

CMS Proposes New Stark Exceptions and Clarifications

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The new Proposed Physician Fee Schedule Rule for 2016 (the “Proposed Rule”) issued by the Centers for Medicare and Medicaid Services (“CMS”) includes a number of revisions to the physician self-referral regulations (the “Stark Law”). The Proposed Rule was published in the Federal Register on July 15, 2015.

The Proposed Rule includes two new exceptions to the Stark Law, clarifies a number of questions providers have raised in interpreting the Stark Law and makes other technical revisions that would provide for more flexibility in the application and enforcement of the Stark Law. These proposed changes, if finalized, would be extremely helpful to providers, since the Stark law is a strict liability statute.

The key changes included in the Proposed Rule are as follows:

Written Agreement / Terms and Signature Requirements. Many of the exceptions included in the Stark Law (including those for realty and equipment leases, personal service arrangements and fair market and indirect compensation) require a signed “writing” or “written agreement” with a term of at least one year.

- The proposed rule indicates that a single formal agreement is not required, but depending on the facts and circumstances of the arrangement and the available documentation, a number of contemporaneous documents, including documents evidencing the course of the parties’ conduct, would satisfy the requirement of a writing or written agreement.
- CMS also indicates that the requirement of a minimum one-year term does not need to be explicitly stated in the written agreement, as long as the arrangement lasts at least one year.
- CMS proposes to allow parties 90 days to ensure that an agreement is fully signed. At present, the temporary non-compliance grace period for a late signature ends after 30 days.

Holdover Arrangements: Under the present regulations, holdover arrangements can be up to six months if: (i) the one year arrangement expires; (ii) the arrangement falls within an exception when it expires; and (iii) the arrangement continues on the same terms and conditions as the original arrangement. Under the Proposed Rule, the time limitations would be eliminated and there could be indefinite holdovers or, alternatively, the holdover period could be for a definite period of time, and would not be limited to six months.

Physician-Owned Hospitals: The Proposed Rule would also remove certain advertising requirements for physician-owned hospitals that have been in place under the current Stark Law. Specifically, the Proposed Rule would limit the types of websites and the forms of advertising requiring that the hospital disclose that it has physician ownership. It also clarifies the nature of disclosure statements that would comply with the disclosure requirements. The Proposed Rule would also permit hospitals, when calculating the baseline and prospective levels of physician investment, to include all physician owners, whether or not such owners are referring physicians.

New Exceptions

- **Timeshare Leases**

The Proposed Rule would include a new exception for qualifying timeshare arrangements between physicians and hospitals. To qualify under the proposed exception, the following factors must be met: (i) the arrangement must involve a situation where a hospital or physician organization is the licensee; (ii) the licensee must use the licensed premises, as well as the equipment, personnel, items, supplies and services predominantly to furnish evaluation and management services to patients of the licensee; and (iii) the arrangement could not involve advanced imaging equipment, radiation therapy equipment or clinical or pathology laboratory equipment. The exception would not protect independent diagnostic testing facilities and clinical laboratories. The Proposed Rule would also require that license fees under part-time arrangements be based on time and not consider the number of patients seen or the amount of revenue raised, earned, billed, collected or otherwise attributable to the services provided by the licensee. The Proposed Rule would not protect part-time and exclusive leases of office space. Such leases would continue to be reviewed under the exception for real property leases.

- **Assistance to Physicians to Employ Non-Physician Practitioners**

The Proposed Rule would include an exception to the Stark Law for payments made by a hospital, Federally Qualified Health Center (“FQHC”) or Rural Health Center (“RHC”) to a physician to assist the physician in employing a non-physician practitioner in the hospital’s, FQHC’s or RHC’s geographic service area. Non-physician practitioners would include physician assistants, nurse practitioners, clinical nurse specialists and certified nurse midwives. The non-physician practitioner would have to be a *bona fide* employee of the physician or practice, and the person would have to be employed for the purpose of providing primary care services to patients of the practice. The Proposed Rule includes a two-year limit and a cap on the amount of payment.

Technical Clarifications and Revisions

The Proposed Rule also includes a number of technical clarifications and revisions to the Stark Law, including a revised definition of “remuneration” which provides that where a physician uses hospital resources but bills the payor for his or her services and the hospital bills the payor for its resources and services, there is no remuneration between the parties. The Proposed Rule also makes technical changes to the “stand-in-the-shoes rules” concept of the Stark Law where an individual physician in a physician organization is considered to “stand in the shoes” of the organization that has a compensation arrangement with a referral entity for the purpose of

determining if there is a Stark Law violation. And, the Proposed Rule defines the method for determining the geographic area served for purposes of the Stark Law's physician recruitment exception when utilized by FQHCs and RHCs.

What do we take away from these changes? As the Preamble to the Proposed rule indicates, CMS recognizes that there may be a need for more flexibility that takes into consideration individual circumstances, given that the Stark Law was originally designed for a fee-for-service health care system, and providers are now moving into new types of purchasing and cooperative arrangements that were not anticipated a number of years ago. This is good news for providers, who need such flexibility to effectively navigate the ever-changing business of health care.

CMS is accepting public comments on the Proposed Rule, until September 8, 2015. CMS will issue the final rule by November 1.

Should you have questions regarding the immediate implications of this Proposed Rule, including its implications for those facing potential violations that the rule, if adopted, might eliminate, please contact your usual Hinshaw & Culbertson attorney or [Michael Dowell](mailto:mdowell@hinshawlaw.com) (mdowell@hinshawlaw.com; 310- 909-8090), health care partner in our Los Angeles office.

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Michael A. Dowell

Partner

📞 213 614-7341