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HEALTHCARE MARKET REVIEW

What Physicians Need to Know About Provider Compensation Issues – New Safe Harbors and Exceptions Offer Opportunities

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PRESENTERS

Lani M. Dornfeld, Esq., CHPC
Member, Brach Eichler LLC

Lani represents a broad range of health care providers– both institutional and individual– in regulatory matters, including fraud and abuse, corporate compliance, HIPAA, OSHA, Medicare and licensure issues. She also represents clients in various corporate and contract matters and manages purchase and sale transactions, including private equity transactions, from letter of intent through due diligence, contract drafting and negotiation, closing and post-closing matters.

Lani is certified in healthcare privacy compliance (CHPC) by the Compliance Certification Board. Named among The Best Lawyers in America© in 2020 and 2021, Lani has also been peer-review rated as AV Preeminent, the highest rating for professional excellence by Martindale-Hubbell. She has also been selected as one of New Jersey's Women Leaders in the Bar by Martindale-Hubbell and ALM, publishers of the *New Jersey Law Journal*. In addition, Lani was recognized as a Top Legal Leader for New York and New Jersey by ALM in 2015 and was named a "2013 Top Rated Lawyer in Health Care" by American Lawyer Media and Martindale-Hubbell.

Carol Grelecki, Esq.
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Carol represents a wide range of health care providers, including single-specialty and multi-specialty physician practices, as well as institutional providers and ancillary services providers. She concentrates her practice on corporate and transactional matters, mergers and acquisitions, private equity and hospital-physician transactions, billing and reimbursement issues, and licensure and regulatory compliance, with a particular concentration in fraud and abuse, Stark and Codey law compliance, Anti-Kickback law, and payor contracting issues.

Carol has been named among The Best Lawyers in America© for Health Law every year since 2015, and New Jersey Super Lawyers every year since 2018. Additionally, she has been named as a top healthcare law practitioner by noted ranking company Chambers USA. According to Chambers, Carol is noted by her peers as an "outstanding lawyer."

Deborah Nappi, CPA, MST
Partner, SAX LLP

Debbie Nappi was named Partner at Sax in 2022 and serves as Co-Leader of the firm's Healthcare Practice. She is an advocate for her clients, and specializes in consulting services, revenue cycle management and physician productivity. Debbie focuses her attention on the rapidly changing healthcare landscape. In this role, she leads the firm's healthcare clients through all aspects of the CARES Act, including PPP and PRF compliance. In addition to specializing in revenue cycle management and productivity analysis, she also serves as interim CFO during M&A transactions, mitigating risk and ensuring a smooth and successful process.

Debbie conducts due diligence for private equity, analyzes Healthcare related transactions on the buy and sell side, reviews practice evaluations and manages post-close transactions. Debbie is an expert at handling multi-site medical practices, navigating multi-state compliance, handling complex profit allocations, and with extensive experience with Supergroups, Debbie is a go-to for evaluating ancillary services. She also has expertise with revenue cycle management that includes payor receipt analysis, payor contract analysis and the development of KPIs.

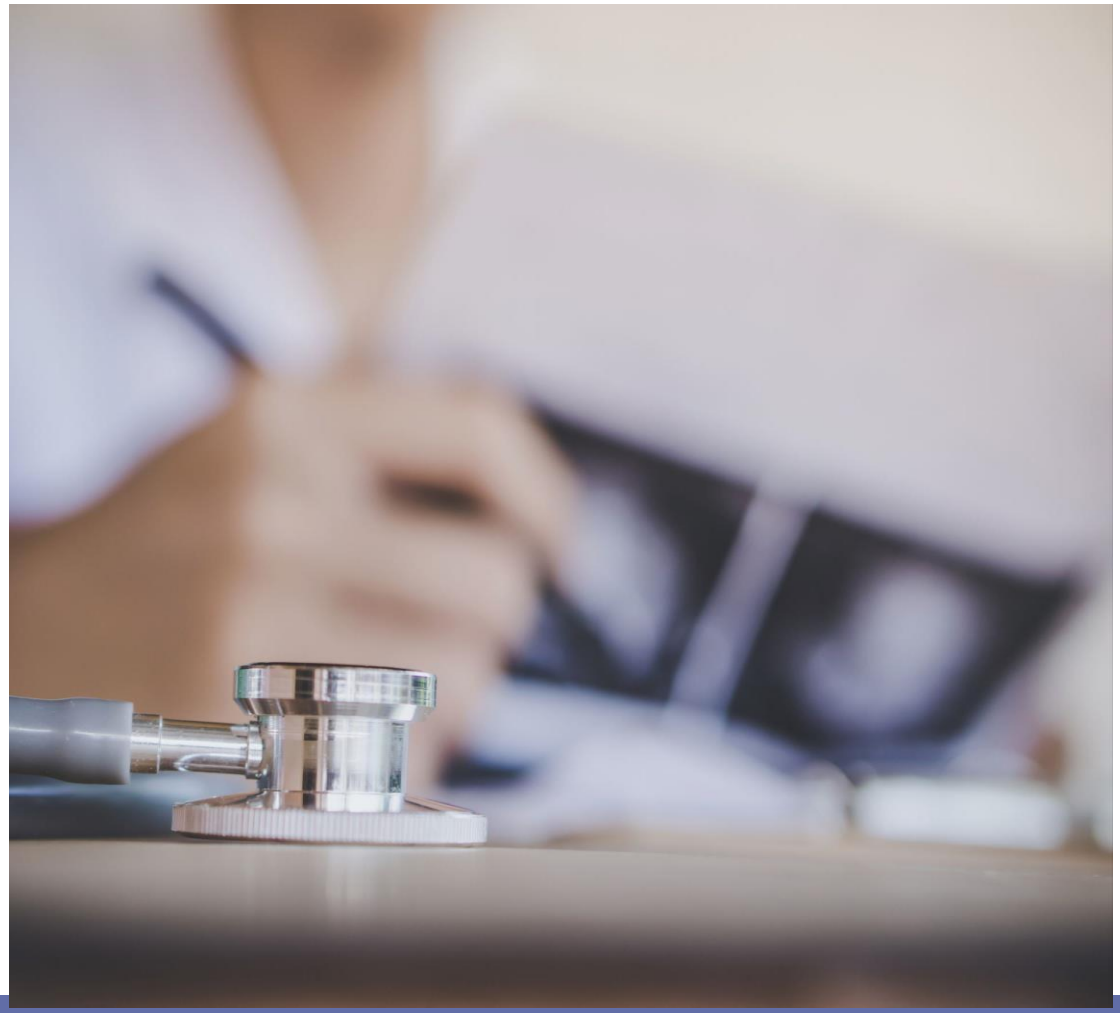
2020 CHANGES, STARK LAW

- November 20, 2020, CMS published new Final Rule to the Federal Physician Self-Referral or "Stark Law."
- 3 new Stark Law exceptions:
  - Value-based compensation arrangements.
  - Limited remuneration arrangements.
  - Donations of cybersecurity technology.
- Clarifies guidance on certain previously undefined terms that are fundamental to interpreting the Stark Law.
- *Changes to the rules governing Group Practice compensation and profit sharing.*
- *Includes special rules on compensation.*
- Amends existing exception relating to electronic health records (EHR).

2020 CHANGES, AKS

- November 20, 2020, HHS OIG published new Final Rule to the Federal Anti-Kickback Statute ("AKS").
- 5 New AKS safe harbors:
  - Cybersecurity technology and services.
  - Value-based compensation arrangements.
  - Patient engagement.
  - CMS-sponsored models and CMS-sponsored model patient incentives.
  - ACO Beneficiary incentive programs.
- Amends 4 existing safe harbors
  - EHR.
  - Warranties.
  - Local transportation.
  - Discount.

KEY CONCEPTS



- CMS has reiterated its position that the value of a physician's services should be the same regardless of whether the employing entity is a health system, a private-equity firm or a physician-owned entity.
- Facts and circumstances should be weighted and considered carefully for each particular transaction before finalizing a physician compensation arrangement.
- CMS has enacted these new rules to provide flexibility as healthcare moves from volume to value-based care.
- Meaningful new guidance in physician value-based arrangements in that the OIG has loosened the requirement for setting aggregate compensation in advance by only requiring that the methodology be set in advance.

REVISED DEFINITION: DESIGNATED HEALTH SERVICES

- Effective Jan 19, 2021, 42 CFR § 411.351.
- Designated Health Services (DHS) means any of the following services :
  - Clinical laboratory services.
  - Physical therapy, occupational therapy, and outpatient speech-language pathology services.
  - Radiology and certain other imaging services.
  - Radiation therapy services and supplies.
  - Durable medical equipment and supplies.
  - Parenteral and enteral nutrients, equipment, and supplies.
  - Prosthetics, orthotics, and prosthetic devices and supplies.
  - Home health services.
  - Outpatient prescription drugs.
  - Inpatient and outpatient hospital services.

With respect to inpatient hospital services, DHS does not include services payable by Medicare if the furnishing does not increase the amount of Medicare's payment to the hospital under certain prospective payment systems (PPS).

REVISED DEFINITION: FAIR MARKET VALUE DEFINITION

- Effective Jan 19, 2021, 42 CFR § 411.351.
- FMV means the value in an arm's-length transaction, consistent with the **general market value** of the subject transaction.
- For rental of equipment and office space, FMV must be consistent with the value for general business purposes (not taking account its intended use).
- Introduced the definition of **general market value** meaning:
  - For Assets: the price that an asset would bring on the date of acquisition of the asset as the result of a bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
  - For Compensation: the compensation that would be paid at the time the parties enter into the service arrangement as the result of a bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for reach other.
  - For Rental of Equipment or Office Space: the price that rental would bring at the time the parties enter into the rental arrangement as the result of a bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for reach other.

FAIR MARKET ASSESSMENTS OF PHYSICIAN COMPENSATION

Physician compensation salary surveys as an established guide. Not all of the surveys have utilized the new Medicare Physician Fee Schedule so be aware of the surveys being utilized	Impact of Covid-19 Pandemic on the healthcare organization	2021 Physician Fee Schedule
Value based incentives	Quality in addition to productivity and quality outcomes	Shared cost savings

COMPENSATION SURVEYS

CMS called into question a strict reliance on compensation surveys to establish fair market value compensation. Surveys should be used strategically.

Surveys should be used in conjunction with other measurements to determine whether compensation is consistent with fair market value and reasonable based upon the specifics to each healthcare entity or physician practice.

Make certain to understand the components of the surveys being utilized and the factors effecting the surveys such as Covid-19, increased wRVU values for the same work effort, and the 2021 fee schedule.

REVISED DEFINITION: COMMERCIALLY REASONABLE

- Effective Jan 19, 2021, 42 CFR § 411.351.

- Means the arrangement must further 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.

- CMS clarified that an arrangement may be commercially reasonable even if it does not result in profit for the parties.

NEW SPECIAL RULE ON COMPENSATION, "SET IN ADVANCE"

- Effective Jan 19, 2021, 42 CFR § 411.354(d)(1).
- Special rule on *compensation only*.
- Compensation is not necessarily required to be "set in advance."
- Compensation is ***deemed*** to be "set in advance" if aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, ***office space, or equipment*** for which the compensation is to be paid.
- **End of prohibition on modifying compensation** (or the formula for compensation) during the term of the arrangement, subject to certain requirements: (1) meet an exception; (2) determined before; and (3) set out in writing before.

NEW SPECIAL RULE ON COMPENSATION, DIRECTED REFERRAL REQUIREMENT

- Effective Jan 19, 2021, 42 CFR § 411.354(d)(4).
- Compensation in employment and personal services arrangements may be conditioned on physician's referrals to particular provider, practitioner or supplier.
- **Existence of compensation arrangement and amount of compensation may not be contingent on the number or value of physician's referrals.**
- **May require that the physician refer an established percentage or ratio of physician's referrals to a particular provider, practitioner or supplier.**
- Set in advance for duration of arrangement.
- **Changes to compensation/formula must only be made prospectively.**
- Must be fair market value (FMV).
- In writing, signed by the parties.
- Patient preference, insurance, and "patient's best medical interest in the physician's judgment" override the directed referral requirement.

NEW SPECIAL RULES ON COMPENSATION, VOLUME OR VALUE OF REFERRALS

- Effective Jan 19, 2021, 42 CFR § 411.354 (d)(5) and (d)(6).
- New objective tests.
- Compensation to Physician (or immediate family member):
  - Compensation takes into account the volume or value of referrals only if the formula used to calculate the physician's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's compensation (or immediate family member) that **positively correlates** with the number or value of the physician's referrals to the entity.
  - Same for "the volume or value of other business generated."
- Compensation from Physician (or immediate family member):
  - Compensation takes into account the volume or value of referrals only if the formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation (or immediate family member) that **negatively correlates** with the number or value of the physician's referrals to the entity.
  - Same for "the volume or value of other business generated."
- Does not apply to certain exceptions.

CHANGES TO STARK LAW – GROUP PRACTICE DEFINITION/SPECIAL RULE FOR PROFIT SHARES

- Effective Jan 1, 2022, 42 CFR § 411.352(i)(1).
- Overall profits: Profits derived from **all** DHS of the entire group or any component of the group that consists of at least 5 physicians.
- If fewer than 5 physicians in the group, "overall profits" means the profits derived from all DHS of the group.
- No "**split pooling**" service-by-service.
- Calculated in a reasonable and verifiable manner.
- Overall profits deemed not directly related to volume or value of referrals if:
  - Divided per capita (*i.e.,* per member of group);
  - Distributed based on the distribution of the group's revenues attributed to services that are not DHS and would not be considered DHS if they were payable by Medicare; or
  - Revenues derived from DHS constitute less than 5% of group's total revenues, and portion of those revenues distributed to each physician in group constitutes 5% or less of his/her total compensation from the group.

STARK LAW – GROUP PRACTICE DEFINITION/PRODUCTIVITY BONUSES

- Effective Jan 1, 2022, 42 CFR § 411.352(i)(2).
- May pay productivity bonus based on services personally performed by physician, or services furnished "incident to" such services, if it is not directly related to volume or value of the physician's referrals.
- Calculated in a reasonable and verifiable manner.
- Deemed not to directly relate to volume or value of referrals if:
  - Based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician;
  - Services on which the productivity bonus is based are not DHS and would not be considered DHS if they were payable by Medicare; or
  - Revenues derived from DHS constitute less than 5% of group's total revenues, and the portion of those revenues distributed to each physician in the group consists of 5% or less of his or her total compensation from the group.

NEW STARK EXCEPTION: LIMITED REMUNERATION ARRANGEMENTS

- Effective Jan 19, 2021, 42 CFR § 411.357(z).
- Protects remuneration from an entity to a physician for the provision of items or services provided by the physician that does not exceed an aggregate of $5,000 per calendar year (adjusted each year for inflation).
- Signed written agreement not required.
- Cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by physician.
- Must be FMV and commercially reasonable.
- Lease or use of office space or equipment subject to limitations regarding percentage and per-click arrangements.
- Physician may provide items or services through employees, wholly-owned entity, or locum tenens physicians.

CHANGES TO AKS SAFE HARBOR AND STARK EXCEPTION FOR EHR ITEMS & SERVICES

- Effective Jan 19, 2021 - AKS: 42 CFR § 1001.952(y)
- Effective Jan 19, 2021 - Stark: 42 CFR § 411.357(w)
- Compensation arrangements or payments for electronic health records (EHR) items and services.
- Nonmonetary items and services in the form of software or information technology and training services, including cybersecurity software and services, ***necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records.***
- Software must be interoperable at the time it is provided to the physician/recipient.
  - Software is deemed to be interoperable if, on the date provided, it is certified by a certifying body recognized by the National Coordinator for Health Information Technology.

DONOR/RECIPIENT RESTRICTIONS & COST-SHARING

- Donor cannot be a laboratory company.
- Cost-sharing by recipient:
  - Stark and AKS: Initial donation of EHR items and services, or replacement of all or part of an EHR system: 15% of the donor's cost, paid in advance.
  - Stark: Items and services donated after the initial donation: 15% of the donor's costs paid "at reasonable intervals."
  - AKS: Updates to previously donated EHR items and services: 15% of the donor's costs but need not be paid in advance.
- Donor cannot loan or finance cost-share amounts.

OTHER KEY REQUIREMENTS

- Recipient cannot make the receipt or amount of the donated items or services a condition of doing business with the donor.
- Cannot directly consider volume or value of referrals or other business generated between the parties.
- Items and services cannot:
  - include staffing of the recipient's office.
  - be used primarily to conduct personal business or business unrelated to clinical practice or operations.
- Agreement in writing.
- AKS: Donor cannot shift costs to federal health care programs.

NEW AKS SAFE HARBOR AND STARK LAW EXCEPTION: "CYBERSECURITY"

- Donation of Cybersecurity Technology and Services.
  - Effective Jan 19, 2021, AKS: 42 CFR 1001.952(jj).
  - Effective Jan 19, 2021, Stark: 42 CFR § 411.357(bb).

- Must be non-monetary.

- Technology and services ***necessary and used predominantly to implement, maintain or reestablish cybersecurity.***

- Technology = software and other types of information technology.
  - Can include hardware if all elements are met.
  - Definition of technology is "agnostic."

- Cybersecurity = the process of protecting information by preventing, detecting and responding to cyberattacks.

CYBERSECURITY – DIFFERENCES BETWEEN STARK LAW AND AKS

Stark Law 42 CFR § 411.357(bb)	AKS 42 CFR § 1001.952(jj)
The eligibility of the physician for the technology or services and the amount or nature of the technology or services is not determined in any manner that directly takes into account the value or volume of referrals or other business generated between the parties	The donor does not directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of technology or services to be donated, nor does the donor condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals.
The arrangement must be in writing.	A general description of the technology and services being provided and the amount of the recipient's contribution, if any, must be set forth in writing and signed by the parties.
	The donor does not shift the costs of the technology or services to any Federal health care program.

TECHNOLOGY & SERVICES

Potentially Protected*	Not or Probably Not Protected
Single-use or stand-alone cybersecurity hardware such as computer privacy screens, two-factor authentication dongles and security tokens, facial recognition cameras for secure access, intrusion detection systems, biometric authentication, intrusion detection systems.	Locks on doors, physical security systems, fire retardant or warning technology, high security doors – these are not "technology."
Services associated with developing, installing and updating cybersecurity software; cybersecurity patches and updates; cybersecurity training services; help desk services specific solely to cybersecurity.	Software or hardware with multiple functionality, even if cybersecurity is one functionality; general IT help desk services.
Cybersecurity services for business continuity and data recovery services to ensure the recipient's operations can continue after a cyber attack.	Payment of ransom to a cyber-attacker; payment of legal fees, fines or penalties stemming from a cyberattack; reimbursement to the recipient for costs expended for cybersecurity software and hardware.

*Assuming all other conditions are met, including that the technology/services are necessary and used predominantly to implement, maintain or reestablish cybersecurity.

AMENDMENTS TO EXISTING AKS SAFE HARBORS

- Personal Services and Management Contracts, 42 CFR § 1001.952(d) – Effective Jan 19, 2021.
  - Amended to provide safe harbor protection to certain payment structures that incorporate value-based care models.
  - Replaced requirement for aggregate compensation to be set forth in advance with a requirement that the *methodology for determining the compensation* be set forth in advance.
  - Increased flexibility for part-time or sporadic arrangements and arrangements for which the aggregate compensation is not known in advance.

AMENDMENTS TO EXISTING AKS SAFE HARBORS

- Warranties (42 CFR § 1001.952(g)) – Effective Jan 19, 2021
  - Expanded the existing safe harbor to protect bundled warranty arrangements involving multiple items or bundles of items and services.
- Local Transportation (42 CFR § 1001.952(bb)) – Effective Jan 19, 2021
  - Expanded mileage limits for rural areas (from 50 to 75 miles).
  - Removed mileage limits for transporting patients discharged from an inpatient facility after spending 24 hours in observation.

THANK YOU!

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