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Stark Law and Anti-Kickback Statute Changes Released in Final Rules

OIG and CMS Issued Final Rules Addressing Physician Self-Referral Regulations

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On November 20, 2020, both the Center of Medicare and Medicaid Services (CMS) and the Health and Human Services (HHS) Office of Inspector General (OIG) issued final rules regarding the physician self-referral regulations, commonly known as the “Stark

Law.” These new rules seek to spark innovation aimed at improved coordination and quality of patient care by reducing regulatory barriers associated with value-based arrangements.



Background

The path to the Stark Law updates started quite some time ago as part of the HHS's "Regulatory Sprint to Coordinated Care." CMS first published a request for information in June 2018 seeking feedback from the healthcare community regarding how to address regulatory barriers to facilitate a shift to value-based care. CMS and OIG both issued proposed rules in October 2019 and subsequently received public comments. The final rules were expected to be released in August 2020; however, in September CMS announced that the final rule publication date was extended until August 2021 given the complexity of the issues involved. Therefore, it was somewhat of a surprise when the final rules were released last week.

CMS Physician Self-Referral Regulations

The Stark Law was originally enacted to protect patients by prohibiting physicians from making referrals for certain health services provided to patients covered by Medicare if the physician or a close family member had a financial relationship with the provider of the service. However, the Stark Law has impeded providers from exploring potentially beneficial arrangements because of fear that such arrangements would violate the law. The [press release](#) issued by CMS to announce the finalized changes to the Physician Self-Referral Law indicates that "with providers taking on the accountability for the total cost of care for their patients, the risks regarding self-referral have changed."¹

According to the press release, many of the policies reflected in the proposed rule issued in October 2019 were incorporated in the final rule, including the following:

1. Finalizing new, permanent exceptions for value-based arrangements;
2. Finalizing additional guidance on key requirements of current exceptions to the Stark Law; including clarification on the definitions of "fair

market value" and "commercially reasonable;"

3. Finalizing protection for "non-abusive, beneficial arrangements" between physicians and other providers, including donations of cybersecurity technology; and
4. Reducing administrative burdens.

OIG Revisions to Safe Harbors

The Federal anti-kickback statute (AKS) and civil monetary penalty (CMP) laws similarly prohibit arrangements in which healthcare providers inappropriately receive financial gain resulting from referrals. The AKS "provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward, among other things, the referral of business reimbursable under any of the Federal health care programs, including Medicare and Medicaid."² The AKS includes specific safe harbors that provide protections to providers that meet the safe harbor requirements.

The CMP law contains provisions that prohibit inducements to beneficiaries, and provides for penalties against "any person who offers or transfers remuneration to a



Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program.ⁱⁱⁱ

According to the [Fact Sheet](#) issued by the OIG, the final rule aims to “reduce regulatory barriers to care coordination and accelerate the transformation of the health care system into one that better pays for value and promotes care coordination.”^{iv} Key provisions of the OIG final rule include the following:

1. Introduction of three new safe harbors to protect Value-Based Arrangements:
 - a. Care Coordination Arrangements;
 - b. Value-Based Arrangements with Substantial Downside Risk, and
 - c. Value Based Arrangements with Full Financial Risk;
2. Introduction of a new safe harbor related to patient engagement and support;
3. Introduction of a new safe harbor related to CMS-sponsored models;
4. Introduction of a new safe harbor for donations of cybersecurity

- technology and services (including hardware, software, and services);
5. Modifications to existing safe harbors, including:
 - a. Enhanced protection related to Electronic Health Records items and services, including removal of sunset date;
 - b. Added flexibility for certain outcome-based payments and part-time arrangements;
 - c. Revision of the definition of “warranty” and expansion to provide protection for bundled warranties;
 - d. Expanded mileage limits for rural areas and other changes to local transportation rules;
 - e. Codification of the statutory exception to the definition of “remuneration” as it relates to the Medicare Shared Savings Program; and
 - f. Amendment to the definition of “remuneration” as it relates to the statutory exception for “telehealth technologies” provided to patients receiving in-home dialysis.

Certain types of entities are ineligible to use certain new safe harbors, as they are deemed to pose a greater risk of fraud and abuse.

Implementation

Both sets of rules have an effective date of 60 days following the date of display in the Federal Register, which is understood to be January 19, 2021, except for one provision in the CMS final rule related to group practice profit sharing. That provision has a delayed effective date of January 1, 2022.



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ⁱ Center for Medicare & Medicaid Services. (2020, November 20). *CMS Announces Historic Changes to Physician Self-Referral Regulations* [Press release]. <https://www.cms.gov/newsroom/press-releases/cms-announces-historic-changes-physician-self-referral-regulations>

ⁱⁱ HHS Office of Inspector General Fact Sheet, Final Rule: Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, November 2020. <https://oig.hhs.gov/reports-and-publications/federal-register-notices/factsheet-rule-beneficiary-inducements.pdf>

ⁱⁱⁱ Ibid.

^{iv} Ibid.