Health Law Alert: CMS Tries to Reduce Stark Law Compliance Burden in 2016 Physician Fee Schedule Final Rule

November 24, 2015

The Department of Health and Human Services (HHS) finalized the 2016 Physician Fee Schedule (also known as the "Final Rule") on November 16, 2015. The Final Rule contains several important changes to the Stark Law and broadly reflects an effort by the Centers for Medicare & Medicaid Services (CMS) to reduce the compliance burden. The flexibility announced by CMS stands in contrast to the extremely aggressive positions taken by the U.S. Department of Justice in recent Stark Law enforcement actions, including the *Tuomey, Halifax Medical Center* and *Adventist Health* cases. **Click here to view the Final Rule, 80 Fed. Reg. 70886.**

The Stark Law prohibits physicians from making referrals for designed health services (DHS) paid for by Medicare if the physician has a prohibited financial relationship with the entity receiving the referral. It is a "strict liability" law in the sense that if the law is triggered, and an exception cannot be met, the Stark Law is violated—regardless of the parties' intent. Violations mean that all claims arising from the prohibited referral are disallowed and need to be refunded. Regulators can also impose significant civil fines for violating the Stark Law, and violations also form the basis for many False Claims Act cases. Key changes announced in the Final Rule include the following:

- New exception for non-physician practitioners
- What does it mean to have a "written agreement"?
- How do we show that an agreement has been in place for at least one year?
- New flexibility for "holdover" arrangements
- Expansion in exception for certain types of "remuneration" from creating a compensation arrangement
- New exception for timeshare arrangements
- Other changes
- Adopting the Stark Law to a non-fee-for-service world

New exception for non-physician practitioners

The Final Rule creates a new exception that allows a hospital, Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) to provide remuneration to a physician organization to employ or contract with certain nonphysician practitioners (NPPs) in the hospital, FQHC, or RHC's geographic area.

The exception is available for NPPs who spend "substantially all" of their time furnishing mental health or primary care services. Qualifying NPPs include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical social workers, and clinical psychologists. The exception includes elements common to other exceptions, including that payment cannot be determined in a manner that takes into account the volume or value of referrals and must reflect a fair market value range for services provided. To qualify, the NPP cannot have practiced in the geographic area within one year of the arrangement. While a welcome addition to the Stark Law, the NPP exception is complex and functions similarly to the existing exception for physician recruitment arrangements.

What does it mean to have a "written agreement"?

A number of key exceptions require that an arrangement be "set out in writing." Providers have long struggled to understand exactly what is required by this element of the exceptions, wondering, for example, whether it means that all aspects of a contract must be spelled out in one formal contract or whether something short of that will suffice. The Final Rule makes a welcome change, clarifying that an arrangement need not be set out in "a single formal contract," but—depending on the facts and circumstances—"a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement[s]."

HHS issued a note of caution, however. Entities providing DHS have the burden of proof to establish that services were not furnished as a result of prohibited referrals and that all elements of an exception were met. The Final Rule opines that the "surest and most straightforward" means to comply with the various writing requirements in the Stark Law is to incorporate the key elements of an arrangement into a signed writing before either party provides items, services, space, or compensation to other party.

How do we show that an agreement has been in place for at least one year?

Several important exceptions, including for rentals and personal service arrangements, require that the arrangement last for at least one year. The Final Rule clarifies that the requirement for an arrangement to last for at least one year need not be set out in a formal contract. Rather, the course of conduct between the parties can establish that the arrangement in fact lasted for the required period of time. HHS explained that the test involves analyzing whether a reasonable person would view the arrangement as continuing for the required period of time. In spite of the more liberal approach adopted with respect to this element of the exceptions, parties should be cautious about using the "course of conduct" option as a regular practice.

New flexibility for "holdover" arrangements

Until now, certain exceptions permitted "holdover" arrangements of up to six months at the expiration of an arrangement of at least one year if the requirements of the exception were met at the time of the expiration and continue to be met during the holdover period. The idea is that if an arrangement met an exception, but expired due to the relevant contract language, the expired arrangement should be allowed to continue in compliance with Stark as long as its terms did not change. The Final Rule permits indefinite holdovers, provided that certain additional safeguards are met. Parties should view the "holdover" exceptions as a last resort, however, as permitting expired arrangements to continue for a protracted period of time can potentially cause the arrangements to fall out of compliance with other important elements of applicable exceptions—including fair market value requirements—in some cases.

Expansion in exception for certain types of "remuneration" from creating a compensation arrangement

Under the Stark Law, providing certain limited types of remuneration does not create a compensation arrangement (for which an exception must be met). This includes providing items or supplies that are "*used solely*" to collect, transport, process, or store specimens for the entity providing the item or supply, or order or communicate the results of tests or procedures for such entity. The Final Rule clarifies that use of these items for *one or more* of the six purposes set forth in the Stark Law statute does not qualify as remuneration that would create a compensation arrangement.

New exception for timeshare arrangements

It is common, especially in underserved areas, for a hospital or local physician practice to ask a specialist from a neighboring community to provide services to the patients of the hospital or the physician practice group on a limited basis. Such a hospital or local physician practice might want to provide a visiting physician—on a limited "timeshare" basis—the space, equipment, and services necessary to treat patients. Regulators have expressed concern that existing exceptions, including the exception for rental of office space, would not apply to a timeshare arrangement.

To address this, the Final Rule creates a new, quite narrow exception for timeshare arrangements. Under the exception, premises, equipment, personnel, supplies, and services covered must be used predominately for the provision of evaluation and management (E/M) and not for the provision of DHS other than those incidental to E/M furnished at the time of the patient's visit. The exception is only available for certain types of providers—physicians and hospitals—and equipment covered by the timeshare must be in the same building as the office where the E/M services are provided. Certain equipment, such as advanced imaging, lab, pathology, or radiation therapy equipment, cannot be used under the exception. Per-click and percentage-based payment terms cannot be used.

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Other changes

The Final Rule makes a number of other changes to the Stark Law, including:

- Uniform 90-day period for failure to comply with signature requirements, regardless of whether failure was inadvertent;
- Changes to the requirements for disclosure of ownership interests in physician-owned hospitals;
- Clarification to the "stand in the shoes" rule;
- New definition of the geographic area served by FQHCs and RHCs (for purposes of recruitment exception); and
- Consistency in language in exceptions related to "taking into account" the volume or value of referrals.

Adopting the Stark Law to a non-fee-for-service world

The delivery of health care services has changed significantly since the enactment of the original Stark Law in 1989. HHS has announced a goal of tying 90 percent of traditional, fee-for-service Medicare payments to quality or value by adopting alternative payment models such as ACOs or bundled payment arrangements. Many stakeholders have expressed concern that the Stark Law prohibits necessary financial relationships between physicians and health care organizations that are needed to reform health care delivery and payment. The proposed rule solicited comments regarding the impact of the Stark Law on payment reform. The Final Rule noted that HHS would review the comments it received as it crafts reports to Congress and considers the need for future Stark Law rulemaking.

Gray Plant Mooty's Health Law Team will be holding a roundtable event on the Stark Law on January 12, 2016. Attendees will receive a free copy of GPM's Stark Law Overview and Checklist, a handy tool for reviewing Stark Law requirements. The book will be updated to reflect changes made in the Final Rule. Look for our invitation in your email inbox soon!

If you have any questions about the new Stark Law regulations, please contract Jesse Berg at jesse.berg@lathropgpm.com (612.632.3374) or Wade Hauser at wade.hauser@lathropgpm.com (612.632.3061).