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OIG and CMS issue long-awaited value-based safe harbors and exceptions; now what?

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On December 2, 2020, the Centers for Medicare & Medicaid Services (CMS)[1] and the Office of Inspector General (OIG)[2] of the Department of Health & Human Services published long-awaited companion final rules modifying and updating the federal Physician Self-Referral Law (commonly referred to as the Stark Law), the federal healthcare program's Anti-Kickback Statute (AKS), and the federal Civil Monetary Penalties Law. These companion final rules comprise more than 400 pages of discussion and regulation and bring to a close Department of Health & Human Services' Regulatory Sprint to Coordinated Care, an initiative ostensibly designed to remove regulatory barriers to coordinated and value-based care, and follow the proposed rules that were issued by both CMS[3] and OIG[4] in 2019. The final rules make changes to the existing regulatory framework, including through the modification and clarification of existing AKS safe harbors and Stark Law exceptions as well as the promulgation of new safe harbors and exceptions. These changes became effective January 19, 2021 (with one exception related to certain modifications of the Stark Law's "group practice" rules, which become effective January 1, 2022).[5]

Notable changes to the AKS regulations finalized by OIG include:[6]

- A new safe harbor for patient engagement and support that protects remuneration provided in the form of in-kind patient engagement tools and supports to patients in a defined target patient population.
- New safe harbors for certain remuneration provided in connection with a CMS-sponsored model and for donation of cybersecurity technology and services, which modifies four existing safe harbors.
- Modifications to the safe harbor for personal services and management contracts to: (1) ease the requirement that the aggregate compensation be set in advance and (2) protect outcomes-based payments that are tied to the achievement of legitimate and measurable outcomes.

Notable changes to the Stark Law regulations finalized by CMS include:[7]

- A new *de minimus* exception that protects "nonabusive business practices" that result in remuneration of up to $5,000 per calendar year paid to a physician for providing items and services if certain requirements are met.[8]
- Similar to OIG, a new exception to protect the donation of cybersecurity technology.
- Significant amendments and clarifications to key definitions and requirements that are instrumental in the application of the Stark regulatory exceptions, including addressing concepts related to "volume and value," "fair market value," "commercially reasonable," and "set in advance."

In addition to the changes noted above, among the most consequential steps taken by both agencies are those related to the adoption of new regulatory protection for value-based arrangements. Specifically, the OIG promulgated three new value-based safe harbors, and CMS promulgated three new Stark Law exceptions. Given the changes that these final rules make to the current AKS and Stark Law regulatory framework, this article focuses on the long-awaited protections for value-based arrangements and, more specifically, the Stark Law exceptions.

According to CMS, value-based healthcare delivery "shifts the paradigm" of analysis under the Stark Law, and fewer "traditional" requirements are needed to ensure that value-based arrangements, and particularly arrangements that have downside risk, do not pose a risk of program or patient abuse, because "a value-based health care delivery and payment system, by design, provides safeguards against harms such as overutilization, care stinting, patient steering, and negative impacts on the medical marketplace."[9] The new exceptions appear to be based in substantial part on the premise that the more financial risk the parties assume, the more likely they are to self-regulate the risks or concerns that were historically addressed by the Stark Law. This viewpoint is logical and largely consistent with CMS' approach to managed care–related exceptions. CMS has long treated risk-bearing entities more favorably, especially where arrangements have downside risk associated with utilization and medical spend.