

HHS RELEASES TRANSFORMATIONAL NEW REGULATIONS UNDER STARK AND THE ANTI-KICKBACK STATUTE

November 23, 2020

On Friday, November 20, 2020, the U.S. Department of Health and Human Services released new regulations under the Physician Self-Referral Act (Stark) and the Anti-Kickback Statute (AKS). The regulations (found [here](#) and [here](#)) include significant changes to existing provisions to the Stark regulations and AKS safe harbors, as well as new exceptions under Stark and new safe harbors under the AKS.

The new Stark regulations, which encompass over 600 pages of regulations and regulatory comments, include updates addressing the following items, among others:

- Value-based entities and value-based arrangements involving different levels of financial risk
- New exception for cybersecurity technology
- New exception for fair market compensation of up to \$5,000 without requirement for contemporaneous documentation
- Commercial reasonableness
- Compensation formulas that are considered to be determined in a manner that takes into account the value or volume of referrals and other business generated
- The definition of “fair market value”
- Distribution of profits from designated health services within a group practice
- Revisions to the definition of “designated health services” to effectively remove some inpatient hospital services ordered after a patient’s admission from the list of referrals prohibited by Stark
- Modifications to the standards relating to the “isolated financial transaction” exception
- Elimination of prior regulations relating to the period of disallowance following a Stark violation
- Reconciliation of payment discrepancies in compensation arrangements
- CMS policy regarding directing a physician’s referrals to a particular provider, practitioner, or supplier
- Guidance on requirements for written documentation for Stark exceptions
- Permitting use of the fair market value exception for office leases
- Permanence and expansion of the EHR exception.

A number of the new AKS regulatory provisions are structured to align with similar modifications to the Stark regulations. The modifications and updates to the AKS regulations include the following, among others:

- New safe harbor for care coordination arrangements to improve quality, health outcomes, and efficiency
- New safe harbors for value-based arrangements
- New safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency
- New safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives
- New safe harbor for cybersecurity technology and related services
- New safe harbor for accountable care organization (ACO) beneficiary incentive programs
- Modifications to the existing safe harbor for personal services and management contracts, warranties, and EHR items and services
- Provisions for telehealth technologies for in-home dialysis.

We will be providing additional Client Advisories with more detailed information on these important regulatory developments in the coming days. In the meantime, if you have any questions or need further guidance regarding these new regulations and their potential impact upon existing and future arrangements, please contact a member of Hancock Daniel's [Fraud & Abuse](#) team.

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