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CMS MAKES VALUE THE CENTERPIECE OF PROPOSED STARK RULES

On October 9, 2019, the Centers for Medicare & Medicaid Services ("CMS") released a much anticipated proposed rule ("Proposed Rule") aimed at modernizing and streamlining the Federal Stark Regulations. The Proposed Rule is one component of the Department of Health and Human Services ("HHS") recently launched "Regulatory Sprint to Coordinated Care" and is intended to provide additional flexibility to health care providers as they continue to face the transition from volume to value.

CMS previously published a Request for Information ("RFI") that sought input regarding how to address regulatory barriers posed by the Stark Law. CMS received responses to the RFI from a wide range of industry stakeholders. Many of the stakeholders inquired about the need for new Stark regulatory exceptions to protect value-based arrangements. Others sought clarifications to key requirements for Stark Law compliance, notably the standards of fair market value, commercial reasonableness and the Stark Law's prohibition on "taking into account" the volume or value of a physician's referrals.

This article is intended to briefly summarize key changes that were proposed by CMS in the Proposed Rule. Future alerts will address specific aspects of the Proposed Rule and will provide further analysis focused on potential opportunities for health care providers.

NEW VALUE-BASED EXCEPTIONS

CMS proposed three new exceptions intended to encourage physicians and health care providers to enter into innovative arrangements that facilitate a "value-based purpose" for health care delivery and payment. The Proposed Rule states that "value-based purpose" means:

- Coordinating and managing the care of a target patient population;
- Improving the quality of care for a target patient population;
- Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
- 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.

The proposed exceptions would protect arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk undertaken by the parties, including:

- An exception for value-based arrangements where a value-based enterprise has assumed full financial risk from a payor for patient care services for a target patient population.
- An exception for value-based arrangements where a physician has meaningful downside financial risk.
- An exception for other value-based arrangements, provided they satisfy specified requirements.

A "value-based enterprise" is defined to require two or more individuals or entities collaborating to achieve a value-based purpose that has documentation prescribing the enterprise and the value-based purpose. "Target patient population" means an identified patient population selected by a value-based enterprise based on legitimate and verifiable criteria that are set out in advance and further the value-based purpose.

Under most circumstances, the proposed value-based exceptions would not have a fair market value requirement or a prohibition on "taking into account" the volume or value of a physician's referrals. According to CMS, value-based arrangements already have sufficient safeguards against harms such as overutilization, care stinting and patient steering. Instead of including traditional requirements, CMS is proposing what it describes as a "carefully woven fabric of safeguards, including requirements incorporated through the applicable value-based definitions."

OTHER PROPOSALS

The Proposed Rule also included other notable additions.

- The Proposed Rule includes a new exception for arrangements where an entity pays a physician less than $3,500 in a calendar year in exchange for items or services. This proposed exception would not have a writing, signature or set-in-advance requirement but would require that compensation paid is consistent with fair market value and that the terms of the arrangement are commercially reasonable. CMS said that it developed this exception in response to numerous nonabusive self-disclosures involving nominal amounts of remuneration.
- CMS proposes to broaden the definition of "electronic health record" for purposes of the current donation exception as well as add a new exception to protect arrangements with physicians for donations of certain cybersecurity technology and related services.
- CMS proposes to expand the current 90-day grace period for obtaining the requisite signatures on written arrangements to also include a 90-day grace period for the written document itself. Note that the parties would still be required to comply with all other elements of the applicable exception, including any set in advance requirements.

NEW GUIDANCE AND CLARIFICATIONS

The Proposed Rule provides the following guidance on three critical Stark Law requirements, fair market value, commercial reasonableness and the prohibition on "taking into account" the volume or value of a physician's referrals:

- **Fair Market Value –** CMS revisited the fair market value standard and confirmed that it is separate and distinct from the volume or value and other business generated standards. CMS proposed revising the definition of fair market value to eliminate cross-references to the volume or value standard. CMS also proposed reorganizing the definition of fair market value into three different components (i.e., general application, equipment rentals, office space rentals) to achieve more clarity. CMS provided additional guidance on fair market value in the Proposed Rule, including in-depth discussion regarding distinctions between "general market value" and "market value" in the context of hypothetical physician recruitment scenarios.
- **Commercial Reasonableness** – CMS addressed what it described as a widespread misconception about its position on the nexus between the commercial reasonableness of an arrangement and its profitability. CMS then proposed the following definition in an attempt to clarify that commercial reasonableness should not turn on whether an arrangement is profitable:

  > *Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.*

  This proposed change corresponds to the more longstanding view under Anti-Kickback analysis that the concept of commercially reasonable should be analogous to a purpose-driven arrangement serving a legitimate need. Along this line, in proposing this definition, CMS found compelling a commenter who suggested that "entire hospital service lines, with their needed management and other physician-provided services, are illustrative for operating at a loss and identified psychiatric and burn units as examples of such service lines."
- **The Volume or Value Standard** – In the Proposed Rule CMS proposes a bright-line standard regarding two circumstances where compensation will be considered to "take into account" the volume or value of referrals. First, the standard would be violated if the formula used to calculate a physician's compensation includes the physician's referrals to an entity as a variable, resulting in an increase or decrease of compensation that positively correlates with the number or value of the physician's referrals to the entity (i.e., compensation increases as referrals increase or compensation decreases as referrals decrease). Second, the standard would be violated if there is a predetermined, direct correlation between a physician's prior referrals to an entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which compensation is determined.

CMS proposes a similar bright-line test for the "other business generated" standard. Regarding the "taking into account" standard more generally, CMS reiterated its prior position on "shadow referrals" in the commentary, noting that a productivity bonus will not take into account the volume or value of a physician's referrals solely because corresponding hospital services are billed each time a physician performs a professional service.

PRACTICAL TAKEAWAYS

The Proposed Rule shows CMS's new value-based framework and outlines its intention to modernize and clarify the Stark Law framework.

However, it is important to note that the Proposed Rule is not in final form and should not be relied upon. Comments on the Proposed Rule must be received by CMS by December 31, 2019.

If you are interested in submitting a comment or would like additional information about this topic, please contact:

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