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ALERTS

Final Rules Amend The Stark Law And Anti-Kickback Statute Regulations To Promote Coordinated Healthcare

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Highlights

CMS and OIG issued long-awaited final rules, set to take effect Jan. 19, 2021, to modernize and clarify the Stark Law and Anti-kickback Statute

New exceptions and safe harbors will promote coordinated services among healthcare providers and emphasize value-based payment and collaborative care

The final rules acknowledge the role of electronic health records and cybersecurity technology – allowing providers to share resources without running afoul of various regulations

On Nov. 20, 2020, the U.S. Department of Health and Human Services (HHS) released final rules clarifying and revising the regulatory exceptions to the Physician Self-Referral Law (also known as the Stark Law), the Anti-Kickback Statute (AKS) safe harbors, and the civil monetary penalty laws related to beneficiary inducements law. The new rules are intended to reduce regulatory barriers, accelerate the shift in service reimbursement from volume to value-based payments, and

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advance coordinated care across healthcare settings.

The Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) finalized these rules as part of its Regulatory Sprint to Coordinated Care.

These changes will go into effect on Jan. 19, 2021, except for an addition to the Stark Law group practice compensation distribution provisions, which becomes effective Jan. 1, 2022.

In its press release announcing the reforms, HHS stated its intention is to "provide greater flexibility for healthcare providers to participate in value-based arrangements and to provide coordinated care for patients[, and] . . . ease unnecessary compliance burden[s] for healthcare providers and other stakeholders across the industry, while maintaining strong safeguards to protect patients and programs from fraud and abuse."

Stark Law Changes

The Stark Law generally governs the financial relationships between physicians and entities that file claims for certain designated health services, and sets forth the exceptions for financial relationships which HHS has determined do not pose a risk of program abuse. In the new final rule, CMS finalized three new exceptions and definitions for certain value-based compensation arrangements between or among physicians, providers and suppliers, and amended the existing exception for electronic health records (EHR) items.

When it comes to value-based arrangements, CMS codified its "tiered" rules, making three "new, permanent exceptions to the physician self-referral law:" 1) during the entire duration of the arrangement, value-based arrangements with full financial risk from a payor for patient care services for a target patient population, 2) value-based arrangements with meaningful downside financial risk for failure to achieve the value-based purposes of the value-based enterprise during the entire duration of the arrangement; and 3) any value-based arrangement provided the enumerated requirements are met.

The specific activities of the parties involved in these compensation relationships will be key to determining whether the proposed value-based arrangement qualifies for an exception under the Stark Law.

A separate section defines critical terms necessary for analyzing particular compensation arrangements, including value-based enterprise and target patient population:

- A "value-based enterprise" is defined as a network of participants (such as clinicians, providers, and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients
- An "enterprise" is focused on functions, and may be a distinct legal entity, such as an accountable care organization, or two parties with written documentation of the value-based arrangement

- A “target patient population” means an identified patient population based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise’s value-based purposes

CMS also added two new exceptions – one for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician, and the other, aligned with OIG, for donations of cybersecurity technology that includes hardware, software, and related services.

Each of these new exceptions includes the requirements that 1) remuneration is not an inducement to reduce or limit medically necessary items or services to any patient, and 2) if a patient expresses a preference for a provider, such preference supersedes any referral conditions. In addition, the new limited remuneration exception includes an annual monetary cap in addition to the general requirement that the payment not exceed fair market value for the items or services provided.

The final rule also includes commentary and insight into how CMS now interprets numerous defined terms and various requirements scattered throughout the Stark Law.

Anti-Kickback Statute Safe Harbors

OIG’s final rule adds seven new safe harbor provisions for certain coordinated care and value-based arrangements, modifies four existing safe harbor protections, and codifies one new exception under the civil monetary penalty prohibitions against beneficiary inducements related to telehealth technologies furnished to certain in-home dialysis patients.

In coordination with the exceptions under the Stark Law, OIG established three “new safe harbors for remuneration exchanged between or among participants in a value-based arrangement.” These value-based safe harbors follow a similar “tiered” framework: 1) care coordination arrangements to improve quality, health outcomes, and efficiency without requiring the parties to assume risk; 2) value-based arrangements with substantial downside financial risk; and 3) value-based arrangements with full financial risk.

OIG also finalized a new safe harbor related to patient engagement tools and supports furnished by a participant in a value-based enterprise to a patient in a target patient population, and a safe harbor for participants in CMS-sponsored model arrangements and model patient incentives (e.g., Medicare Shared Savings Program) to provide greater predictability and uniformity across models.

The other safe harbor provisions include cybersecurity technology, tools, and related services, and EHR items and services, similar to Stark, along with personal services arrangements, warranties, and local transportation.

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