



Alerts

CMS Adopts Final Stark Rule Exceptions and Clarifications

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Health Law Alert

On October 30, 2015, CMS issued its final changes to the physician self-referral regulations (the "Stark Law") as part of the Physician Fee Schedule Rule for 2016, published in the Federal Register on November 16, 2015. The Final Rule adopts most of the provisions set forth in the July 15 proposed rule, which Hinshaw & Culbertson LLP previously summarized [here](#). A brief summary of the Final Rule, highlighting changes to the July proposed rule, follows:

Timeshare Arrangements

Under the Stark Law regulations pre-dating the Final Rule, timeshare arrangements had to be analyzed under the exception for the rental of office space. CMS, recognizing the distinct differences between more traditional office space lease agreements and timeshare arrangements, created a new exception for qualifying timeshare arrangements, while leaving the rental of office space exception intact.

The exception protects only those arrangements granting a right or permission to use the premises, equipment, personnel, items, supplies and services of another party without establishing a possessory leasehold interest in the medical office space that constitutes the premises. Drawing comparisons between a timeshare arrangement and a license, the Final Rule refers to the parties to a timeshare arrangement as "licensor" and "licensee." While CMS specifies that the terminology used by the parties in the documentation describing the timeshare arrangement will not control whether the parties have satisfied the exception, healthcare providers nonetheless might consider the use of such nomenclature in applicable agreements.

The exception applies to those timeshare arrangements between a physician (or the physician organization in whose shoes the physician stands) and a hospital or a physician organization of which the physician is not an owner, employee or contractor - *regardless* of which party grants and which party receives permission to use the premises, equipment, personnel, items, supplies and services of the other party. The proposed rule contemplated applicability of the exception only in those arrangements in which a hospital or physician organization was the licensor and a physician the licensee. In addition, while the proposed rule contained a requirement that all equipment be located in the same office suite in which the physician performs evaluation and management services, the Final Rule requires only that the equipment covered under the arrangement be located in the "same building" as where the evaluation and

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management services are furnished.

Additional factors must be met to qualify for protection under the exception. We recommend that hospitals, physician organizations and physicians that are currently party to, or are contemplating entering into, a timeshare arrangement carefully review both the Final Rule and their current or proposed timeshare agreements to ensure compliance with the various requirements and limitations of this exception.

Assistance to Compensate Nonphysician Practitioners

The Final Rule creates a second new exception for payments made by a hospital, Federally Qualified Health Center (FQHC) or rural health clinic (RHC) to a physician to assist the physician in employing or contracting with nonphysician practitioners (NPPs) in the hospital's, FQHC's or RHC's geographic service area. The existing exception permits payment to assist in relocation of physicians. The Final Rule expands the scope of the exception to permit both compensation arrangements between physicians and NPPs for employment *and* for contracted services – noting, however, that it must be a *direct* compensation arrangement between the physician and NPP. The Final Rule also expands the exception, at the urging of commenters, to cover the employment or contracting of mental health care providers, specifically expanding the definition of "nonphysician practitioner" to include clinical social workers and clinical psychologists, in addition to the nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwives called out in the proposed rule. Finally, the Final Rule adopts a "substantially all" standard (meaning at least 75%) for the minimum amount of primary care services or mental health services that an NPP must furnish to patients of the physician's practice.

Hospitals, FQHCs and RHCs interested in pursuing their options under this exception should carefully study the Final Rule in order to understand all relevant limitations.

Clarifications

In addition to the two new exceptions summarized above, the Final Rule clarifies a number of questions that providers have raised in interpreting the Stark Law and makes certain technical revisions to provide for more flexibility in the application and enforcement of the Stark Law. Among these clarifications and technical revisions are the following:

- Updating various exceptions to use the terminology "takes into account," with respect to the volume or value of referrals, rather than the phrase "based on" volume or value of referrals. This change is intended to provide for uniform interpretation of the concept, although CMS has, to date, declined to define the term "takes into account."
- Clarification that the requirement that arrangements be "in writing" does not equate to a requirement for a single, formal contract; rather, a collection of documents evidencing the course of conduct between the parties *may* be sufficient, depending on the facts and circumstances of the arrangement and the available documentation.
- Approval of indefinite holdovers under the office space and equipment lease exceptions and the personal service arrangements exception, provided certain safeguards are met. Prior to the Final Rule, these exceptions permitted a holdover arrangement for up to six months if a compliant arrangement of at least one year expired but the parties continued to act under the same terms and conditions. The Final Rule permits indefinite holdover arrangements, provided the holdover must continue on the same terms and conditions as the original agreement and the holdover satisfied all of the elements of the applicable exception when the arrangement expired and continues to satisfy such exception on an ongoing basis during the holdover.
- Extension of the requirement to obtain required signatures, from 30 days to 90 days, regardless of whether the failure to obtain the signature(s) was inadvertent.
- Clarification and modification of the restrictions on physician ownership and investment in hospitals.

Healthcare providers interested in learning more about the two new exceptions, and/or any of the clarifications and modifications set forth in the Final Rule are encouraged to contact their usual [Hinshaw attorney](#) or [Stephen T. Moore](#).