

Stark and Anti-Kickback Final Rules: The Regulatory Sprint Crosses the Finish Line

Session One: Stark and AKS Final Rules

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Agenda

- **What we are not covering today: the Value-Based Stark Law exceptions and Anti-Kickback safe harbors.**
 - Please join us again on 12/17!
- **What we are covering: everything else**
 - Changes to Stark Law exceptions and regulations (Jesse Witten and Tom Schroeder)
 - Stark Law “group practice” definition (Jennifer Breuer)
 - New AKS safe harbors (Steve Lokensgard)
 - EHR and Cybersecurity Stark Law exceptions and AKS safe harbors (Jeff Ganiban)
 - New AKS safe harbor for telehealth for dialysis patients (Kelley Taylor Hearne)

New Definitions for “the Big Three” Requirements

- **“Separate and distinct” requirements that address different questions.**
 - “Commercially Reasonable” – Does the arrangement make sense as a means to accomplish the parties’ goals?
 - “Take into Account the Volume or Value of Referrals” – How did the parties calculate the remuneration?
 - Fair Market Value – Did the calculation result in compensation that is fair market value?

“Commercially Reasonable”

- **“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.”**
 - Defined for first time in regulations, but “consistent” with prior preamble discussions.
 - Not a valuation question. “Sensible” is subjective test, i.e., from perspective of the particular parties.
 - Duplicative agreements are not commercially reasonable (e.g., hospital with redundant and unnecessary medical directorships).
 - Unprofitable arrangement may be commercially reasonable, e.g., due to community need, to promote timely access to care, for licensure/regulatory needs, for charity care, to improve quality.
 - Profitability not entirely irrelevant. If “no identifiable need or justification other than to capture the physician’s referrals” there may be no legitimate business purpose.

“Volume or Value of Referrals”

- **Several exceptions state that compensation may not be determined in a manner that “takes into account the volume or value of referrals [or other business generated between the parties].”**
 - “Referrals” means referrals of Medicare patients.
 - “Other business generated between the parties” includes private pay and any other business.
- **Previously, the volume/value standard was not defined. Instead, “special rules on compensation” told us only when unit-based compensation would *not* be deemed to vary with volume/value.**
- **Now, CMS adopts an objective definition of when compensation *does* vary with volume/value.**
- **Compensation takes into account volume/value only if “the formula used to calculate the ... compensation includes the physician’s referrals to the entity as a variable” that positively correlates with the number or value of the physician’s referrals [or other business generated].**

“Volume of Value of Referrals”

- **The definition of volume/value only applies prospectively. The unit-based special rule remains, but only has historical relevance.**
 - In other words, the pre-existing “special rules” on unit-based compensation will not protect prospective compensation that falls within the new definition.
- **Previously, DOJ and courts (e.g., Tuomey) had viewed wRVU-based compensation as “taking into account the volume or value” of referrals when there is a corresponding service that the hospital bills for.**
 - CMS expressly rejects this position. The “correlation theory” is dead.
 - Compensation for personally performed services (i.e., wRVU-based compensation) does not pose a “volume or value” problem even if the physician’s services are associated with a facility or service fee that the hospital can bill (e.g., DRG, APC, etc.).

Some “Volume or Value” Questions

- **Can hospital compensate physician based on hospital’s overall achievement of financial goals? *E.g.*, bonus if hospital achieves a 2% gross margin.**
 - CMS said it depends.
- **Does tiered compensation take into account the volume or value of referrals? Paying physician \$X dollars for first 50 procedures and \$(X+20) for additional procedures?**
 - CMS declined to answer.

“Volume or Value” & Directed Referrals

- **Previously, Stark regulations allowed for “directed referrals” in employment, professional services and managed care agreements – with three exceptions for patient preference, insurance, physician judgment.**
- **Now, the directed referrals provision is broadened and cross-referenced in certain exceptions: academic medical centers, employment, personal services, FMV compensation, indirect compensation and limited remuneration.**
 - Existence or amount of compensation may not be contingent on “number or value” of physician’s referrals to a particular provider, practitioner, supplier.
 - May require a certain percentage of referrals be to particular provider, practitioner, supplier.
 - Same three exceptions apply as before.
- **Keep in mind:**
 - If your physician employment contracts include directed referral provisions, Stark will not allow you to change the compensation “for the duration of the arrangement.”
 - Requiring referrals poses potential AKS problems where there is no safe harbor protection.

Fair Market Value

- **Clarifies and reorganizes existing definitions of “fair market value” and “general market value.”**
- **Keeps requirement that GMV reflects price that would be agreed to by parties not in position to make referrals/generate business.**
- **Separate statements for compensation, rental of equipment, rental of space, purchase of assets.**
- **FMV: Value of an arms-length transaction, consistent with GMV.**
- **GMV: With respect to [compensation] [rental of equipment] [rental of space] [asset purchase], the amount that would be determined based on “bona fide bargaining” between “well-informed” parties “that are not otherwise in a position to generate business for each other.”**
- **Also for rental of office space:**
 - No “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.” (This is not new).

Fair Market Value *cont.*

- **FMV can be determined based on any reasonable method.**
- **FMV for physician services “may not always align with” salary surveys but they provide an “appropriate starting point” and “may be all that is required.”**
 - Example – Orthopedic surgeon is one of the “top” in the country, highly sought after by professional athletes with knee injuries due to specialized techniques and success rate.
 - Example – Family physician in a geographic area is low, but location has good schools and recreational opportunities, and hospital with tenuous finances. FMV may be less than salary survey.
 - Example – To attract a cardiothoracic surgeon who can perform emergency surgeries – may require payment above salary survey specified range.
- **CMS disclaims having any policy that compensation above 75th percentile “is suspect,” or that compensation below 75th percentile is always appropriate.**

DHS Redefined to Exclude Services Ordered for an Inpatient that Don't Increase Reimbursement

- **Revised definition of DHS such that services ordered by a physician that do not increase a hospital's inpatient PPS reimbursement are not DHS.**
 - Acute Care Hospital Inpatient PPS
 - Inpatient Rehabilitation Facility PPS
 - Inpatient Psychiatric Facility PPS
 - Long-Term Care Hospital PPS
- **Examples:**
 - Writing an order for an inpatient admission is referring for DHS.
 - Specialist orders an x-ray for an already-admitted inpatient. The x-ray is not considered DHS unless the case is an outlier.
- **Outlier – Cases with very high costs receive additional payment in addition to the DRG-based reimbursements.**
- **Revised definition does not apply to Hospital Outpatient PPS.**

New Tools for Non-Substantive Issues

- **90 days to obtain writing and signature, where writing and signature are required; electronic signatures okay if “valid under Federal or state law” (including a typed signature)**
- **Easier for compensation to qualify as “set in advance”**
 - Initial compensation terms need not be in writing to be “set in advance” so long as they are agreed to (and 90 days to obtain the writing).
 - But a change in compensation must be in writing before items/services are furnished in order to be “set in advance.”
 - Day One – \$500 per shift for on-call agreement need not be in writing. Day 75 – Rate upped to \$600; the \$600 term must be in writing before the rate change takes effect.
 - Need not extend contract for a year if compensation terms change.
 - Can change compensation terms any number of times.
- **New provision allowing 90 days at end of financial relationship to reconcile payments.**
 - No violation if discrepancies are corrected as discovered, but knowing failure to correct discrepancy could create a whole new comp arrangement.

New Exception: “Limited Remuneration to a Physician”

- **Covers remuneration from an entity to a physician for furnishing items and services if remuneration does not exceed an aggregate \$5,000 per calendar year (inflation-adjusted) and following elements are met:**
 - Compensation does not take into account volume or value of referrals or other business generated between the parties
 - FMV compensation
 - Commercially reasonable even if no referrals made
 - For lease of office space or equipment, rental rate is not per-click and not a percentage of revenues from use of the space or equipment
 - Directed referrals provision applies
 - (No “set in advance” requirement)
- **Physician may provide the items or services through others.**
- **“Stand in the shoes” applies – Payments to a group practice count towards the \$5,000 limit for each shoe-standing doctor.**
- **The \$5,000 limit resets each calendar year. Arrangements straddling 12/31 could have more than \$5,000 protected.**
- **Can be combined with other exceptions (this might cover first \$5,000 and then the arrangement is documented and covered by another).**

Other Stark Regulatory Changes

- **Decoupling Stark from other requirements:**
 - Removes compliance with AKS as an element of Stark exceptions, except keeps it as an element of the FMV Compensation Exception.
 - Removes compliance with Medicare billing rules as an element of Stark exceptions.
- **Rental of Office Space and Rental of Equipment Exceptions**
 - Clarifies that provision requiring “exclusive use” by lessee does allow for other lessees to use the space or equipment, only that the lessor cannot.
 - FMV exception may now be used for rental of space or equipment!
- **Isolated Transaction Exception**
 - Explains that this exception covers an agreement to settle a good-faith dispute, but does not cover the underlying arrangement that gave rise to the dispute.
 - Clarifies that exception does not cover a single payment for services provided over multiple occasions.

Other Stark Regulatory Changes *cont.*

- **Payment by a Physician**

- Covers FMV payments by a physician for items or services not specifically addressed by another statutory exception (e.g., can't be used for office space, but could be used for residential rental).
- Removes all other elements of this exception.

- **Fair Market Value Compensation Exception**

- Can now be used for rental of office space (helpful because does not require one year duration).

- **Physician Recruitment Exception**

- Requires a physician practice to sign the recruitment agreement only if it receives a payment from the hospital that is not entirely passed through to the recruited physician.

- **Remuneration Unrelated to the Provision of DHS Exception**

- Did not change this exception, which currently has virtually no application.
- Will continue to evaluate.

Other Stark Regulatory Changes *cont.*

- **Changes to Exception for Compensation Arrangements with Physicians for Recruitment of Nurse Practitioners**
- **Technical changes to definition of “indirect compensation arrangement” that narrows its scope.**
- **Clarified the carveout from “remuneration” of free single-use specimen collection items provided to a physician.**
 - Single-use items provided by an entity to a physician for, and in fact used for, specimen collection for the entity are not “remuneration.”
 - Deletes former limitation of the carveout to specimen collection items that were classified as “surgical.”
- **Revises definition of ownership to carve out “titular” ownership by a physician and ownership by a physician through an Employee Stock Ownership Plan.**

Group Practice Definition

- **The Final Rule “clarifies” the definition of Group Practice, including what it means to distribute “overall profits” of the Group Practice.**
- **Historically, “overall profits” were:**
 - Group Practice’s entire profits derived from DHS
 - Profits derived from DHS of any component of the Group that includes at least five physicians
- **Allowed for argument that “split pool” of DHS profits was permissible, such that profits could be allocated on service-by-service basis**
- **As clarified, “overall profits” means:**
 - Group Practice’s entire profits derived from all DHS; or
 - Profits derived from all DHS ordered by any component of the Group that includes at least five physicians
- **In both instances, DHS profits must be aggregated before distribution; no split pool (i.e., service-by-service) allocation allowed**
 - Allocation need not be the same for each pod of at least five physicians

Group Practice Definition *cont.*

- **Example of Overall Profit Distribution**

- Group Practice comprised of 15 physicians, divided into three pods (A, B and C) of five physicians each.
- Step One: Allocate all DHS profits from the physicians to their respective pods (A, B and C)
- Step Two: Distribute all DHS profits allocated to each pod among its members: A – per capita; B – personal productivity; C – other methodology not directly related to volume or value of DHS referrals
 - OK to use eligibility standards to determine who is eligible for distributions
 - Length of time with practice
 - Full- vs. part-time status
 - OK to retain some portion of the profits and distribute others
 - Not OK to distribute DHS profits from DHS [X] one way, DHS [Y] another way
- **To allow Group Practices the time to change any noncompliant compensation formulas in manner that will be “set in advance,” clarifications do not take effect until January 1, 2022**

Anti-Kickback Statute Safe Harbors

- **Patient Engagement Tools and Supports**
- **Warranties**
- **Local Transportation**
- **EHR and Cybersecurity**
- **Telehealth for Dialysis**

Patient Engagement Tools and Supports

- **Historic Background**

- Incentives to promote preventive services
 - Gift card if you got a mammogram or colonoscopy
- Waivers to promote:
 - Adherence to a treatment regime
 - Adherence to a drug regime
 - Adherence to a follow-up care plan
 - Management of a chronic disease or condition

Patient Engagement Tools and Supports *cont.*

- **New Safe Harbor**

- Permits a **Value-Based Enterprise**
- To provide a **target population**
- With **Tools and Supports**
- Worth less than \$500 per year
- To promote:
 - Adherence to a treatment regime
 - Adherence to a drug regime
 - Adherence to a follow-up regimen
 - Prevention or management of a disease or condition
 - Ensure patient safety

Patient Engagement Tools and Supports *cont.*

- **Tools and Supports**

- Health-related **technology**
 - Example: TytoCare Kits
- Patient health-related **monitoring tools and services**
 - Dexcom G6 Continuous Glucose Monitoring
 - Wi-Fi scale
- Supports and services designed to identify and address **social determinants of health**
 - Home modifications such as grab bars, air filters or purifiers
 - Broadband access to enable remote patient monitoring
 - Grocery or meal delivery services
 - Exercise or fitness programs or equipment
- Must not be cash or a “cash equivalent”
 - Limited-purpose gift cards OK
 - Payment to a utility company could be OK

Warranties

- **Expands the warranty safe harbor to include bundled items and services**
 - The bundled item or service cannot have an independent value to the patient
 - Example: can't provide free or discounted lab service as part of a warranty agreement because it has an independent value
- **No extension of warranty safe harbor for services**
 - Example: warranty on a joint replacement service

Local Transportation

- **The local transportation safe harbor contains certain key elements.**
 - The transportation provided must not involve air, luxury or ambulance-level transportation
 - The transportation may only be provided to an “**established patient**”
 - The transportation must be provided within a provider’s **primary service area**, which is identified as a certain radius from the provider’s location
 - The transportation may be in the form of a shuttle service
 - The provider must not publicly market or advertise the free or discounted local transportation services
- **Primary Service Area**
 - 25-mile radius
 - 2020 rule expands to 75-mile radius for providers in rural areas
- **Clarification**
 - Permissible to use taxis and ride share services like Uber or Lyft

EHR Items, Services Exception and Safe Harbor

- **Summary of key changes:**

- Sunset date of December 31, 2021 has been eliminated, making the EHR exception and safe harbor permanent
- The “no equivalent technology” requirement has been eliminated, allowing for protection of donations of replacement technology
- 15% “in advance” contribution requirement remains in effect for new and replacement EHRs
- Expanded the list of “protected donors” allowing entities such as parent companies of hospitals, health systems and accountable care organizations (ACOs) as permissible donors
- Donation of cybersecurity fits within the EHR exception and safe harbor so long as the donated cybersecurity items are “necessary and used predominately to ... protect health records”
- Clarification of the definition of interoperable and the circumstances under which EHR technology will be deemed interoperable
- Elimination of prohibitions around information blocking, as such prohibited conduct will now be regulated under the Information Blocking Rule

Cybersecurity Exception and Safe Harbor

- **Exception and Safe Harbor are intended to be broad in scope, with the stated intent being protection of arrangements that are intended to address the growing threat of cyberattacks impacting the health ecosystems.**
- **Broader in scope than the EHR Donation Exception and Safe Harbor.**
- **Donation can cover 100% of the costs of donation of eligible cybersecurity technology and services.**
- **Donation-eligible cybersecurity technology and services are broadly defined:**
 - Safe Harbor covers cybersecurity technology and services that are “necessary and used predominantly to implement, maintain reestablish effective cybersecurity.”
 - Stark Exception adopts the same definition, with elimination of “effective.”
 - Can include cybersecurity hardware that is “necessary and used predominantly to implement, maintain reestablish effective cybersecurity,” although OIG and CMS expressed significant concerns about the donation of “multifunctional hardware”?

Cybersecurity Exception and Safe Harbor *cont.*

- **No limitations on who can be a donor or recipient.**
- **Limitations:**
 - Donations must be non-monetary.
 - The donor does not directly take into account the volume or value of referrals or other business generated between the parties.
 - The recipient does not require the donation as a condition of doing business (including future referrals) with the donor.
 - The arrangement is documented in writing (with flexibility regarding the manner of documentation).
 - Note: Safe Harbor requires that the documentation be signed by the parties.
 - The Safe Harbor requires that the donor must not shift the cost to any Federal health care program.

AKS Safe Harbor for Telehealth for Dialysis Patients

- **Exception to definition of “remuneration” for the provision of telehealth technologies to patients receiving in-home dialysis services.**
- **A technology agnostic definition of “telehealth technologies”:**
“hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention, or ongoing care management.”
 - May include multifunctional devices that have purposes beyond furnishing telehealth services related to ESRD.
 - Technology examples in the Final Rule are not intended to be exhaustive.

AKS Safe Harbor for Telehealth for Dialysis Patients *cont.*

- **The provision of telehealth technologies will not constitute prohibited remuneration if all of the following conditions are met:**
 1. Provided to an individual with ESRD
 2. Individual is receiving in-home dialysis care
 3. In-home dialysis care is being paid for under Medicare Part B
 4. Provided by the provider of services, physician or the renal dialysis facility that (i) is currently providing the in-home dialysis, telehealth services or other ESRD care to the individual, **or** (ii) has been selected or contacted by the individual to schedule an appointment or provide ESRD related services (i.e. patient-initiated contact)
 5. Not offered as part of an advertisement or solicitation
 6. Provided for the purpose of providing telehealth services related to the individual's ESRD
 - **Best practice:** Document how the telehealth services are related to the individual's ESRD care, such as to management of care, monitoring of health, or treatment, since it is a facts and circumstances assessment.