

Stark Law and Anti-Kickback: Update and Examples

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Stark Law Prohibition

- Physician may not refer Medicare / Medicaid patients to a DHS entity if the physician (or immediate family member) has a financial relationship with the entity.
- DHS entity cannot bill for the services.
- Unless the financial relationship qualifies for an exception.



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Anti-Kickback Law

- Prohibits the willful and knowing offer, solicitation, payment, or receipt of any remuneration, directly or indirectly for
 - Referring an individual covered by a government health program or arranging for such a referral; or
 - Purchasing, leasing, ordering, arranging for, or recommending the purchase, lease, or order of any good, facility, service, or item covered by a government health program.

What's New in Stark Regulations?

- Minor change to the delayed signature provision
 - By regulation, parties have up to 90 days to procure the necessary signatures in order to satisfy the written agreement requirement of certain exceptions.
 - Section 50404 of the Bipartisan Budget Act of 2018 removed the restriction that the provision can be used only once every three years with respect to the same referring physician.

What's New in Stark Regulations?

- Codification of policy on collection of documents to satisfy written agreement requirement
 - In CY 2016 PFS Final Rule, CMS clarified that writings can be aggregated to satisfy the written agreement requirement in certain compensation exceptions.
 - Section 50404 of the BiBA of 2018 codified this policy in section 1877 of the Act, stating that the written agreement can be satisfied by such means as determined by the Secretary.
 - In CY 2019 PFS Proposed Rule, CMS proposed a special rule on compensation arrangements at § 411.354(e), which states that the writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

CMS Issues RFI for Stark

- On June 25, 2018, CMS published a Request for Information on Stark.
- Primary motivation appears to be CMS's awareness that Stark may have an adverse effect on health care providers' willingness to participate in "integrated delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost."
- CMS notes that the President's Budget for FY 2019 includes a legislative proposal for a new Stark exception for arrangements involving alternative payment models.

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