Stark and AKS - 2021 Update

Georgia Society for Healthcare Risk Management

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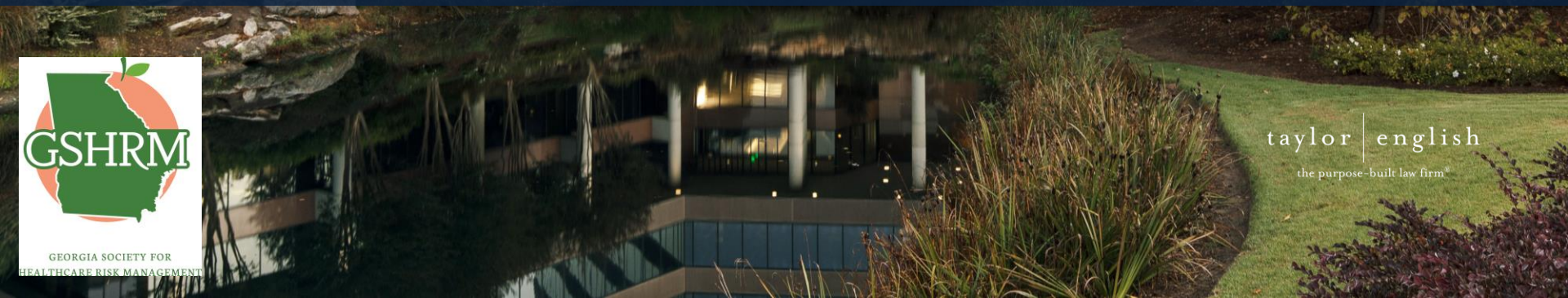

Housekeeping

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The materials referenced here are subject to change, so frequent review of the source material is suggested.

Agenda

1. Stark Law Overview

2. Stark Final Rule:
   A. Modified Definitions for FMV, Commercial Reasonableness, and Volume and Value Concepts
   B. New Exceptions

3. Value Based Concepts and Exceptions

4. Anti-Kickback Modifications

Adoption of Final Rules Modifying Certain Stark Rules

Final Rules Publishes the Final Regulations in the Federal Register on December 2, 2020

The Regulations became effective on January 19, 2020 -- EXCEPT for the revised special rules addressing Profit Shares and Productivity Bonuses in Group Practices, which become effective on January 1, 2022.

The Stark Law

The federal Stark Law prohibits
/a physician /
/from making a referral/
/for a designated health service/
/ to an entity/
/in which the physician (or an immediate family member)/
/has a financial relationship/
/if the service is reimbursed by Medicare (or Medicaid)

See, 42 U.S.C. §1395nn(a)(1).

Unless the arrangement satisfies the requirements of an applicable exception

Designated Health Services

- Clinical laboratory
- Physical therapy
- Occupational therapy
- Speech-language pathology
- Radiology and other imaging services Radiation therapy services
- DME
- Home Health Services
- Outpatient Prescription Drugs
- Inpatient and outpatient hospital services

DHS Exception:
Certain Inpatient Services Are Not DHS

If an inpatient hospital service does not increase the Medicare amount paid to the hospital, then it's not an item of DHS.

Certain Inpatient Services Are Not DHS

An inpatient service is not a DHS payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS):

(i) Acute Care Hospital Inpatient (IPPS);
(ii) Inpatient Rehabilitation Facility (IRF PPS);
(iii) Inpatient Psychiatric Facility (IPF PPS); or
(iv) Long-Term Care Hospital (LTCH PPS).

Isolated Transaction (411.357[f])

The exception protects "single payments for a single exchange of value“ – like the one time purchase of a physician practice.

CMS clarified that the exception cannot be used to “cure” inadvertent Stark Law violations. For example, say a hospital discovered it paid a referring 1099 physician for services that were not set forth in a signed writing. The services were provided over a period of months.

Cannot use the Isolated Transaction exception to find an exception where no others applied. The problem is that the services here weren’t isolated.

Limited Physician Remuneration (411.357[z])

A "get out of jail free" card – covers payments to physicians up to $5,000 in the aggregate per calendar year.

CMS kept seeing hospital self-reporting to CMS for payments they made to referring physicians whose services were needed -- but the hospitals failed to put the payment in a written agreement or failed to sign the agreement.

This new exception allow physicians to be paid up to $5,000 per calendar year (adjusted for inflation), in the aggregate, for items or services provided by the physician (directly or through employees, a wholly owned entity or through *locum tenens* physicians) without a signed writing or compensation set in advance.

Reconciling Non-Compliant Compensation (411.353[h])

Say a compensation arrangement with a hospital ends and 60 days later the hospital accounting office finds that the hospital paid the doctor too much during the term of the arrangement.

This new exception says that no Stark Law violation will occur if if all payment discrepancies are reconciled within 90 consecutive calendar days of expiration or termination of the compensation arrangement.

Physician Recruitment Modification
42 CFR 411.357(e)(4)

Stark permits hospitals and FQHC's to pay a physicians or physician practice certain costs to recruit doctors to the hospital's area without incurring Stark violations.

The former rule required that the recruiting entity (hospital), the physician practice, and the recruited physician all had to sign one document.

Sometimes the recruitment payments go directly to recruited physician or the physician practice passes all of the payment directly to the recruited physician who joined the practice.

"Gotcha" moments occurred when hospitals discovered that not all three parties signed the agreement, likely because the practice did not receive any money. The hospitals had to self-report the error.

The Final Rules change the rule to require the physician practice to sign the documents only if the practice keeps any of the recruitment money.

Writing & Signature Requirements (411.354[e])

Say that a physician practice hires a physician and starts paying the doctor before all the paperwork is signed. Any DHS referral of the doctor to the entity before signing the paperwork is a Stark violation.

The Final Rule modifies the rule to say that as long as parties obtain the required writings and signatures within 90 consecutive calendar days, the arrangement is *deemed* to have met the writing and signature requirement.

Office and Equipment Lease Exception (411.357[a] and [b])

This modification loosened the requirement that for purposes of the Leased Office Space and Equipment exceptions, the lessor may lease the equipment to more than one lessee.

In other words, use of the space and items is exclusive as against the lessor, but not to any one or more lessees.

Modification to Directed Referrals Rule (42 CFR § 411.354(d)(4))

Stark has always permitted entities that employ or contract with physicians to require the doctor to refer to the employer (such as the employer-hospital) as long as the compensation is set in advance, not related to the volume or value of referrals, and the patient does not show a desire for another provider.

The Final Rules add the following requirements:

- **The contract cannot be contingent on referring a minimum number of patients. So a hospital cannot fire a physician for not referring enough patients.**
- **But the hospital and doctor can set a minimum number based on the a percentage of the total patients seen by the physician to be referred to the hospital. If the physician failed to refer that percentage to the particular provider, the employer could fire the doctor.**

Group Practice Changes (411.352)

Special Rules for Profit Distribution.

Confirmed the principle that distributions of DHS profits cannot be based on the volume or value of referrals – but added a provision allowing payment of DHS profits directly to the referring physician in the group if the profits derive from a Value Based Enterprise

Clarified that revenues do not equal profits. Distributions are based on the profits from DHS, not revenues derived from DHS.

Group Practice Changes (411.352)

Special Rules for Profit Distribution.

Clarified that a "profit per service line" interpretation is inaccurate. All DHS profits earned throughout the group (or a five-member or more pod) must be aggregated before distribution. Cannot segregate and distribute on a service-by-service basis.

Clarified that Groups can create as many pods of five or more physicians who refer a certain line of DHS. Each pod can establish a distribution formula different for each pod, as long as each doctor in the pod is treated the same.

Tweaking Three Key Definitions Used to Insure Compliant Compensation Arrangements

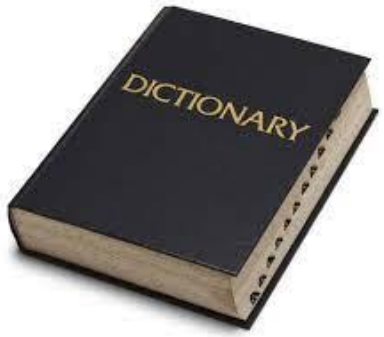
Hospitals and other must be sure that anything paid to physicians must meet a compensation exception to comply with Stark.

Meeting a compensation exception usually requires that the dollars satisfy the following three elements.

"Commercial Reasonableness"

"Volume or Value" and "Other Business Generated" Standards

"Fair Market Value" and "General Market Value" Definitions



The Final Rules attempt to clarify these concepts by tweaking the language.

Commercial Reasonableness

No Prior Definition

The Concept is key in the Stark Universe:

All Stark compensation exceptions, except the value-based arrangement exceptions, that have a "commercially reasonable" element require that the compensation to the physician (or immediate family member) be paid pursuant to an arrangement that would be commercially reasonable (as defined above) *even if there were no referrals by the physician to the employer or between the parties*.

CMS clarifies that the reference to "even if no referrals were made [to the employer] or between the parties" means *designated health services (DHS) (Medicare-covered) referrals*, not "other business generated.

Commercial Reasonableness – New 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."

Losers Accepted. Not tied to CMS clarified that "commercially reasonable" arrangements may be money losers. For example, paying doctors fees for on-call coverage may exceed the value of the services, but hospital call is necessary to keep the hospital open

Individual Cases. Determinations will be made on a case-by-case, facts and circumstances basis primarily asking whether the arrangement "makes sense as a means to accomplish the parties' goals."

Establishing Commercial Reasonableness

Questions to Ask:

- Is there genuine need for the services/property?
- Is there a genuine need for the *amount* of
- services/property?
- Is there a lower cost alternative to the referral source?
- Does the referral source have the training, experience, skills and time to perform the service as well as a non-referral, or lower-referral source?

"Fair Market Value" and "General Market Value"

Tweaked FMV Definition. FMV, as it relates to compensation arrangements, is now defined as "[t]he value in an arms-length transaction, consistent with the general market value (GMV) of the transaction."

General Market Value. GMV means "with respect to compensation for services, 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."

FMV of Leased Space and Equipment. CMS provides slightly different definitions of FMV and GMV when applied to leased assets or space and equipment.

Salary Surveys ≠ FMV of Physician Compensation

Salary surveys, in and by themselves, do not constitute FMV.

"It is not CMS policy that salary surveys necessarily provide an accurate determination of fair market value in all cases."

Compensation set at or below the 75th percentile is not always FMV

CMS expressly disavowed the urban myth that compensation set at or below the 75th percentile of the physician compensation survey data is always appropriate, and that compensation above the 75th percentile is suspect, if not presumed inappropriate."

A hospital may not value a physician's services any differently than an independent, private physician practice.

A hospital may not value a physician's services at a higher rate than a private equity investor or another physician practice would.

Volume or Value Standard

Does a Compensation Formula Consider "Volume or Value" of Referrals or Other Business Generated?

To Find Out, Ask these Two Questions:

1. Does the formula have a mathematical formula that includes DHS or other business generated as a variable?

2. Does the doctor's compensation increase or decrease based on a positive or negative correlation with the physician's referrals or other business generated?

If answer to both questions is "YES," then the compensation reflects the value or volume of DHS referrals or business generated.

Value Based Exceptions

Value Based Arrangements

The Stark rules generally operate to restrict coordinated care among related providers, driving up costs and perhaps reduced outcomes.

CMS used the Final Rules to eliminate many of these frictions by adopting sweeping exceptions for use in “Value-Based Arrangements.”

The Final Rules adopt three new exceptions related to remuneration for arrangements between a Value-Based Enterprise (“VBE”) and one or more VBE participants that are intended to achieve one or more Value-Based Purposes.

Value Based Definitions

"**Value-based enterprise**" means two or more VBE participants that are 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. The VBE is required to have an accountable body and a governing document.

• "**Value-based purpose**" means (1) coordinating and managing the care of a target patient population, (2) improving the quality of care for a target patient population, (3) appropriately reducing costs without compromising quality, or (4) transitioning from health care delivery mechanisms based on volume to mechanisms based on value.

• "**Value-based arrangement**" means an arrangement to provide at least one "value-based activity" for a target patient population to which the only parties are (1) the VBE and one or more VBE participants or (2) two or more VBE participants in the same VBE.

• "**Value-based activity**" is defined as providing an item or service, or taking or refraining from taking an action, that is reasonably designed to achieve at least one of the VBE's value-based purposes. A value-based activity does not include the making of a referral.

Three Remuneration Exceptions

The new exceptions operate to remove Stark prohibitions on remuneration paid:

(1) within a value-based enterprise that assumes “full financial risk”;

(2) to a physician who assumes “meaningful downside financial risk”;

(3) when participants to a value-based arrangement do not assume financial risk, but the arrangement nonetheless encourages the delivery of coordinated patient care and promotes the goals of transitioning to a value-based payment model.

Creating a Value Based Arrangement

Memorialize the Arrangement in a writing signed by the VBE Participants

The "value-based arrangements exception" to the Stark Law protects value-based arrangements that are set forth in a writing (signed by the parties) that details the following:

- the value-based activities to be undertaken under the arrangement;
- how the value-based activities are expected to further the value-based purpose(s) of the VBE;
- the target population for the arrangement;
- the type or nature of the remuneration;
- the methodology used to determine the remuneration; and
- the outcome measures against which the recipient of the remuneration is assessed, if any (which outcome measures must be objective, measureable, and selected based on clinical evidence or credible medical support).

Industry Response

Baby Steps on a Long Road

Anti-Kickback Law

There Can Be No Quid Pro Quo

It is unlawful for anyone to knowingly and willfully solicit or receive any payment in return for referring an or induce individual to another person or entity:

for the furnishing, or arranging for the furnishing, of any item or service that may be paid in whole or in part by any federally-funded health care program.

See 42 U.S.C. § 1320a-7b(b)

Anti-Kickback Law

The statute is a two-way street.

Soliciting for and accepting payments in return for referrals is as bad as paying the kickback itself

Value Based Remuneration Exceptions - AKS

The new exceptions operate to remove AKS prohibitions on remuneration paid:

(1) within a value-based enterprise that assumes “full financial risk”;

(2) to a physician who assumes “meaningful downside financial risk”;

(3) Substantial Downside Risk.

Full Financial Risk Exception - AKS

Full Financial Risk Arrangement

A full financial risk arrangement exists where a VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target population for a term of at least 1 year. 42 C.F.R. § 1001.952(gg)(10)(i).

Must satisfy 9 requirements:

Meaningful Downside Risk Exception – Stark/AKS

Meaningful Downside Risk Arrangement

Requires a physician to be at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value- based enterprise during the entire duration of the value- based arrangement.

"Meaningful downside financial risk" means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

Substantial Downside Risk Exception – AKS

Substantial Downside Risk Arrangement

"Substantial downside financial risk" circumstances for AKS purposes exists under a variety of criteria, each of which reflects a physician's facing a risk of losing certain reimbursement based on meeting or failure to meet certain bona fide benchmarks.

AKS Change - Personal Services and Management Contracts Safe Harbor (42 CFR 1001.952[d])

- Eliminates requirement that part-time arrangements must specify the exact schedule, precise length and the exact charge for those intervals
- Modifies set-in-advance compensation element in favor of a "set-in-advance" formula for compensation

New AKS Safe Harbor for Patient Engagement and Support (42 CFR 1001.952[hh])

- Allows value-based enterprise participants or their "eligible agents" to provide certain support tools to certain targeted patients to engage them in promote improved quality, health outcomes, and efficiency.

- Support tools include health-related technology, patient monitoring tools and services, and services designed to identify and address social determinants of health

- Certain restrictions, including:
  - The VBE participant is an eligible participant (ie, not a device supplier);
  - The tools or support are furnished directly to the patient by a VBE participant or eligible agent;
  - The aggregate retail value of the tools or support on an annual basis does not exceed $500.

New AKS Safe Harbor for Cybersecurity Technology
(42 CFR 1001.952[jj])

- Donations can be hardware or software
- The donation must be “necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity.
- Requires a Written agreement
- No monetary cap on the cost of technology distributed
- Anybody can be a donor or a recipient.

Examples of Items of Cybersecurity under the Safe Harbor

Valuable Items you can accept from referral sources without AKS Risk:

- Locally installed and cloud-based cyber security software
- EHR, devices, and other information technology
- Patches and updates
- Cybersecurity training services, such as training recipients on how to:
  use the cybersecurity technology
    - prevent, detect and respond to cyber threats
    - troubleshoot problems with the cybersecurity technology (for example, "help desk" services specific to cybersecurity)
- Business continuity software that mitigates the effects of a cyberattack
- Data recovery services
- Services associated with performing a cybersecurity risk assessment or analysis, vulnerability analysis or penetration test
- Cybersecurity hardware

QUESTIONS?

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