Final Stark and Anti-Kickback Regulations Released Friday

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On November 20, 2020, the Centers for Medicare and Medicaid Services (CMS) released long-awaited final rules revising regulations implementing the Physician Self-Referral Law (known as "Stark"). Simultaneously, the Office of Inspector General (OIG) for Health and Human Services published final regulations modifying the safe harbors available to providers under the Anti-Kickback Statute (AKS). Below are highlights from the final rules.

New Safe Harbors

1. Value-Based Payment Arrangements

Generally

Both final rules add new safe harbors for value-based arrangements. A value-based arrangement: (a) requires a value-based enterprise with at least two participants (referred to in the regulation as a "VBE participant"); (b) that provides a value-based activity; (c) for a target population. The safe harbors protect remuneration between the value-based enterprise and a VBE participant or between VBE participants in the same value-based enterprise.

A value-based enterprise does not have to be an ACO or other formally organized clinically integrated network. It can be written documentation between parties describing how the parties intend to achieve specifically identified value-based purpose(s).

Only an arrangement reasonably designed to achieve a "value-based purpose" may qualify. A value-based purpose is one of the following:

- 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 the target patient population
- 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 controlling of costs of care for a target patient population

Stark Safe Harbors

The Stark final rule creates three new compensation arrangement safe harbors for value-based arrangements based

on the level of risk the parties assume. They include:

(1) Full financial risk

(2) Medium downside risk

(3) Arrangements which present no financial risk, but which are set forth in writing and meet specifically defined criteria, including a requirement to monitor the effectiveness of the value-based activities and terminate or modify activities determined to be ineffective.

Notably, while the arrangement must be "commercially reasonable" there is no requirement that the compensation be fair market value or not take into account the volume or value of referrals.

In connection with the new safe harbors, CMS also revised the group practice regulation to allow group practices to distribute profits to a physician derived from designated health services attributable to the physician's participation in a value-based enterprise.

AKS Safe Harbors

Similar to the Stark rule, the OIG created three new safe harbors for value-based arrangements based on the level of risk assumed by the parties as well as a fourth safe harbor for patient engagement and support tools.

The AKS safe harbors for value-based arrangements and patient engagement are generally not available to the following types of providers:

- pharmaceutical manufacturers, distributors, and wholesalers
- pharmacy benefits managers
- laboratories
- pharmacies that primarily compound drugs or dispense compounded drugs
- DMEPOS suppliers other than a pharmacy or a physician, provider, or other entity that primarily furnishes services
- medical device distributors or wholesalers

Additionally, the value-based arrangement for non-risk bearing relationships is limited to in-kind remuneration for care coordination purposes and the recipient of the remuneration must pay at least 15% of the cost or fair market value of the in-kind item.

Related to the value-based arrangement additions, the AKS rule includes a new safe harbor for CMS supported payment models consistent with prior regulatory waivers for these models.

2. Cybersecurity Safe Harbors

Both final rules create new safe harbors for non-monetary remuneration in the form of technology and services used predominantly to implement, maintain or re-establish cybersecurity provided the remuneration does not vary based on volume or value of referrals and is not conditioned on future referrals.

3. Non-Abusive Business Practices

The Stark final rule creates a new safe harbor for remuneration for the provision of items or services provided by the physician to the entity that does exceed an aggregate of $5,000 per calendar year (adjusted for inflation).

Modifications to Existing Safe Harbors

1. Stark Modifications

The final rule adds additional clarification on compensation arrangements that CMS considers to be determined in a manner taking into account the volume or value of the physician's referrals and adds a definition of "commercially reasonable."

CMS also revised portions of the group practice regulation relating to profit shares and productivity bonuses to align it with these revisions. For example, CMS has clarified that a group practice may not divide profits from designated health services on a service by service basis, such as dividing profits from laboratory services in one manner and imaging services in another. CMS anticipates these clarifications may require some group practices to revise governance documents or agreements and therefore, has delayed the effective date for the changes until January 1, 2022.

Other notable changes to the final Stark rules:

- Removing in-patient hospital services paid under prospective payments systems from the definition of "designated health services"
- Clarifications to the isolated financial transaction safe harbor
- Creating exceptions for "titular" ownership/investment interests and ESOPs
- Allowing the lease of office space to utilize the fair market value compensation safe harbor
- Making the electronic health record safe harbor permanent

2. AKS Modifications

The AKS final rule also modifies several existing safe harbors, including changing the personal services safe harbor to increase flexibility for part-time or sporadic arrangements and arrangements for which aggregate compensation is not known in advance and adding new protections for outcome-based payments. The regulation also expanded the local transportation safe harbor by expanding mileage limits in rural areas to up to 75 miles and eliminating mileage limits for transportation of hospital patients to their place of residence after discharge.

Effective Date

Both final rules are effective on January 19, 2021, with the exception of the group practice changes which will not go into effect until January 1, 2022.

The Big Picture

By far the biggest change is the addition of new safe harbors to protect value-based arrangements. These safe harbors will give providers more flexibility to design business relationships that advance value-based goals. Also notable are the additional clarifications added by CMS in the final rule and throughout the commentary to the final rule, including a formal definition of "commercially reasonable" and a formal statement of compensation arrangements CMS considers as taking into account the volume or value of referrals. Physician relationships should be reviewed to ensure compliance with these clarifying provisions.

Group practices that may be impacted by the changes to the profit sharing and productivity bonus provisions should carefully review their underlying governance documents and agreements to determine if changes are needed prior to January 1, 2022.

The final rules do little to reduce the complexity of the Stark and Anti-Kickback regulations. Providers should engage experienced regulatory counsel to assist them in structuring financial relationships between referral sources to ensure they do not run afoul of these rules.

Your Key Contacts

Susan J. Freed
Shareholder, West Des Moines
D +1 515 246 7891
susan.freed@dentons.com