CMS Finalizes Two New Exceptions and Modifications to the Stark Law

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Practice Area: Health Law

The Centers for Medicare and Medicaid Services (CMS) recently published its final rule modifying several aspects of the federal physician self-referral law (the "Stark Law") and adding two new exceptions: one for recruitment of non-physicians providing primary care and the other for timeshare arrangements.

For the most part, CMS's changes lessen the Stark Law's compliance burden and aim for uniformity among the exceptions. At the same time, the two new exceptions create additional compliance and monitoring requirements for individuals and entities wishing to take advantage of the exceptions.

Most of the changes are effective January 1, 2016.

Stark Law Background
The Stark Law prohibits a physician from receiving remuneration, such as cash or other goods, from certain types of entities to which the physician refers patients for certain types of "designated health services" (DHS). This general prohibition is subject to numerous exceptions. If the general prohibition applies and the arrangement does not meet an exception to the Stark Law, the physician may not refer DHS to the entity.

New Exception: Assistance to Physicians to Employ Nonphysician Practitioners
Noting the need to increase access to care and primary care physician shortages, CMS now permits hospitals, federally qualified health centers, and rural health clinics to provide remuneration to a physician for the physician's recruitment of nonphysician practitioners into the entity's service area. The nonphysician practitioner must be an employee or directly contracted with a physician or physician group and provide primary care or mental health services.

CMS considers primary care to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology. Nonphysician practitioners include physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives. Certified registered nurse anesthetists are specifically excluded. In the final rule, CMS added clinical social workers and clinical psychologists to its list of nonphysician practitioners.

This new exception has several other requirements:

1. 75% of the practitioner's services must be primary care or mental health services.
2. In the year prior to the entity's provision of assistance to the physician or physician group, the practitioner must not (1) have practiced in the entity's geographic area or (2) have been employed by a physician or physician group within the entity's geographic area.
3. The entity may provide assistance for two consecutive years of the practitioner's engagement.
4. The assistance is limited to 50% of the practitioner's actual salary, signing bonus, and benefits actually paid by the physician or physician group to the practitioner.

New Exception: Permissible Timeshares
CMS finalized a new exception for timeshare arrangements for the use of premises, equipment, personnel, items, supplies, and services. In addition to traditional Stark law requirements (*e.g.*, requirement that the arrangement is in writing), the new exception requires that:

1. The arrangement is between (1) a hospital or physician organization in which the physician is not an owner, employee, or contractor and (2) a physician.
2. The premises, equipment, personnel, items, supplies, or services must be used predominantly for evaluation and management services and at the same time the evaluation and management services are provided.
3. The equipment must be in the same building where the evaluation and management services are furnished.
4. The timeshare cannot include advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment for CLIA-waived laboratory tests).

This exception provides additional flexibility in allowing certain arrangements that might not qualify for the exception for lease arrangement. The lease exception generally requires exclusive dominion and control of the premises for a specified period of time. In contrast, the proposed rule stated that the timeshare exception is for "licensees" on the hospital or physician organization's premises. CMS clarified in its final rule that the arrangement must not convey a "possessory leasehold interest" in the office space. So while non-exclusive sharing arrangements might now be eligible for protection under this new exception, exclusive-use arrangements for space and equipment (including landlord-tenant relationships) should continue to be analyzed under the existing leasing exceptions.

Terminology and Phrase "Clean Up"
The final rule "cleans up" differences between certain phrases in the Stark exceptions. For example, several existing exceptions prohibit compensation that "takes into account" or is "based on" the volume or value of DHS referrals. The final rule eliminates these inconsistent terms by modifying the exceptions to use "takes into account" on a consistent basis.

The final rule aims to create uniformity on the "writing" requirement found in many exceptions. For example, CMS removed the term "agreement" from certain exceptions in favor of the more general term "arrangement." CMS does note that the exceptions still require a "writing" but not a particular kind of writing (*e.g.*, a formal contract). Writings should be contemporaneous in order to satisfy the writing requirement.

CMS clarified that employees and independent contractors of a physician organization do not "stand in the shoes" of their physician organization. Only physicians with an ownership or investment interest stand in the shoes and are the parties to an arrangement for purposes of an exception's signature requirements. However, when determining whether a compensation arrangement takes into account volume or value of referrals or other business generated, CMS will look at all physicians in the physician organization regardless of whether they stand in the shoes of that organization.

The final rule adopts a straightforward definition of the "geographic area" of an FQHC or RHC. This definition is important for recruitment purposes in the Stark exception. "Geographic area" means the area composed of 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.

Modifications to Term, Holdover, and Signature Requirements
Certain exceptions, such as rentals of office space or equipment and personal service arrangements, require a minimum one year term. CMS clarifies that the arrangement need not have an explicit one year term provision to satisfy that requirement so long as the facts and circumstances of the arrangement and available documents (including other contemporaneous documents) can establish that the one year term requirement was met.

The final rule also permits indefinite holdover periods for office space or equipment rental or personal service arrangements, so long as the holdover is on the same terms and conditions as the preceding arrangement and the arrangement otherwise continues to comply with an applicable exception.

Under the fair market value exception, arrangements for less than one year can be renewed any number of times. CMS expanded this exception so that arrangements of any timeframe may be renewed any number of times.

CMS finalized its proposal to adopt a uniform 90 day timeframe to obtain signatures on otherwise compliant arrangements, regardless of whether the failure to obtain signatures was inadvertent or not inadvertent. However, hospitals may still only rely on this once every three years for the same referring physician.

Publically-Traded Stock and Physician-Owned Hospitals
CMS also finalized its proposal that stocks on standardized and publicly transparent electronic stock markets and OTC quotation systems may now fit into the publicly-traded securities exception.

CMS also finalized changes to the physician-owned hospital exception. This includes changes to the public web site and public advertising disclosure requirements and calculation of physician ownership.

Conclusion
Overall, CMS's changes to the Stark Law should be advantageous to entities. For the most part, its modifications to existing exceptions relax the strict compliance requirements. However, taking advantage of the two new exceptions will create additional compliance and monitoring burdens on individuals and entities seeking to comply with the exceptions.

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