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THE KEY TO WORKING WITH PHYSICIANS IS UNDERSTANDING THE NEW STARK LAW GUIDANCE

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INTRODUCTION

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- Physician Self-Referral Law, or "Stark Law", is a civil statute that states that if a physician (or an immediate family member) has a financial interest in a health care provider then the physician cannot refer a Medicare/Medicaid patient to the provider for Designated Health Services ("DHS") unless a Stark exception is met.
    - DHS includes DME
- Enacted in 1989 when Medicare was mainly Fee-For-Service and covered services were paid based on volume.

INTRODUCTION

- The lifespan of Baby Boomers is greater than earlier generations.
- Baby Boomers are retiring in greater numbers and living longer, causing a financial strain on the nation's health care delivery system.
- Industry is shifting to value-based care and care coordination models ("VBC") to help meet demand .
  - Promotes health care professionals to collaborate and achieve set patient health goals. Health care professionals are then rewarded for achieving the goals.
  - VBC results in providers referring patients to each other, providing services to each other, and sharing in the remuneration paid for the care of the patient.

INTRODUCTION

- Prior to Final Rule, both Stark and the federal anti-kickback statute ("AKS") inhibited providers, suppliers, and physicians from entering into VBC/care coordination arrangements.
- CMS and OIG acknowledged the challenges Stark Law and AKS imposes on providers utilizing VBC arrangements.
- HHS launched a "Regulatory Sprint to Coordinated Care" in an effort to remove any potential regulatory barriers to VBCs by the Stark Law.
- October 2019 - CMS issued proposed rules modifying Stark and OIG proposed rules to modify AKS.
- November 20, 2020 – CMS and OIG publish the Final Rules.

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STARK LAW FINAL RULE

STARK LAW FINAL RULE

- Goal is to encourage health care providers to collaborate in the provision of health care without being restricted by Stark.
- Changes included:
    - New Definitions
    - New Value-Based Exceptions
    - Modifications to Fundamental Terminology
    - Other Modifications (i.e., writing/signature requirements, disallowance, and office space and rental equipment exceptions)

NEW DEFINED TERMS

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- Value-Based Activity:
  - Any of the following activities, provided the activity is reasonably designed to achieve at least one valued-based purpose of the Value Based Enterprise (“VBE”):
    - (i) the provision of an item or service;
    - (ii) the taking of an action; or
    - (iii) the refraining from taking an action
  - A referral is not a value-based activity.

NEW DEFINED TERMS

- Value-Based Arrangement:
  - An arrangement for the provision of at least one value-based activity for a target patient population between or among:
    - (i) the VBE and one or more of its VBE participants or
    - (ii) VBE participants within the same VBE.

NEW DEFINED TERMS

- Value-Based Enterprise:
  - Means two or more VBE participants:
    - (i) collaborating to achieve at least one value-based purpose;
    - (ii) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the VBE;
    - (iii) that have an accountable body or person responsible for financial and operational oversight of the VBE; and
    - (iv) that have a governing document describing the VBE and how the VBE participants intend to achieve their value-based purpose.

NEW DEFINED TERMS

- Value-based purpose:
  - Means:
    - (i) coordinating and managing the care of a target patient population;
    - (ii) improving the quality of care for a target patient population;
    - (iii) appropriately reducing the costs to, or growth of, expenditures of payors without reducing the quality of care for a target patient population; or
    - (iv) transition from health care delivery and payment mechanisms based on the quality of care and control of costs of care for a target patient population.

NEW DEFINED TERMS

- VBE Participant:
  - An individual or entity that engages in at least one value-based activity as part of a VBE.
- Target patient population:
  - Identified patient population selected by a VBE or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and furthers the VBE's purpose.

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NEW STARK EXCEPTIONS

NEW STARK EXCEPTIONS

- New Stark Exceptions:
  - Full financial risk,
  - Meaningful downside financial risk to the physician,
  - Other value-based arrangements.
- Organized by the amount of risk a VBE takes on. The more risk the VBE takes on the fewer the requirements within the exception.

NEW STARK EXCEPTIONS

- Full Financial Risk:
  - VBE participants assume "full financial risk" for the costs of all patient care items and services covered by the applicable payor for each patient in the target patient population for a defined period of time.
- Value-based arrangement with meaningful downside financial risk to the physician:
  - Protects remuneration paid under a value-based arrangement where the physician assumes a certain level of financial risk for failure to meet the value-based purpose of the VBE.
  - VBE is not taking on full financial risk.

NEW STARK EXCEPTIONS

- Value-Based Arrangements:
  - Protects value-based arrangements with no downside financial risks.
  - Because the parties are assuming less risk, additional requirements not mandated by the other two value-based exceptions must be met.

NEW STARK EXCEPTIONS

- Indirect Compensation Arrangements:
  - Value-based exceptions are available for certain indirect compensation arrangements.
  - The arrangement must have an unbroken chain of financial relationships between a referring physician and the DHS entity which includes a value-based arrangement.
    - Physician must be a party of the value-based arrangement.
  - The link closest to the physician may not be an ownership interest. It must be a compensation arrangement that meets the definition of a "value-based arrangement."

MODIFICATIONS TO FUNDAMENTAL TERMINOLOGY

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- New Definition for "Commercially Reasonable":
  - 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.
  - An arrangement may be commercially reasonable even if it does not result in a profit for one or more of the parties.

MODIFICATIONS TO FUNDAMENTAL TERMINOLOGY

- Revised Definition of “Fair Market Value”:
  - Definition depends on the type of application:
    - **General Application** – Fair Market Value means the values in an arm’s-length transaction consistent with the general market value of the subject transaction.
    - **Rental Equipment** – Fair Market Value means 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.

MODIFICATIONS TO FUNDAMENTAL TERMINOLOGY

- **Rental of Office Spaces** – Fair Market Value means 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.

MODIFICATIONS TO FUNDAMENTAL TERMINOLOGY

- New Special Rules for the value and volume/business generated standards:
  - Creation of objective tests for determining whether an arrangement "takes into account the volume or value of referrals or other business."
  - Compensation takes into account the volume or value of referrals or other business if:
    - Mathematical formula includes referrals or other business generated as a variable.
    - The amount of compensation correlates with the number or value of referrals or other business generated.

OTHER MODIFICATIONS

OTHER MODIFICATIONS

- Disallowance:
    - Prior to the final rule, the regulations included “bright-line” rules that determined the point in time when a financial relationship would end and a physician could make referrals without violating Stark.
    - Final Rule removed the period of disallowance and these “bright line” rules.

OTHER MODIFICATIONS

- Writing and Signature Requirements:
  - Writing and signature requirements are satisfied if:
    - Parties obtain the required writing(s) and signature(s) within 90 days immediately after the beginning of the arrangement and
    - the arrangement satisfies all requirements of an applicable exception except with respect to writing and signature requirement within the exception.
  - Electronic signatures valid under applicable federal and state law may now satisfy the signature requirement.

OTHER MODIFICATIONS

- Writing and Signature Requirements (cont'd):
  - Revised the definition of "set in advance."
    - Compensation can be modified during the term of an agreement and satisfy the "set in advance" requirement so long as the following conditions are met:
      - All of the requirements of an applicable exception are met;
      - The modified compensation is established prior to the furnishing of the services/products; and
      - The modified compensation is set out in writing in sufficient details that allow it to be verified.
    - Note: The new rule allowing 90 days to prepare and execute documentation is not applicable to the modification of compensation.

OTHER MODIFICATIONS

- Ownership and Investment Interests:
  - The following are excluded from the definition of "ownership or investment interests":
    - Titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or
    - An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under the Employee Retirement Act.
- Compliance with Anti-Kickback Statute:
  - Removed the requirement that arrangements not violate the anti-kickback statute from all Stark exceptions except the fair market value exception.

OTHER MODIFICATIONS

- Office Space and Equipment Rental Exceptions:
  - Clarified that the meaning of "exclusive use" for purposes of these exceptions to mean that the lessee uses the same office space or equipment to the exclusion of the lessor.
  - Also clarified that these exceptions do not prohibit multiple lessees from using the space or equipment or prevent a lessee from inviting another party (other than the lessor) to use the rented office space/equipment.

OTHER MODIFICATIONS

- Limited Remuneration to a Physician:
  - Limited remuneration may be paid to a physician if certain requirements are met including:
    - Compensation may not take into account the volume or value of referrals;
    - Must reflect fair market value; and
    - Must be commercially reasonable.
  - The remuneration cannot exceed $5,000 per calendar year.

OTHER MODIFICATIONS

- Patient Choice and Directed Referrals:
  - Prior to Final Rule, a DHS entity may require a physician to refer their patients to a specific provider, practitioner, or supplier but only if certain restrictions are in place to preserve patient choice, comply with the third-party payor's guidelines, and protect the physician's medical judgments.
  - Final rule expanded this requirement within the text of certain Stark exceptions including:
    - Personal Services Arrangements,
    - Fair Market Value Compensation,
    - Indirect Compensation Arrangements, and
    - Value-Based Arrangements.

OTHER MODIFICATIONS

- Group Practices:
  - Finalized provision related to the distribution of profits from DHS that are directly attributable to a physician's participation in a VBE.
  - If a physician group practice establishes a valid value-based model, distribution of profits to physician members will be construed as not taking into account the volume or value of the physicians' referrals.
  - Effective January 1, 2022.

KEY TAKEAWAYS

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- Unlike the new final rules for the AKS safe harbors, CMS did not exclude any specific entities (i.e., DME suppliers) from participating in a VBC arrangement.
  - When structuring a VBC arrangement, make sure to comply with each definitional requirement.
  - Document how the arrangement meets the new Stark Law exceptions including:
    - The value-based purpose of the VBC arrangement.
    - The value-based activities the participants are undertaking to further the value-based purposes.
    - The criteria for selecting the Target Patient Population.
    - The type or nature of the renumeration and the methodology for calculating it.
    - Any quality or performance measures.

KEY TAKEAWAYS

- More clarity on the meaning of "commercial reasonableness," which is within several Stark Law exceptions.
  - Specifically, clarifying that:
    - The key question is whether the arrangement makes sense as a means to accomplish the parties' goals and
    - Commercial reasonableness is not one of valuation - it is expressly not based on whether the arrangement is profitable or not.

KEY TAKEAWAYS

- Clarification on the volume or value standard and other business generated standard.
  - Stark issue if the formula used to calculate compensation to or from a physician includes the volume or value of referrals or other business generated as a variable.
- Clarification that the Stark definition of "fair market value."
  - Arm's-length transaction that is consistent with general market value.
  - General application, rental equipment application, and rental office spaces application.

KEY TAKEAWAYS

- The ability of the parties to a transaction to sign documents within 90 days after the start of the arrangement.
- Modification to the Stark definition of "set in advance."
    - Allows DME suppliers to modify compensation during the term of an agreement so long as the following requirements are met:
        - All of the requirements of an applicable exception are met;
        - The modified compensation is established prior to the furnishing of the services/products; and
        - The modified compensation is set out in writing in sufficient details that allow it to be verified.

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QUESTIONS?

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THANK YOU

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