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Physician Compensation and Recent Changes to the Stark, Anti-Kickback and Beneficiary Inducement Laws

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Agenda

1) The Stark Law & New Rule
2) Anti-Kickback Statute & New Rule
3) New CMP Beneficiary Inducement Rule
4) Recent Case Law – Physician Compensation
5) Discussion

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The Stark Law

- A strict liability statute prohibiting physician self-referrals.
- If a physician (or immediate family member) has a direct or indirect financial relationship (ownership or compensation) with an entity that provides designated health services ("DHS"), the physician cannot refer the patient to the entity for DHS and the entity cannot submit a claim for the DHS, unless the financial relationship fits an exception.
- The prohibition relates to claims submitted to Medicare (and perhaps Medicaid).

Designated Health Services ("DHS")

- 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.

Key Exceptions – Physician Compensation

- Employment Exception
- Personal Services Exception
- Fair Market Value Exception
- Indirect Compensation Exception
- In-office Ancillary Services
- Academic Medical Centers
- Isolated Transactions Exception

New Stark Law Rule (General Comments)

- Modernizing and Clarifying the Physician Self-Referral Regulations (85 Fed. Reg. 77,492 - December 2, 2020) – Final Rule.
- This Final Rule comes approximately one year after CMS issued its Proposed Rule. This is the most ambitious and significant Stark Law rulemaking since 2007.
- Final Rule is CMS's attempt to ease administrative burdens and modify key definitions including the volume/value standard, fair market value, and commercial reasonableness.
- Effective January 19, 2021, with the exception of the group practice special rules for profit shares and productivity bonuses effective January 1, 2022.

New Stark Law Rule (Value-Based Arrangement Terms)

- **Value-based Activity** 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: (1) the provision of an item or service; (2) the taking of an action; or (3) 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— (1) the value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.
- **Value-based Enterprise** ("VBE") means two or more VBE participants— (1) collaborating to achieve at least one value-based purpose; (2) 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; (3) that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

New Stark Law Rule (Value-Based Arrangement Terms)

- **Value-based Purpose** means any of the following: (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 the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (4) 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.
- **Target Patient Population** means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that— (1) are set out in writing in advance of the commencement of the value-based arrangement; and (2) further the value-based enterprise's value-based purpose(s).

New Stark Law Rule (Value-Based Arrangements)

- Three new exceptions apply to value-based arrangements - an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are— (1) the value-based enterprise (VBE) and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.
  - **Full Financial Risk**
    - Protects remuneration paid under value-based arrangements where a VBE has assumed full financial risk from a payor for patient care services for a target patient population during the entire duration of the value-based arrangement.
  - **Value-Based Arrangements with Meaningful Downside Financial Risk to a Physician**
    - Protects remuneration paid under value-based arrangements where a physician has taken on meaningful downside financial risk (at risk or forgo 10%) for failure to achieve the value-based purposes of the VBE.
  - **Value-Based Arrangements**
    - Generally protects remuneration paid under value-based arrangements regardless of the level of risk undertaken by the VBE or any of its VBE Participants as long as specific requirements are met.

New Stark Law Rule (Clarifying Key Terminology)

- **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.
- **Volume or Value of Referrals or Other Business Generated**
  - Compensation from an entity furnishing DHS to a physician 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, or other business generated by the physician, to 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. 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.
- **Fair Market Value**
  - The value in an arm's-length transaction, consistent with the general market value of the subject transaction.
  - General market value 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.

New Stark Law Rule (Group Practice Revisions)

- Provided a new volume or value standard consistent with the one in the special rule at 411.354 (previously discussed in key terminology)
  - When determining whether the physician's compensation, share of overall profits, or productivity bonus is based on, is directly or indirectly related to, or takes into account the volume or value of the physician's referrals to the group practice, the special rule at final § 411.354(d)(5) applies (volume/value standard).
- New rule address downstream compensation that derives from payments made to a group practice that relate to physician's participation a value-based arrangement.
- Clarifying revisions:
  - Restructure of the regulation at 411.352
  - Overall Profits
    - Profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. Must be *all* DHS, cannot be distributed on a service-by-service basis.
    - If there are fewer than five physicians in the group, "overall profits" means the profits derived from all the designated health services of the group.
    - Removed reference to Medicaid from the definition of "overall profits."
  - Productivity bonuses
    - Minor edits for consistency and by virtue of restructuring.
    - Groups may continue to pay a productivity bonus based on services that the physician has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus does not directly take into account the volume or value of the physician's referrals (except that the bonus may directly take into account the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).
- All revisions to the group practice rules at 411.352 are effective January 1, 2022.

New Stark Law Rule (Notable Additions/Revisions)

- **New Limited Remuneration to a Physician Exception.** New §411.357(z) will protect remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed $5,000 in the aggregate per calendar year.
- **Amendment to DHS Definition**. If the services furnished to inpatients by a hospital do not increase the amount of Medicare's payment to the hospital under the IPPS, it will not be considered a Designated Health Service. CMS extended that exception to additional prospective payment systems, including those for Inpatient Rehabilitation Facility, Inpatient Psychiatric Facility and Long-Term Care Hospital. It did not extend the policy change to apply to hospital services furnished to outpatients.
- **Set in Advance**. CMS clarified that parties may meet the "set in advance" requirement at §411.354(d) through a writing, or by using another avenue (but did not provide examples).

The Anti-Kickback Statute

- An intent-based statute with broad prohibition on kickbacks for referrals or business payable by federal health care programs.
- Prohibits a person from knowingly and willfully soliciting or receiving, or offering or paying, any remuneration to a person in return for referring, or to induce such person to refer, an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a federal health care program.
- Key Safe Harbors for Hospital/Physician Arrangements:
  - Personal services and management contracts
  - Employment
  - Practitioner recruitment

New AKS Rule (General Comments)

- Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (85 Fed. Reg. 77,684 – December 2, 2020) – Final Rule.
- Final rule adds new safe harbors and modifies existing safe harbors that protect certain payment practices and business arrangements from sanctions under the anti-kickback statute.
- Effective January 19, 2021
- The Stark and AKS Rules are complimentary, but still distinct (just like the laws and regulations). For example, both create 3 new exceptions/safe harbors for value-based arrangements, however, the Stark exceptions and AKS safe harbors are *not* identical.

New AKS Rule (Value-Based Arrangement Terms)

- Same 6 main definitions as the Stark rule, with minor exceptions:
  - The Value-Base Activity definition includes an additional requirement that the activity does not include the making of a referral.
  - VBE Participant cannot be a patient acting in their capacity as a patient

New AKS Rule (Value-Based Arrangements)

- 3 new safe harbors to the AKS protect remuneration between eligible participants in a value-based arrangement involving both publicly and privately insured patients with the intent that such arrangements are used to improve quality, outcomes, and efficiency through the use of innovative methods and novel arrangements.
  - **Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency without Requiring the Parties to Assume Risk**
    - Protects in-kind remuneration exchanged between qualifying VBE participants that do not assume any risk or assume less than substantial downside risk.
  - **Arrangements with Substantial Downside Financial Risk**
    - Protects in-kind and monetary remuneration as long as the VBE has assumed substantial downside risk form a payor for a period of at least one year, and the remuneration is used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk.
  - **Arrangements with Full Financial Risk**
    - Protects in-kind and monetary remuneration as long as the 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 patient population for a term of at least 1 year. This Safe Harbor does not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment approach.

New AKS Rule (Notable Additions/Revisions)

- **Personal Services and Management Contracts Safe Harbor:**
  - OIG replaced the requirement that aggregate compensation under these agreements be set in advance with a requirement that the methodology for determining compensation be set in advance.
  - OIG eliminated the condition that requires that if an agreement provides for the services of an agent on a periodic, sporadic, or part-time basis, the contract must specify the schedule, length and exact charge for such intervals.
  - The Safe Harbor was modified to protect certain "outcomes-based payments" so long as certain conditions are met. "Outcomes-based payments" are limited to "payments between or among a principal and an agent that: (A) reward the agent for successfully achieving an outcome measured described paragraph (d)(2)(i) [of the Safe Harbor]; or (B) recoup from or reduce payment to an agent for failure to achieve an outcome measure described in paragraph (d)(2)(i) [of the Safe Harbor]." The agreement must be set out in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement.

CMP Beneficiary Inducement

- The Beneficiary Inducements Civil Monetary Penalty (CMP) prohibits any person from offering or transferring any remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services.
- The issued a new **exception for telehealth technologies for in-home dialysis** to the term "remuneration" related to the CMP beneficiary inducement provision:
  - A donation of technology may be protected under this exception if the telehealth technology is provided for the purpose of furnishing telehealth services related to the recipients' end-stage renal disease.
  - The exception is available only to telehealth technologies furnished by a provider of services, physicians, or a rental dialysis facility currently providing in-home dialysis, telehealth services, or other ESRD care to the patients or has been selected or contracted by the patient to schedule an appointment or provide services.
  - The telehealth technologies may not be offered as part of any advertisement or solicitation.

Recent Case Law

- In a False Claims Act ("FCA") case, the defendant must:
  - Submit a claim (or cause a claim to be submitted)
  - To the Government
  - That is false or fraudulent
  - Knowing of its falsity
  - Seeking payment from the Federal Treasury
  - Damages (maybe)

U. S. ex rel. Baklid-Kunz v. Halifax Medical Center, (M.D. Fla. 2014)

- Employment agreements with 6 medical oncologists included a bonus pool with revenue from outpatient oncology pharmacy services ordered by the oncologists that Halifax billed to Medicare.
  - The bonus pool was divided among the oncologists based on their personally performed services.
  - Halifax argued the Stark bona fide employment or indirect compensation exceptions applied.
  - The U.S. argued the exceptions were not met because the oncologists' compensation varied based on their referrals for DHS.
  - The district court granted partial summary judgment to the U.S., holding that Halifax violated Stark because the bonus pool included revenue from their referrals of DHS not personally performed, i.e., outpatient pharmacy for administration of chemotherapy.
- Employment agreements with 3 neurosurgeons included a base salary, benefits, and a bonus equal to the difference between their base salaries and collections.
  - The neurosurgeons received a guaranteed salary and 100% of their collections with no overhead expense.
  - The U.S. presented expert testimony that (i) the neurosurgeons were paid double the amount paid to neurosurgeons at the 90th percentile despite collections falling below the 90th percentile; and (ii) the neurosurgeons' productivity numbers were improperly inflated by services performed by advanced practitioner providers.
  - The district court denied Halifax's summary judgment motion because issues existed as to whether the arrangement was consistent with FMV.
- In 2014, Halifax settled for $86 million and entered into a CIA. The relator (Halifax's director of physician services) received $20.8 million.

U. S. ex rel. Drakeford v. Tuomey, (4th Cir. 2015)

- To stem the loss of outpatient surgery business, Tuomey entered into 10-year part-time employment contracts with 19 physicians. The physicians received guaranteed annual base salaries, adjusted from year-to-year based on prior year collections; a productivity bonus equal to 80% of their collections; an incentive bonus based on the earned productivity bonus; and other benefits.
- Dr. Drakeford, an orthopedic surgeon, contended that the contracts violated Stark because the physicians were paid more than their collections.
- The 4th Circuit affirmed the $237 million judgment, finding sufficient evidence that Tuomey paid aggregate compensation to physicians that varied with or took into account the volume/value of anticipated referrals in two respects:
  - The base salary was adjusted depending on prior year collections; and
  - The productivity bonus pegged at 80% of their collections.
- The court clarified that facility fees associated with the physicians' outpatient procedures were "referrals" under the Stark Law, despite the physicians' personal performance of those procedures.
- Tuomey settled for $72.4 million and a CIA; Dr. Drakeford received $18.1 million; and the case resulted in sale of the hospital and CEO/CFO individual liability.

U.S. ex rel. Reilly v. North Broward Hospital District, (S.D. Fla. 2015)

- In 2010, Dr. Michael Reilly, orthopedic surgeon employed by NBHD, sued NBHD under the FCA, alleging:
  - Physicians and physician groups were excessively overcompensated for services.
  - NBHD maintained secret compensation records called "Contribution Margin Reports" for cardiologists, oncologists and orthopedic surgeons, who collected salaries of $1 million and higher.
  - The records indicated the physicians were compensated based on the value and volume of referrals for hospital services, such as radiology and physical therapy.
  - Penalized the physicians for taking on low-paying charity cases.
- NBHD settled for $69.5 million (with Dr. Reilly receiving $12 million) and entered into a CIA.

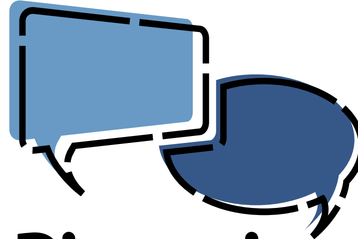
U.S. ex rel. Longo v. Wheeling Hosp., Inc., (N.D. W. Va. Sept. 2019)

- 12/2017: Relator (former hospital executive VP) alleged hospital and its management firm hired physicians at inflated salaries to capture referrals in violation of AKS and Stark.
- 03/2019: U.S. intervened and filed a complaint in intervention alleging that the defendants compensated physicians based on the volume or value of their referrals and/or that such compensation was above fair market value.
- 09/2019: District court denied motions to dismiss holding: (i) complaint sufficient to meet Rule 9(b) pleading requirements, and (ii) complaint plausibly alleged that AKS and Stark violations were material.
- 09/2020: Hospital settled for $50 million with the relator receiving $10 million.

U.S. ex rel. Bookwalter v. UPMC, (3d Cir., Sept. 2019 & Dec. 2019)

- Allegation: The pay of 13 neurosurgeons employed by UPMC exceeded FMV because (i) the pay exceeded their collections; (ii) the pay exceeded the 90th percentile; (iii) the wRVUs generated were above industry norms; (iv) the bonus per wRVU exceeded the amount collected; and (v) the wRVUs were fraudulently inflated.
- 09/2019 3d Circuit decision reversing the district court's order granting UPMC's motion to dismiss:
  - Standard wRVU comp methodology (base pay per wRVU + bonus pay per wRVU) conclusively "varies with volume/value of referrals." Since the neurosurgeons referred to the hospital for surgeries via the technical component and every time they performed a service that generated a wRVU, it therefore varied with their referrals.
- 12/2019 3d Circuit decision on rehearing:
  - The 3d Circuit vacated its prior opinion and held that the relator sufficiently alleged that the neurosurgeons received excessive compensation and that the compensation indicates referrals are taken into account. Compensation takes into account referrals if there is a causal relationship between the two.
  - The rehearing decision removed the panel's prior reliance on *Tuomey*.
- The case is pending in the W. D. Pa. for discovery and pre-trial proceedings (*Docket checked 10.19.2020*).

Discussion



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