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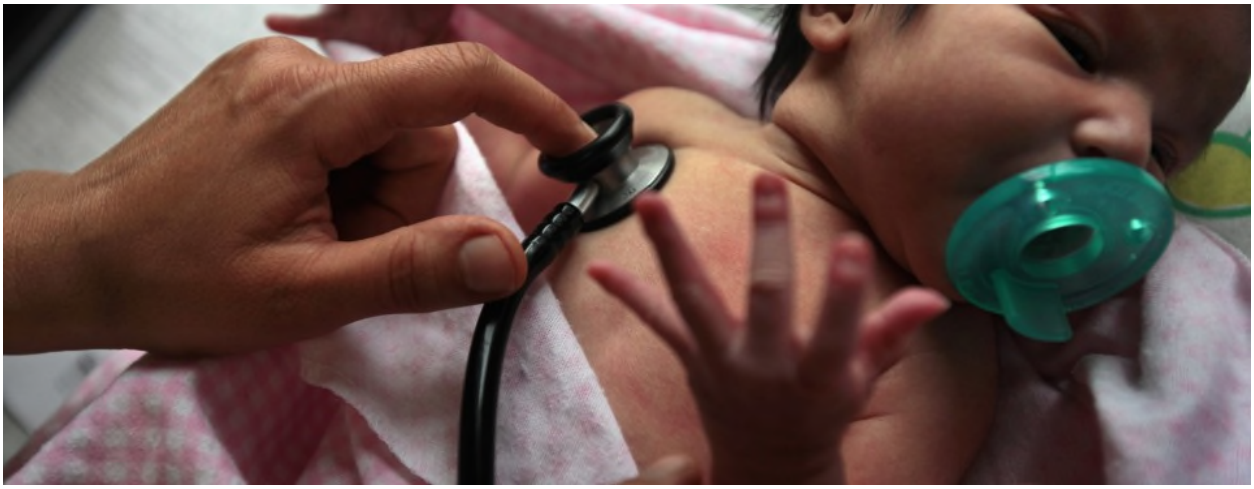

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INSIGHT: Proposed Stark Exceptions and Anti-Kickback Safe Harbors—Similar, But Different By Design

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Morgan Lewis attorneys look at recent proposed Stark Law and anti-kickback law regulations aimed at promoting the transition from a fee-for-service to value-based payment system. In Part 1 of a two-part series, they look at their similarities but say if they are made final as proposed, health providers will still face potential challenges to the future transition to a value-based care and payment system.

On Oct. 9, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) released highly awaited proposed updates to the Stark Law exceptions and the anti-kickback statute (AKS) safe harbors. A focus of the proposed rules is eliminating barriers to the adoption of value-based arrangements, consistent with HHS's Regulatory Sprint to Coordinated Care.

To accomplish this objective, the proposed rules include one new Stark Law exception and three AKS safe harbors that address value-based arrangements. The proposed rules also revise the Stark Law exception and AKS safe harbor for personal service arrangements to accommodate value-based arrangements.

Sharing Some Similarities

While the value-based arrangements exception and safe harbors are not uniform, they share some similarities. The exception and safe harbors can be divided into three categories: (i) arrangements with full financial risk; (ii) arrangements with substantial or meaningful downside financial risk; and (iii) arrangements with little or no downside financial risk.

Full-financial-risk arrangements are limited in the Stark Law exception and the AKS safe harbor to those where the parties assume financial responsibility for the cost of all items and services covered by a payor for patients in the target population.

The Stark Law exception for arrangements with "meaningful" financial risk requires that the physician be at risk for at least 25% of the value of the remuneration the physician is eligible to receive under the arrangement.

The comparable AKS safe harbor generally requires that: (i) the participant is at risk for 8% of the amount for which the enterprise is at risk; (ii) a partial or full capitation payment or similar payment methodology is used; or (iii) if the participant is a physician, the payment meets the requirements of the comparable Stark Law exception.

Any value-based arrangement that does not involve full or meaningful financial risk would fall into the third category of value-based arrangements, which requires no downside financial risk.

Based on the shared view by CMS and OIG, that assumption of downside financial risk may curb the improper incentives linked to the fee-for-service payment system, the requirements necessary to meet the exception and safe harbors increase as the financial risk involved in the arrangement decreases.

Stark Law Exception Easier to Satisfy

The requirements imposed by the Stark Law exception are easier to satisfy as compared to those imposed by the AKS safe harbors. For example, the proposed Stark Law exception does not require payor participation, while two of the proposed AKS safe harbors do.

For value-based arrangements with little to no financial risk, the AKS safe harbor requires the arrangement to be commercially reasonable and only permits in-kind remuneration, such as services and staff, and the recipient must contribute 15% of the cost of the in-kind remuneration. The Stark Law exception does not limit payments to in-kind remuneration.

In recognition of the differences in statutory structures and penalties, the OIG intended the proposed safe harbors to be different and more restrictive.

FMV Requirement Notably Absent

Notably absent from the value-based Stark Law exception and the AKS safe harbors is the fair market value (FMV) requirement that is present in most exceptions and safe harbors. The proposed Stark Law exception takes it a step further by not requiring that the compensation be commercially reasonable or that it not be determined in any manner that takes into account the volume or value of a physician's referrals or other business generated.

Once satisfied, the Stark Law exception is liberal with respect to compensation to physicians. CMS provides, as an example of the application of the value-based arrangement exception, a hospital's desire to have physicians follow cancer-screening guidelines incorporating dual-modality screening.

The hospital offers to pay physicians $10 for each instance when they order dual-modality screening. While this arrangement may meet the Stark Law exception for value-based arrangements, safe harbor protection for the arrangement would not be available unless the arrangement involves full or substantial financial risk. Because the physician is receiving monetary compensation, compliance with the no financial risk AKS safe harbor is not possible, as it is limited to in-kind remuneration.

In addition, because payments to the physician in CMS's example are tied directly to each screening order, it is related to the volume or value of referrals. Compliance with the revised personal services safe harbor for outcome-based arrangements is not possible, as it prohibits volume-based compensation.

CMS acknowledges that the exception for value-based arrangements where there is no financial downside risk is a "bold reform" to encourage physicians to participate in care coordination activities even though they are not accustomed to risk-sharing or not suited to absorb downside risk.

However, without the ability to obtain safe harbor protection, these same physicians and hospitals contemplating value-based arrangements may be reluctant to enter into arrangements where physicians are paid directly based on the number of referrals and without comfort that the payment is consistent with FMV.

While the growth of value-based arrangements will continue, query whether healthcare providers other than large health systems and physician groups will be able to obtain payor participation and assume the substantial downside financial risk, as required by two of the three proposed AKS safe harbors.

CMS and OIG pressed hard to make value-based arrangements more accessible and attractive for all, but if the rules are finalized as proposed, for those health systems entering into value-based arrangements not involving full or substantial financial downside risk, issues of commercial reasonableness, FMV and payments based on the volume or value of referrals will remain potential challenges to the future transition to a value-based care and payment.

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