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Stark Law, Anti-Kickback Statute Changes: The Impact on Healthcare M&A

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Buchanan Ingersoll & Rooney PC

BAKER DONELSON

Stark Law, Anti-Kickback Statute Changes: The Impact on Healthcare M&A

June 2, 2022

Agenda

- Brief Overview: Road to the Final Rules
- The M&A Hypothetical
- New, Revised Stark and AKS Rules and Application to M&A Hypothetical
- Potpourri of Additional New, Modified AKS Safe Harbors

The Road to the Final Rules

- June 2018: Initiation of Regulatory Sprint to Coordinated Care with RFI regarding potential changes to Stark Law regulations
- August 2018: Follow-on RFI regarding potential changes to AKS regulations
- October 2019: Issuance of Proposed Rules with stated goal of issuing Final Rules by end of 2020
- December 2020: CMS and OIG publish new Stark/AKS Final Rules in Federal Register, effective 01/19/21, except changes to 42 C.F.R. 411.352 to be effective 01/01/22
- January 20, 2021: Executive Order ordering 60-day pause on Trump Administration regulations not yet effective
- February 18, 2021: CMS issues statement confirming effectiveness, other than those intentionally delayed provisions under 42 C.F.R. 411.352

M&A Hypothetical

Buyer, a private equity company, wants to acquire Ortho, PC, an orthopedic practice with five physicians that also provided in-office PT and radiology. Buyer plans to consolidate Ortho with other orthopedic practices it has acquired and plans to acquire. Buyer will set up a MSO in PA to manage a captive PC (the "Practice") that will acquire the clinical assets of Ortho, PC and employ the Ortho PC physicians after the acquisition, and will compensate the physician under an incentive compensation model. The selling physician shareholders of Ortho, PC will receive cash and roll-over equity in MSO as consideration for the sale of Ortho, PC. The sole shareholder of the Practice is also the medical director of Buyer and will serve simply as a straw/accommodating shareholder. MSO will enter into a management services agreement (MSA) with the Practice and charge the Practice a management fee of 25% of the net patient collections of the Practice. Buyer will also provide Practice with an updated EHR system, including cybersecurity protections, for consistency with other acquired practices.

New, Modified Stark Rules

Stark Issues Identified in Hypo

- DHS
- Employment Agreements
- Productivity Bonuses
- Group Practice
- Management Service Agreement
- Referrals within Practice
- Physician Ownership Interest in MSO

Stark Rules Implicated

- Value and Volume
- Other Business Generated (OBG)
- FMV
- Commercial Reasonableness
- Indirect Compensation
- Personal Service Arrangements (Catch All)

Value and Volume/OBG

- *Compensation Received by a Physician.* Compensation received by a physician takes into account the volume/value of referrals or OBG by the physician only if the formula used to calculate the physician's compensation includes the physician's referrals to or other business generated for 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 to the entity. §411.354(d)(5)(i)
- *Compensation Paid by a Physician*. Compensation paid by a physician takes into account the volume/value of referrals or OBG only if the formula used to calculate the entity's compensation includes the physician's referrals to or other business generated 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 or other business generated for the entity. §411.354(d)(6)(i)

Value and Volume/OBG

- ***"Variable"***
  - According to CMS -- The term "variable" has the meaning it does with respect to general mathematical principles—a symbol for a number we do not yet know.
  - CMS Example: ***Positively Correlates*** -- If an entity pays a physician one-fifth of a bonus pool that includes all collections from a set of services furnished by an entity, including those from designated health services referred by a physician to the entity, the formula used to calculate the physician's compensation is: (.20 × the value of the physician's referrals of designated health services) + (.20 × the value of the other business generated by the physician for the entity) + (.20 × the value of services furnished by the entity that were not referred or generated by the physician). The value of the physician's referrals to the entity is a variable in this formula, as is the value of the other business generated by the physician.

Value and Volume/OBG

- ***"Variable"***
  - CMS Example: ***Negatively Correlates*** – A hospital charges a physician rental charges $5,000 per month and the arrangement provides that the monthly rental charges will be **reduced** by $5 for each diagnostic test ordered by the physician and furnished in one of the hospital's outpatient departments.
  - Under the CMS example, the compensation (that is, the rental charges) would take into account the volume or value of the physician's referrals to the hospital. The mathematical formula that illustrates the rental charges paid by the physician to the hospital would be: Compensation = $5,000 - ($5 × the number of designated health services referrals).

Value and Volume/OBG

- Under a *bona fide* employment relationship, personal service arrangement, or indirect compensation arrangement, a physician may be compensated for his or her **personally performed** services using a **unit-based** compensation formula—even when the entity with which the physician has a direct or indirect compensation arrangement bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the **volume or value** of the physician's referrals or OBG by the physician.
- CMS also acknowledges that the Stark employment exception's "productivity bonus safe harbor" (to the volume/value of referrals standard) is no longer relevant but has not deleted it because it is statutory.

Value and Volume/OBG

- **Application**. The new "definitions" apply to the important exceptions for compensation to physicians for services, personal services, employment, indirect compensation, rent for space or equipment leases.
- Under the past volume/value of referrals and OBG standards, the special "deeming" rules or "safe harbors" for unit-based compensation at § 411.354(d)(2)-(3) were commonly key to complying with the standards. CMS acknowledges that the new volume/value "definitions" have made these "safe harbors" irrelevant but did not delete them.

FMV

- **OLD:** *The value in arm's-length transactions, consistent with the general market value.*
- **NEW:**
  - **General** -*The value in an arm's-length transaction, consistent with the "general market value" of the subject ransaction*.
  - **Fair Market Value Equipment Rental** -*The value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction*.
  - **Fair Market Value 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, and consistent with the general market value of the subject transaction.*

FMV

- CMS reiterated its position from prior rulemakings that it will not prescribe any particular method for determining fair market value and that it will accept a range of methods for determining fair market value. CMS noted that the appropriate method will depend on the nature of the transaction, its location, and other factors. CMS alluded to discussions in prior rulemakings where it provided extensive commentary on potentially acceptable valuation methods (e.g., providing a list of comparable, independent appraisals, documentation of public transactions, and "cost-plus" reasonable rate of return methodologies).
- CMS made clear that it has never said that parties have to obtain an independent appraisal to document fair market value.

Commercial Reasonableness

- **OLD DEFINITION:** No codified definition, but commonly interpreted to have a meaning consistent with 1998 commentary stating that an arrangement is commercially reasonable *if it is a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals*
- **NEW DEFINITION:** *The particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including size, type, scope and specialty.*
- **Profitability:** CMS adopted language that an arrangement need not be profitable to be commercially reasonable but explicitly declined to say commercial reasonableness is unrelated to profitability.

Commercial Reasonableness

- **CMS:** *[A]rrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements. For example, a hospital may enter into an arrangement for the personal services of a physician to oversee its oncology department. If the hospital needs only one medical director for the oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable.*

Indirect Compensation

- General: The financial arrangement can either be direct in that it is between the physician and the DHS provider or indirect in that there are intervening entities.
- Definition
  - Unbroken Chain of Financial Relationships
  - At lease one link in chain must be comp running towards the referring physician – If more than one link, then look to the link closest to the referring physician
  - Comp received by physician will vary with their referrals or OBG for the DHS Entity
  - DHS Entity knows or *should know* the aggregate compensation varies with or takes into account the volume or value of the physician referrals or OBG for the DHS Entity

Indirect Compensation

- NEW
  - Unbroken Chain – Same as pre-Regs
  - At lease one link there is physician compensation running from DHS Entity – Same as pre-Regs
  - The aggregate compensation ***varies*** with the volume or value of referrals or OBG for the DHS Entity down the chain.
  - The ***individual unit of compensation*** is:
    - NOT FMV; or
    - Includes the physician's referrals to or OBG for the DHS Entity as a ***variable***
  - DHS Entity knows or *should know* the aggregate compensation varies with the volume or value of the physician referrals or OBG for the DHS Entity

Personal Services

- Nothing New
  - Set out in writing
  - Arrangement covers all services to be provided
  - Aggregate services contracted do not exceed those that are reasonably necessary for the legitimate business purposes of the arrangement
  - Term of at least one year
  - Compensation is set in advance, does not exceed FMV and is not determined in a manner that takes into account the value or volume of referrals or OBG between the parties
- Percentage fee arrangements?

M&A Hypo Issues – Stark

- Group Practice
- DHS
- MSO management fee percentage of revenues
- Practice PC physician ownership in MSO
- Indirect Ownership by Practice PC physicians in DHS Entity
- Solutions:
  - Fixed Management Fee
  - Carve Out DHS?

New, Modified AKS Safe Harbors Impacting M&A Hypothetical

Personal Services & Management Contracts…

- Eliminates requirement that if agreement provides for services on a periodic, sporadic, or part-time basis, the contract must specify the schedule, length, and exact charge for such intervals
- No longer requires “aggregate” amount of compensation to be set in advance – only method of compensation to be paid over term of agreement must be set in advance

…and Outcomes-Based Payment Arrangements

- Payment triggered by achieving one or more legitimate outcomes measures selected based on clinical evidence or credible medical support to improve quality, material reduction in payor costs or growth in payor expenditures, or both
- Signed, written agreement for at least 1 year that details, at a minimum:
  - General description of services to be performed
  - Outcome measures to be achieved in order to be eligible for outcomes-based payment
  - Clinical evidence/credible medical support relied upon by parties to select outcome measures
  - Schedule for parties to regularly monitor and assess outcome measures
  - Set in advance, commercially reasonable, FMV, does not take into account volume/value of referrals
- No restrictions on medical decision-making or incentives to reduce medically necessary care
- Policies or procedures to address and correct identified material performance failures or deficiencies in quality of care resulting from arrangement

EHR Items and Services Exception and Safe Harbor

- Eliminated 12/31/21 sunset date for safe harbor (and parallel Stark exception)
- Protected donations may include: (i) cybersecurity/other software and services necessary for protection of EHR; (ii) replacement technology
- Expanded eligible donors: (i) individuals or entities engaged in delivering and submitting claims for health care services; or (ii) entities comprised of such individuals or entities (like ACOs)
- Recipient must still contribute 15% of initial or replacement donation, but in the case of updates to previously donated EHR, need not be paid in advance
- Defines "interoperable"

Cybersecurity Technology and Services

- Broader in scope that EHR protections
  - Permits donations of cybersecurity technology, services, and hardware **"necessary and predominantly used"** to implement, maintain, or reestablish **effective** cybersecurity
    - Only covers non-monetary donations, not funds for cybersecurity technology, services, hardware
  - No 15% contribution requirement (can be 100% costs)
  - No limitation on who can be donor or recipient
    - Patients can be eligible recipients of donation
- Other exceptions/safe harbors may apply *(e.g.*, EHR safe harbor, new value-based safe harbors, pre-participation waivers under Shared Savings programs), so consider all possible options when structuring arrangements

Other New and Additional Modifications to Existing AKS Safe Harbors

Local Transportation Safe Harbor

- Expands and modifies mileage limits applicable to patient transportation:
  - From 50 to 75 miles in rural areas
  - Eliminated mileage limits on transportation from inpatient facilities post-discharge (including discharge to home)
- Safe harbor protection remains narrow/limited, and other prior terms still apply
  - 25 mile limitation remains for non-rural areas
  - Does not cover transportation of patients to location of choice or for non-medical purposes
  - Marketing/advertising prohibited
- Prohibition on air, luxury, or ambulance-level transportation remains, but comments to Final Rule permit ride-sharing, taxis services as permitted

Warranties Safe Harbor

- Expands existing safe harbor to include bundled items and services – protects the remedies offered and given if bundled items and services fail to perform as warranted
  - But does not expand to service-only warranties
- Broader definition of "warranty"
- Additional safeguards:
  - 1. All items and services covered under bundled warranty remedy must be reimbursed by same federal health care program and in same federal health care payment (*e.g.*, same MS-DRG payment or same Medicaid managed care payment)
  - 2. Sellers may not impose exclusive-use or minimum-purchase conditions on bundled warranties

Patient Engagement Tools and Support Safe Harbor

- Permits most VBE participants to provide tools and supports up to $500 per patient per year in aggregate as part of a value-based arrangement
- OIG did not specify list of tools/supports but imposed restrictions:
  - Limited to in-kind item, good, or service (not cash or cash equivalent) with direct connection to coordination and management of care of target patient population
  - Must be recommended by patient's health care professional and either: (i) ensure patient safety; or (ii) advance (a) adherence to a treatment, drug regimen, or follow up care plan by licensed professional, or (b) prevention/mgmt. of disease or condition as directed by licensed professional
  - Does not result in medically unnecessary or inappropriate reimbursable items or services
- Availability of tool or support cannot turn on patient's insurance coverage

CMS-Sponsored Model Arrangements…

- Parties to arrangement protected if:
  - CMS-sponsored model parties reasonably determine that CMS-sponsored model arrangement will advance 1+ goals of CMS-sponsored model
  - Exchange of value does not induce parties or other providers/suppliers to furnish medically unnecessary items or services or limit medically necessary items or services
  - Do not offer, pay, solicit, receive remuneration in return for or to induce reward for federal healthcare program referrals or business generated outside the program
  - Advance or contemporaneous signed writing specifying at a minimum: (i) the activities to be undertaken; and (ii) and nature of remuneration to be exchanged
  - Parties make all records available to Secretary upon request
  - Parties satisfy any programmatic requirements imposed by CMS in connection with model arrangement

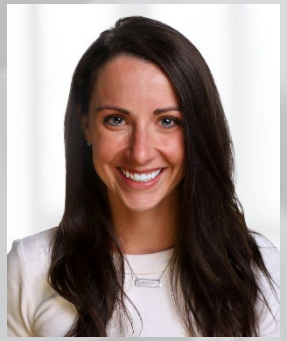
… and CMS-Sponsored Model Patient Incentives

- CMS-sponsored patient incentives protected if:
  - CMS-sponsored model participant reasonably determines that CMS-sponsored model patient incentive will advance 1+ goal of CMS-sponsored model
  - Patient incentive has direct connection to patient's health care unless the participation documentation expressly specifies a different standard
  - Patient incentive is furnished by CMS-sponsored model participant (or by agent under direction and control of participant), unless otherwise specified by participation documentation
  - Records made available to Secretary upon request
  - Patient incentive satisfies any programmatic requirements imposed by CMS

ACO Beneficiary Incentive Program Safe Harbor

- Codified Bipartisan Budget Act of 2018 statutory exception for ACO Beneficiary Incentive programs for MSSP
- Protects incentive payments made by ACO to assigned beneficiary under CMS-approved beneficiary incentive programs, if payments made in accordance with Section 1899(m) of the Social Security Act

THANK YOU



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