Breaking Healthcare News:
Long Awaited Final Rules to the Stark Law & Anti-Kickback Statute Released

Introduction

The long-awaited final rules to the Stark Law ("Stark") and Anti-Kickback Statute ("AKS") have arrived. On November 20, 2020, the final rules were simultaneously released by the Centers for Medicare and Medicaid Services ("CMS") and the Office of Inspector General ("OIG"). In them, the federal government's Department of Health and Human Services ("HHS") provided further clarity on the shift to a value-based care model. The revised rules reflect the first major overhaul of both Stark and AKS since they were first introduced and are designed to provide additional flexibility to providers engaging in value-based arrangements as opposed to traditional fee-for-service models.

In fact, because the final rule addresses the fact that the healthcare landscape has changed from a volume-based system to a value-based system, CMS has stated that the new rules open additional avenues for healthcare provider to coordinate their patients' care. In particular, the new rules are meant to focus on allowing providers across various healthcare settings to collaborate to ensure patients receive the highest quality of care.

The final rules become effective January 19, 2021, for all but one provision (which is effective January 1, 2022). Given the impact healthcare delivery across the country, Pinnacle is assessing these updates and has outlined a high-level overview of notable Stark and AKS revisions – as well as key takeaways – for reference in the following sub-sections.

Overview of Stark Revisions

In the final rules for the Stark Law, HHS titles the updates "Modernizing and Clarifying the Physician Self-Referral Regulations". As is suggested in the title, the revisions aim update the regulations to adapt to contemporary healthcare delivery models which focus on value-based care. In its summary, HHS highlights several key issues addressed in the final rule as related to Stark (42 CFR Part 411).

Said summary indicates that the final rule:

- Addresses any undue regulatory impact and burden of Stark;
- Is being issued in conjunction with CMS' Patients over Paperwork initiative and HHS' Regulatory Sprint to Coordinated Care;
- Establishes exceptions to Stark for certain value-based compensation arrangements between or among physicians, providers, and suppliers (see Compliance Note below);
- Establishes a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician;
- Establishes a new exception for donations of cybersecurity technology and related services;
- Amends the existing exception for electronic health records ("EHR") items and services; and,
- Providers critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by Stark.

COMPLIANCE NOTE: HHS further clarified its definition of "commercially reasonable" ("CR") which is a key component that must be met in developing arrangements between or among physicians, providers, and suppliers. Pinnacle's proprietary **CR checklist** will incorporate relevant updates and is available on request.

Overview of Anti-Kickback Revisions

The OIG finalized changes to the AKS to help streamline the alignment of providers in the improvement of healthcare quality and the reduction of healthcare cost. To that end, the OIG has developed a definition of what qualifies as a Value Based Entity ("VBE"), the regulations that must be met in developing a VBE, and certain safe harbors to protect the participants in VBEs when renumeration is exchanged. The OIG also noted that certain entities are not protected by the safe harbors such as pharmaceutical and medical device companies.

When developing a VBE, credit for the contribution must either be developed through an assessment of fair market value ("FMV") or through an accounting of cost. In addition, the contributions and all of the arrangements must be commercially reasonable, for which the definition was finalized to be consistent with the definition under the Stark Law.

COMPLIANCE NOTE: Accounting for all cost of the contributions in developing a VBE can prove difficult. In fact, the OIG expresses concern with provided IT systems that includes modules that likely exceed those needed by the VBE. If a party can contribute access to a system with reduced functionality than that used by the contributor, documenting the cost of the reduced system could be challenging.

If the VBE enters into a value-based arrangement without downside risk, the compensation paid under the arrangement must be consistent with FMV. If the arrangement includes partial or complete downside risk, the compensation under the arrangement does not have to comply with the FMV standard. While FMV documentation might not be required, the value-based arrangement (i) must still have incentives around meaningful outcomes and (ii) must be audited to assess the achievement of results and that no skimping for care occurred.

COMPLIANCE NOTE: While arrangements with downside risk might not have to comply with FMV, understanding the potential opportunities for revenue (e.g., shared savings) or expense reductions that should result in remuneration to a VBE and the participants in the VBE.

The OIG has also modified the safe harbor for personal services and management contracts. If these contracts have outcome measures tied to improved patient care, population health management, or reducing the cost of health care, the compensation does not have to be set in advance to comply with the safe harbor.

Key Takeaways

As outlined above, these final rules become effective January 19, 2021. As a result, healthcare providers have less than two months to evaluate its arrangements to ensure continued compliance. Pinnacle is evaluating these regulatory updates and the potential impact for our clients. Please stay on the lookout for additional analysis on these new rules in the upcoming weeks. **Please contact our team if you have any questions about immediate or future impact on your organization. Before setting up your VBE, please direct questions to:**

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