical evidence or credible medical support*

*This new protection for “outcome-based” compensation arrangements appears to be an adjunct to the new Safe Harbors for Value-Based Arrangements, but the exact connection is not clear based on available information

Warranties Safe Harbor

Major Re-Write

- OIG performed a substantial re-write of the Warranties Safe Harbor similar to what OIG did when it re-wrote the Discounts Safe Harbor as part of its 1999 revisions and additions to the Safe Harbor Regulations
- The Warranties Safe Harbor is one of the least used Safe Harbors; as a result, the impact of the re-write is difficult to gauge

Complimentary Local Transportation Safe Harbor

Major Modifications

- Increased mileage limitation for transportation provided to patients in rural communities
- Removed mileage limitation for transportation following inpatient admission or release from observation status of at least 24 hours to the patient's place of residence or another residence selected by the patient

Focus on New Value-Based Enterprise Exceptions/Safe Harbors

Basic Premise of Value-Based Enterprise Exceptions/Safe Harbors

Each Exception/Safe Harbor protects:

- Payments or other remuneration
- Between a Value-Based Enterprise (VBE) and a VBE Participant
- Provided that:
  - the payment or other remuneration is in furtherance of accomplishing the goals of a Value-Based Arrangement; and
  - the arrangement meets the requirements of one of three Value-Based Exceptions/Safe Harbors

Important Definitions

Value-Based Activity (VBA) 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

Value-Based Arrangement means an arrangement for the provision of at least one Value-Based Activity for a target patient population to which the only parties are—

- The Value-Based Enterprise and one or more of its VBE participants; or
- VBE participants in the same value-based enterprise

Important Definitions

Value-Based Purpose (VBP) means any of the following:

- Coordinating and managing the care of a Target Patient Population;
- Improving the quality of care for a Target Patient Population;
- Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a Target Patient Population; or
- Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a Target Patient Population

VBE Participant means a person or entity that engages in at least one Value-Based Activity as part of a Value-Based enterprise

Important Definitions

Target Patient Population (TPP) means an identified patient population selected by a Value-Based Enterprise or its VBE Participants based on legitimate and verifiable criteria that—

- Are set out in writing in advance of the commencement of the Value-Based Arrangement; and
- Further the Value-Based Enterprise's Value-Based Purpose(s)

Value-Based Enterprise (VBE) means two or more VBE Participants—

- Collaborating to achieve at least one Value-Based Purpose;
- Each of which is a party to a Value-Based Arrangement with the other or at least one other VBE Participant in the Value-Based Enterprise;
- That have an accountable body or person responsible for the financial and operational oversight of the Value-Based Enterprise; and
- That have a governing document that describes the Value-Based Enterprise and how the VBE Participants intend to achieve its Value-Based Purpose(s)

Value-Based Enterprise Exceptions/Safe Harbors

Stark Law	**Anti-Kickback Statute**
Value-Based Arrangement involving Full Financial Risk	Value-Based Arrangement with Full Financial Risk
Value-Based Arrangement with Meaningful Downside Risk for Physicians	Value-Based Arrangements with Substantial Downside Financial Risk
Value-Based Arrangements	Core Coordination Arrangements to Improve Quality, Wealth Outcomes and Efficiency

Value-Based Arrangements with/involving Full Financial Risk

	Elements	Stark Exception	Anti-Kickback Safe Harbor
1.	VBE at Full Financial Risk within 12 months	✓	✓
2.	Remuneration is for or results from VBA for TPP	✓	✓
3.	Remuneration is not inducement to reduce or limit medically necessary care	✓	✓
4.	Remuneration is not conditioned on referrals of patients outside TPP or business not covered by VBA	✓	✓
5.	If remuneration paid to physician is conditioned on physician's referrals to particular providers, practitioners, or suppliers, the requirement (a) must be set forth in writing, (b) must be signed, and (c) must not apply if contrary to patient preference, contrary to insurer direction, or contrary to physician judgement	✓	N/A
6.	Records maintained for 6 years	✓	✓
7.	Full Financial Risk means the cost of all care prospectively	✓	✓

Value-Based Arrangements with/involving Full Financial Risk

8.	The arrangement is set forth in written agreement	N/A	✓
9.	The VBE does not include remuneration from (a) pharmaceutical manufacturer, wholesaler, or distributor, (b) PBM, (c) laboratory company, (d) compounding pharmacy, (e) manufacturer of medical devices or supplies, (f) DME supplier, or (g) medical device distributor or wholesaler	N/A	✓
10.	Remuneration not in the form of ownership and is not used for marketing	N/A	✓
11.	VBE provides or arranges for quality assurance program service for services furnished to TPP	N/A	✓

Value-Based Arrangements with Meaningful/ Substantial Downside Financial Risk

	Elements	Stark Exception	Anti-Kickback Safe Harbor
1.	Party at Risk	Physician(s)	Any VBE Participants
2.	Excludes participation by (a) pharmaceutical manufacturer, distributor, or wholesaler, (b) PBM, (c) laboratory company, (d) compounding pharmacy, (e) manufacturer of medical devices or supplies, (f) DME company, and (g) medical device distributor or wholesaler.	N/A	✓
3.	Commencement of Risk	Immediate	Within 6 months
4.	Duration of Risk	N/A	1 year
5.	Description and Nature of Risk in Writing	✓	✓
6.	Methodology used to determine remuneration set in advance	✓	✓
7.	Remuneration is for or results from VBA for TPP	✓	✓
8.	Remuneration is not an inducement to reduce or limit medically necessary items or services	✓	✓

Value-Based Arrangements with Meaningful/ Substantial Downside Financial Risk

9.	Remuneration is not conditioned on referrals of patients outside the TPP or business not covered by the VBE.	✓	✓
10.	If remuneration paid to physician is conditioned on referrals to particular providers, practitioners, or suppliers, the requirement (a) must be set forth in writing, (b) must be signed, and (c) must not apply if contrary to patient preference, contrary to manage care requirement, or contrary to physician's judgement.	✓	✓
11.	Records maintained for 6 years	✓	✓
12.	Meaningful/Substantial Downside Risk	Physician responsible to repay or forgo no less than 10% of total value of remuneration earned/received	20 to 30% of losses (depending on how loss is calculated) or PMPM designed to produce material supplies
13.	Full arrangement in writing.	N/A	✓

Value-Based Arrangements

	Elements	Stark Exception	Anti-Kickback Safe Harbor
1.	Arrangement in writing (in detail)	✓	✓
2.	The outcome measures against which remuneration is assessed are objective, measurable and selected based on clinical evidence or credible medical support	✓	✓
3.	Any change in outcome measure is prospective and set forth in writing	✓	N/A
4.	The methodology used to determine remuneration is set in advance	✓	✓
5.	The remuneration is for or results from VBA for a TPP	✓	✓
6.	The arrangement is commercially reasonable	✓	✓
7.	No less frequently than annually the VBE monitors (a) whether parties have actually engaged in VBA, (b) whether/how continuation of VBA will further the VBP of the Value-Based Arrangement, and (c) progress toward obtaining identified outcome measures.	✓	✓

Value-Based Arrangements

8.	If monitoring indicates VBA are not expected to further VBP of Value-Based Arrangement, VBE must terminate the ineffective VBA and either terminate arrangement or replace with new VBA	✓	✓
9.	Remuneration is not an inducement to reduce or limit medically necessary services	✓	✓
10.	Remuneration is not conditioned on referrals of patients not part of TPP or not covered by Value-Based Arrangement	✓	✓
11.	If remuneration conditioned on referrals to particular providers, practitioners, or suppliers, the condition (a) is set forth in writing, (b) signed, and (c) does not apply if contrary to patient preference, contrary to managed care requirement, or contrary to physician judgement.	✓	✓
12.	Records maintained for 6 years	✓	✓
13.	Excludes monetary remuneration	N/A	✓
14.	Recipient pays at least 15% of the cost of items provided	N/A	✓

Value-Based Arrangements

15.	If item relates to technology, cannot limit recipient's use of other technology or mandate additional purchases of technology from donor	N/A	✓
16.	Remuneration must not include: (a) pharmaceutical manufacturer, distributor, or wholesaler, (b) PBM, (c) laboratory company, (d) compounding pharmacy, (e) manufacture of medical devices or supplies, (f) a DME company, or (g) distributor of medical devices or supplies.	N/A	✓

Focus on Cybersecurity Exception/Safe Harbor

Cybersecurity Technology and Related Services

Elements		Stark Exception	Anti-Kickback Safe Harbor
1.	Nonmonetary remuneration consisting of technology (including hardware) and services necessary and used predominantly to implement, maintain, or reestablish cybersecurity	✓	✓
2.	Donor does not determine eligibility for nor amount of technology or services donated in manner that directly takes into account the volume or value of referrals or other business generated between the parties	✓	✓
3.	Donor does not condition donation of technology or services on promise of future referrals	N/A	✓
4.	The recipient does not make the receipt of technology or services or the amount or nature of the technology or services a condition to doing business with the donor.	✓	✓
5.	The arrangement is documented in writing	✓	✓
6.	The documentation is signed by the parties	N/A	✓
7.	The donor does not shift the cost of the donation to Federal health care programs	N/A	✓

Modifications to EHR Donation Exception/Safe Harbor

Modifications

- Removed “blocking” prohibition (deferring to the “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” to address this issue)
- Removed prohibition on the provision of replacement items and services
- Permits recipient’s contribution toward the cost of replacement items and services to be paid after receipt of such items and services
- Permits provision of items intended to protect the security of EHR system as part of items and services provided under the Safe Harbor

QUESTIONS?

Thank You

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