

CMS Changes and Clarifications to Stark Regulations Now Effective

The Centers for Medicare & Medicaid Services ("CMS") finalized numerous modifications to the physician self-referral law, known as the Stark Law, in the Calendar Year 2016 Physician Fee Schedule Final Rule (the "Final Rule"). Among the changes described in detail below are: two new exceptions; some clarification to the writing, term and holdover requirements; and additional technical revisions.

While many of the changes arise from CMS's Self-Referral Disclosure Protocol ("SRDP") experience and reflect CMS's stated intent to relax some of the more rigid and prescriptive requirements of the Stark Law, the Final Rule does not indicate that federal enforcement officials are any less concerned about the potential fraud and abuse found in physician arrangements. As such, hospitals and health systems should shift their focus from technical compliance to substantive compliance—in particular, fair market value and commercial reasonableness.

Most of the changes finalized by CMS became effective on January 1, 2016.

Revisions to the Stark Law Regulations

1. Two New Exceptions. CMS adopted two new Stark Law exceptions.
 - Recruitment of Non-physician Practitioners. CMS created a new exception that allows hospitals to provide remuneration to a physician to assist with the employment or contracting of a non-physician practitioner, which is defined to include physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives, clinical social workers and clinical psychologists. To fit the exception, the non-physician practitioner needs to provide substantially all primary care services, which CMS considers to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services, or mental health services. As with all Stark Law exceptions, there are various additional elements to address concerns of misuse including, without limitation, requirements for the arrangement between the physician or physician practice and the non-physician practice, a limitation of recruitment incentives to 50% of the actual aggregate

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compensation, signing bonus and benefits paid to the non-physician practitioner, and a limit on the frequency of providing such incentives.

- Timeshare Leases. The popularity of "timeshare" leases and the significant number of SRDP disclosures related to such leases led CMS to create a new exception for circumstances under which, among other requirements, the physician uses the licensed premises, equipment, personnel, items, supplies or services predominately for evaluation and management of patients.

1. Clarifications Regarding Writing, Term and Holdover Provisions of Certain Exceptions. Due to the large number of SRDP disclosures based on technical noncompliance, CMS adopted various clarifications and changes to the writing, term and holdover requirements found in many of the Stark Law exceptions. In particular:

- Writing. CMS clarified that an "arrangement" for purposes of the Stark Law need not be reduced to a single "formal" written contract in order to satisfy the writing requirements of an applicable Stark Law exception. Rather, to satisfy the writing requirement, the facts and circumstances of an arrangement must be sufficiently documented to permit the government to verify compliance with the applicable exception. As such, a collection of contemporaneous documents evidencing the course of conduct between the parties is sufficient to meet this requirement. While CMS declined to give an example of contemporaneous documents that would, taken as a whole, satisfy the writing requirement, it did provide examples of documents that may be considered in the analysis including, without limitation, board meeting minutes, written communications between two parties, fee schedules, check requests or invoices, time sheets and call coverage schedules.
- Term. CMS clarified that the one-year requirement found in the space, equipment and personal service exception does not actually require a written contract with a term of one year. Rather, this requirement may be satisfied if the parties have contemporaneous writings establishing that the arrangement actually lasted for at least one year, or are able to demonstrate that the arrangement was terminated during the first year but that the parties did not enter into a new arrangement for the same space, equipment or services during the first year.
- Holdover. CMS amended the holdover provisions in various Stark Law

exceptions to permit indefinite holdovers as long as the holdover continues on the same terms and conditions as the original arrangement.

1. Other Technical Revisions. In addition to the two new exceptions set forth above, CMS adopted various technical revisions that provide clarity, offer flexibility and promote compliance. Specifically, CMS:

- Added a definition of the geographic area served by a federally qualified health center ("FQHC") or rural health clinic ("RHC") to the exception for physician recruitment to ensure that the geographic area served by these entities appropriately captures the areas where their patients actually reside. CMS defined the geographic area served by a FQHC or RHC as the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90% of its patients, as determined on an encounter basis.
- Amended certain exceptions to ensure references pertaining to the volume or value of referrals consistently use the phrase "takes into account."
- Revised the exception for retention payments to clarify that such payments shall not exceed 25% of the physician's current income, measured over the entire 24-month period preceding the payment.
- Revised the definition of "remuneration" to make it clear that, to be exempted from the definition, an item must be used solely for one or more of the six purposes listed in the statute.
- Amended the "stand in the shoes" provisions to clarify that, for all purposes other than the signature requirement, all physicians in a physician organization are considered parties to a compensation arrangement between the physician organization and a DHS entity.
- Revised the definition of "locum tenens" physicians to remove the reference to "stand in the shoes" for clarity purposes.
- Revised the exception for ownership or certain publicly traded securities and mutual funds to include securities listed for trading on an electronic stock market or OTC quotation system in which the quotations are published on a daily basis and trades are standardized and publicly available. Note that, unlike the other revisions, this revision has an effective date of January 1, 2017.
- Amended the exception for temporary noncompliance with signature



requirements to allow the parties 90 days to obtain the required signatures, regardless of whether or not the failure to obtain the signature(s) was inadvertent.

In light of these recent changes to the Stark Law, hospitals and health systems should carefully review and revise their physician contracting policies and procedures to ensure compliance. In addition, audit and monitoring plans should be revised to focus on fair market value and commercial reasonableness.

Reinhart's Health Care team is available to assist you in reviewing your policies, procedures and plans, as well as analyzing your relationships with physicians and physician organizations. Please feel free to contact [Heather Fields](#) or any member of Reinhart's Health Care team or your Reinhart attorney to discuss any questions or concerns related to your hospital or health system.

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