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Sweeping Changes Proposed for Medicare and Medicaid Anti-Kickback Statute and Self-Referral Rules

14 October 2019

On October 9, 2019, the U.S. Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) and Centers for Medicare and Medicaid Services (“CMS”) released notices of proposed rulemaking that seek to expand, modify and introduce new regulatory “safe harbors” and exceptions, respectively. These Anti-Kickback Statute (“AKS”) safe harbors and Ethics in Patient Referrals Act (the “Stark Law”) exceptions, when squarely met, afford protection for certain financial relationships between healthcare providers and other entities under the AKS and Stark Law. The stated purpose of the proposed changes is to remove barriers to the implementation of “value-based” patient care models in order to “transition [from] healthcare delivery and payment mechanisms based on the volume of items/services provided to mechanisms based on quality of care and control of costs of care.”

The proposed rules – which have no immediate effect and are subject to the regulatory notice-and-comment process – would safeguard several types of arrangements that are currently prohibited, or whose legality is called into question, by the existing AKS and Stark Law framework. The proposed safeguards, however, are highly fact-specific and, like the existing safe harbors and exceptions, would require strict adherence by parties seeking protection from potential AKS and Stark Law liability.

Value-Based Enterprises and Arrangements are Central to the Proposed Safe Harbors

Both OIG and CMS, in a coordinated and collaborative manner, proposed rules centered on the concept of “value-based enterprises” (“VBEs”) and “value-based arrangements” between participants in VBEs. A central purpose of the proposed modified and new safe harbors and exceptions is to provide greater flexibility for remuneration between participants in VBEs to permit incentive structures that promote quality in patient care and reduce payor costs.

A VBE is defined as two or more participants collaborating pursuant to a written arrangement to achieve at least one of these “value-based purposes”: (1) improving the coordination/management of patient care; (2) improving quality of care for a specific patient population; or (3) reducing costs to payors while maintaining quality of patient care. An activity is “value-based” if it is reasonably designed to achieve at least one “value-based purpose.”

Pharmaceutical Manufacturers, Durable Medical Equipment Manufacturers/Suppliers, and Laboratories Are Excluded from the Definition of “Value-Based Enterprises”

Notably, pharmaceutical manufacturers, manufacturers, suppliers and distributors of durable medical equipment, prosthetics, orthotics or supplies, and laboratories are expressly excluded from being “participants” in a VBE due to concerns that their dependence on physician prescriptions and referrals could create an incentive to misuse the safe harbors and exceptions. Interestingly, the proposed rules as drafted do not explicitly exclude medical device manufacturers from VBE-participant status, although some of the examples of potential misuse of the safe harbors cited in the OIG proposed rule reference implantable medical devices, and the OIG is considering excluding such manufacturers.

Highlights of Specific Proposed AKS Safe Harbors and Stark Law Exceptions

The "Care Coordination Arrangements" Safe Harbor

The “Care Coordination Arrangements” safe harbor would provide an AKS safe harbor for in-kind remuneration (for example, a hospital’s provision of a nurse coordinator to a

skilled nursing facility at no charge to facilitate patient transitions) between VBE participants. The safe harbor would apply only where both parties are participants in the same VBE.

The proposed safe harbor would require that the arrangement: (1) be commercially reasonable; (2) be documented in a written agreement that describes the value-based activities to be undertaken; (3) define the target patient population; and (4) specify at least one specific, evidence-based outcome measure that the agreement is intended to advance. The agreement must also document the cost of the in-kind remuneration to the offeror and, notably, the recipient must pay at least 15% of the offeror's cost in order to ensure that the recipient is incentivized to benefit the target population. The VBE would be required to review the arrangement at least annually to determine whether the arrangement was achieving its stated outcomes, and terminate the arrangement within 60 days if the VBE determined that the arrangement was not advancing its stated goals or was adversely affecting patient care.

The "Downside Financial Risk" Safe Harbors

The OIG's proposed rule would also create two distinct AKS safe harbors for VBEs and VBE participants who bear "substantial" or full "downside financial risk" from their agreements with payors. A VBE is deemed to have assumed downside financial risk where, for example, it receives partially or fully capitated payments from a payor for a target patient population, or where a VBE shares in the payor's "losses" as determined by comparing costs to historical expenditures.

Unlike the "Care Coordination Arrangements" Safe Harbor, the proposed "Downside Financial Risk" safe harbors apply to both in-kind and monetary remuneration between VBEs and VBE participants. This safe harbor only applies, however, where the VBE participant "meaningfully shares" in the VBE's downside financial risk (for example, where the VBE participant must share in any loss payment made by the VBE, or the VBE participant is subject to full or partially capitated payment from the VBE). Moreover, the safe harbor would apply only to remuneration that is directly connected to the VBE's value-based purposes and that is primarily used to engage in value-based activities directly connected to the items or services as to which the VBE has assumed downside financial risk.

CMS's proposed rulemaking includes downside financial risk exceptions, which largely mirror the OIG proposals above and provide that such financial arrangements would also be excluded from the application of the Stark Law.

The “Patient Engagement and Support” Safe Harbor

The OIG's proposed rule would exclude from the definition of “remuneration” under the AKS and Civil Monetary Penalty Law (“CMP”) – a law which prohibits beneficiary inducements – “in-kind patient engagement tools or supports” furnished directly by a VBE participant to patients where such tools or supports are directly connected to specified goals, including: adherence to treatment/drug regimens; adherence to a follow-up care plan; disease/health condition management; improving health outcomes; and ensuring patient safety. All services must be recommended by the patient’s personal licensed healthcare provider.

Notably, this safe harbor would not cover cash or cash equivalents, nor would it permit routine waivers of patient cost-sharing obligations. The safe harbor would be capped at \$500 per year, measured by the fair market value to the recipient, but this limit could be extended based on a VBE’s individualized, good-faith determination of patient need.

As noted above, pharmaceutical manufacturers are expressly excluded from the definition of a VBE participant, and therefore are not covered by this proposed safe harbor.

The “Outcomes-Based Payments” Expansion of the Personal Services and Management Contracts Safe Harbor

The OIG's proposed rule would also expand the existing AKS safe harbor for personal services and management contracts to accommodate contracts where the agent’s compensation is dependent on the achievement of particular outcomes. Under the existing safe harbor, contracts for personal services and management contracts must specify the agent’s aggregate compensation in writing. Contracts for part-time or periodic services must also specify the timing, duration and amount of compensation for the periodic services to be provided.

The proposed rule would modify the existing safe harbor to allow for contracts that do not specify the agent’s aggregate compensation so long as they clearly set forth the methodology for determining the agent’s outcomes-based compensation. This expansion to the safe harbor would apply only to outcomes-based compensation tied to specific, evidence-based measures that relate to improving quality of care or reducing costs to payors while improving or maintaining quality of care to patients. Notably, the proposed expansion would not apply to outcomes that relate solely to internal cost savings by the principal.

Similarly, CMS's proposed rule excludes contracts based on measurable outcomes relating to value-based activities from the application of the Stark Law.

The "CMS-Sponsored Care Delivery and Payment Arrangements" Safe Harbor

The OIG's proposed rule would create a new safe harbor for care delivery and payment arrangements among participants in CMS-sponsored programs. Under existing law, protection from AKS and CMP liability must be requested on a case-by-case basis. The proposed rule reasons that CMS-sponsored programs are already under close CMS oversight, and therefore present less risk of fraud and abuse. The proposed safe harbor would apply to remuneration under a CMS-sponsored program so long as the remuneration is consistent with the goals of the CMS-sponsored model.

Clients with questions regarding the proposed rulemakings discussed above should contact one of the attorneys listed below.

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