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Kutak Rock Client Alert

Stark Law and AKS 2020 Final Rules

On Friday, November 20, 2020, the U.S. Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) released final rules revising the regulations implementing the Ethics in Patient Referrals Act (commonly known as the “Stark Law”),¹ (the “Stark Law Final Rule”) and the Federal Anti-Kickback Statute² (the “AKS Final Rule” and, collectively with the Stark Law Final Rule, the “Final Rules”). Both Final Rules are scheduled to be published December 2, 2020. The unpublished Final Rules are located [here](#) (for the Stark Law Final Rule) and [here](#) (for the AKS Final Rule).

The Final Rules are substantial. We are issuing this Client Alert to make you aware of the Final Rules and to provide you with a high-level and cursory summary of the significant provisions of the Final Rules. We are preparing a more comprehensive overview of the Final Rules and will make that available to our clients once complete. In the interim, if you have questions regarding the Final Rules or their applicability to your business arrangements, please reach out to a member of [Kutak Rock's National Healthcare Practice Group](#).

Stark Law Final Rule

The Stark Law Final Rule, generally effective January 19, 2021, establishes new exceptions to the physician self-referral law prohibitions for:

1. Certain value-based compensation arrangements between or among physicians, providers and suppliers.
2. Certain arrangements where a physician receives limited remuneration for items or services actually provided by the physician that does not exceed \$5,000 per calendar year.
3. Donations of cybersecurity technology and related services.

Additionally, the Stark Law Final Rule provides for additional definitions and clarifications of existing definitions, as follows:

1. New definitions for *Commercially reasonable*, *Cybersecurity*, and a number of terms relating to the new value-based compensation arrangement exception (i.e., *Target patient population*, *Value-based activity*, *Value-based arrangement*, *Value-based enterprise*, *Value-based purpose*, and *VBE participant*).
2. Clarification of when *inpatient hospital services* would not be considered designated health services.
3. Revised definitions of *Fair Market Value* and *Interoperable*.

CMS has also (i) revised language relating to the isolated transactions exception (and provided helpful commentary as to the scope of that exception), (ii) deleted language related to determining the period of disallowance (and confirmed prior commentary contained in the proposed rule relating to correcting errors during a current compensation arrangement) and made revisions to 42 CFR 411.354 to provide a

new special rule for reconciling compensation during the 90 days following the expiration or termination of a compensation arrangement with a physician; (iii) revised the definition of indirect compensation arrangements; (iv) revised the set in advance requirements; (v) clarified language related to directed referrals requirements in employment, personal service, and managed care arrangements with a physician; and (vi) clarified the rules for changing compensation more frequently than annually. CMS has also made clarifications to permissible allocation methodologies for group practices that will be effective January 1, 2022.

Finally, with respect to rental of office space or equipment, CMS has included clarifications to exclusive use requirements in the rental of office space and equipment rental exceptions and has made the fair market value exception available to protect office space leases and equipment leases by physicians.

Anti-Kickback Statute

The AKS Final Rule, also effective January 19, 2021, adds new safe harbors and modifies existing safe harbors to the federal Anti-Kickback Statute that protect certain payment practices and business arrangements from sanctions under the Anti-Kickback Statute.

The OIG is finalizing new safe harbors as follows:

1. Value-Based Arrangements Safe Harbor to protect remuneration exchanged between or among participants in a value-based arrangement.
2. Patient Engagement and Support Safe Harbor for patient engagement tools and supports furnished by a participant in a value-based enterprise to a patient in a target patient population.
3. CMS-Sponsored Models Safe Harbor for CMS-sponsored model arrangements and patient incentives that would require OIG fraud and abuse waivers.
4. Cybersecurity Technology and Services Safe Harbor for remuneration in the form of cybersecurity technology and services.

Additionally, the OIG is finalizing modifications to the following safe harbors:

1. Electronic Health Records Safe Harbor to update and remove provisions regarding interoperability; remove the sunset provision and prohibition on donation of equivalent technology; and clarify protections for cybersecurity technology and services included in an EHR (Electronic Health Record) arrangement.
2. Personal Services and Management Contracts and Outcomes-Based Payments Safe Harbor to facilitate protection under safe harbor for part-time or sporadic arrangements and arrangements for which aggregate compensation is not known in advance and to finalize new protections for outcomes-based payments.
3. Warranties Safe Harbor related to the definition of warranty and provide protection for warranties for one or more items and related services.
4. Local Transportation Safe Harbor to expand mileage limits for rural areas and eliminate mileage limits for transportation to convey patients discharged from the hospital to their place of residence.

The AKS Final Rule further codifies statutory revisions by adding the statutory exception to remuneration related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program and to add the new statutory exception to remuneration under the beneficiary inducements CMP (Civil Monetary Penalties law) for “telehealth technologies.”

¹ 42 U.S.C. § 1395nn

² 42 U.S.C. § 1320a-7b(b)

