

## **CMS Publishes Final Stark Law Regulations**

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On October 30, 2015, as part of a larger final rule revising the Medicare Physician Fee Schedule (MPFS) and implementing other revisions to Part B for calendar year (CY) 2016, the Centers for Medicare & Medicaid Services (CMS) released final regulations under the physician self-referral law known as the Stark Law. See 80 Fed. Reg. 70886, 71300 (Nov. 16, 2015). The provisions of the final rule are effective on January 1, 2016, except for certain changes on calculating ownership percentages for physician-owned hospitals, which are effective January 1, 2017. The final rule, which is substantially similar to CMS' proposal issued in July 2015,<sup>[1]</sup> creates two new exceptions, relaxes certain technical requirements, and clarifies some existing regulations. This article focuses on those changes to the Stark Law and the implications of those changes for providers seeking to ensure compliance with the Stark Law.

### **New Exceptions to the Stark Law**

#### *Recruitment and Retention of Non-Physician Practitioners*

In its Phase III Rule,<sup>[2]</sup> CMS declined to expand the existing physician recruitment exception at 42 C.F.R. § 411.357(e) to cover the recruitment of non-physician practitioners (NPPs). Given the recent and significant changes in the health system and Medicare payment systems, as well as the continued projected shortages in the primary health care workforce, CMS has now adopted a new exception allowing recruitment assistance to physicians to assist with the employment of NPPs under certain circumstances.<sup>[3]</sup>

The new direct compensation exception at 42 C.F.R. § 411.357(x) permits remuneration from hospitals, federally qualified health centers (FQHCs), and rural health clinics (RHCs) to a physician to assist in the bona fide employment of, or contracting with, an NPP by that physician to provide primary care or mental health services within the geographic area served by the hospital, FQHC, or RHC. The new exception is designed to facilitate primary care and mental health services and, as such, CMS will require that "substantially all" (i.e., 75%) of the patient services provided by a NPP recruited under this exception must be primary care or mental health services. The substance of the exception generally tracks the existing physician recruitment exception.

It is important to note that this exception is available to protect those arrangements under which a physician retains some of the compensation provided by the hospital, FQHC, or RHC. If the remuneration provided by a hospital, FQHC, or RHC to a physician is passed through directly to the NPP (i.e., the physician does not retain any of the remuneration to cover overhead or other expenses), then the Stark Law does not apply to the arrangement and it does not need to be structured to comply with this (or another) exception.

The most significant limitations under the new exception are the time limits imposed on the assistance offered by a hospital, FQHC, or RHC. Generally, a hospital, FQHC, or RHC may only assist the same physician with employing a NPP once every three years. Additionally, there is a two-

year limit on the assistance given by a hospital, FQHC, or RHC for a particular NPP. In short, the exception is designed to allow for start-up assistance and not long-term subsidies.

### *Time-Share Arrangements*

Many DHS entities entering into time-share arrangements with physicians have done so utilizing the existing space rental exception found at 42 C.F.R. § 411.351(a). Among other things, an arrangement protected under that exception needs to provide for the exclusive use of space by the lessor--a requirement that is inherently challenging for some time-share arrangements to meet. Recognizing that certain time-share arrangements may not fit easily within the existing space rental exception, and acknowledging that time-share arrangements serve an important role in delivering health care services particularly in rural or underserved areas, CMS created a new exception specific to time-share arrangements at 42 C.F.R. § 411.351(y).<sup>[4]</sup>

The new exception includes elements familiar from the existing space rental exception. For example, the arrangement must be set out in writing, signed by the parties, and document the premises, equipment, personnel, supplies, and services covered by the arrangement, and the compensation to be paid under the arrangement must be set in advance and consistent with fair market value. The new exception also imposes additional requirements; for example, the equipment covered by the arrangement must be located in the office suite where the physician-licensee performs his or her services and the equipment covered by the arrangement cannot include advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (with the exception of CLIA-waived laboratory tests).

There are important limitations on the circumstances under which the new exception can apply to protect a time-share arrangement. *First*, it only applies to those arrangements that do not establish a possessory leasehold interest in the property being rented under the time-share arrangement. *Second*, the new exception is only available to arrangements between a physician and a (i) hospital or (ii) a physician organization of which the physician is not an owner, employee or contractor. *Third*, all locations under the arrangement must be used on identical schedules. *Fourth*, compensation formulas based on a percentage of the revenue attributable to the services provided while using the time-share and per-unit fees will be prohibited. CMS expressly declined to prohibit compensation using time-based formulas (e.g., per hour or per day), however.

### **Relaxation of Technical Requirements**

#### *Writing Requirement*

Many exceptions to the Stark Law require that the arrangement be set forth in writing. The prior regulations did not make clear, however, whether an arrangement had to be set forth in a single written agreement or whether it could be set forth through several writings. The revised regulatory language makes it clear that it is the arrangement as a whole that must be evidenced in writing, not that the parties need one written contract.<sup>[5]</sup> Rather, the writing requirement can be satisfied through a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. Although the documents that could be used to show compliance with an exception will vary based on the facts of a particular arrangement, CMS provided several examples of the types of documents that providers can consider in determining whether an arrangement complies with the writing requirement of an applicable exception: board meeting minutes authorizing payments for specified services, written communications between the parties (including emails), fee schedules for specified services, check requests, invoices, time sheets documenting services performed, call coverage schedules or similar documents, accounts payable or receivable documenting payments, and checks issued for services or rent.

### *Arrangements for a Term of One-Year or More*

Consistent with its view that arrangements do not need to be memorialized by one written contract, CMS has clarified that an arrangement does not need to include an explicit provision setting forth a term of the arrangement of at least one year. Similar to the “writing” requirement, a party can show compliance with the “one-year term” requirement through contemporaneous documentation establishing that the arrangement in fact lasted for at least one year.[6]

### *Holdover Arrangements*

Previously, exceptions for space and equipment rentals and personal services arrangements[7] permitted a “holdover” of the arrangement for up to six months after an existing arrangement expired if that arrangement had been in place for at least one year and continued on the same terms as the prior arrangement. CMS has extended the six-month holdover period to an indefinite holdover period *provided that* an arrangement continues on the same terms and conditions as the original agreement and otherwise continuously satisfies the elements of an applicable exception, including the fair market value compensation requirement.[8]

### *Signature Requirement*

Several exceptions to the Stark Law require that an arrangement be signed by the parties. Under the prior regulations, parties had 90 days to obtain a signature if failure to obtain a signature was inadvertent but only 30 days to obtain a signature if such failure was not inadvertent. The new regulations grant parties 90 days to obtain a missing signature, regardless of whether the failure to obtain such signature was inadvertent, although an entity can use the exception only once every three years for the same referring physician.[9]

## **Clarifying Changes**

### *“Takes into Account” the Volume or Value of Referrals*

CMS declined to clarify what “takes into account” means, particularly compared against “varies with.” For a detailed discussion regarding the need for such guidance, particularly in the wake of *Tuomey*,<sup>[10]</sup> refer to the Reed Smith Client Alert: *The Implications of CMS’ Proposed Stark Law Regulations*.<sup>[11]</sup> CMS, however, did conform its terminology throughout the regulations regarding the manner in which an arrangement “takes into account” the volume or volume of referrals between the parties to state that the compensation provided under the arrangement “may not take into account (directly or indirectly)” the volume or value of any referrals. Affected provisions include 42 C.F.R. §§ 411.357(e) (physician recruitment), 411.357(m) (medical staff incidental benefits), 411.357(r) (obstetrical malpractice insurance subsidies), and 411.357(s) (professional courtesies).

### *Retention Payments in Underserved Areas*

CMS clarified the text of 42 C.F.R. § 411.357(t) to reflect its intent that retention payments be based on the prior two years of a physician’s income, as stated during its implementation of the Phase III revisions to that section.<sup>[12]</sup>

### *Definition of “Remuneration”*

CMS has adopted its proposed rule to make it clear that the definition of “remuneration” in 42 C.F.R. § 411.351 does not include an item, device or supply that is used for one or more of six purposes listed in the statute.<sup>[13]</sup> CMS also confirmed its existing policy that a physician’s use of hospital resources when treating hospital patients (e.g., exam rooms) does not qualify as “remuneration”

when the hospital bills for its resources and services and the physician bills for her professional fees. If the hospital and physician submit a global bill to a payer and then pays the physician for professional services, however, CMS views the relationship as involving remuneration between the parties and the Stark Law is implicated.

#### *“Stand in the Shoes” Requirement*

The Phase III Rule included a provision under which physicians must be, or may be, treated as “standing in the shoes” of their physician organizations for purposes of applying the exceptions regarding direct and indirect compensation arrangements.<sup>[14]</sup> The new rule clarifies that all physicians in a physician organization are considered parties to a compensation arrangement between the organization and a DHS entity for all purposes under a relevant exception, except for the signature requirements.<sup>[15]</sup> Thus, the compensation to a physician organization may not take into account referrals from any physicians in the physician organization, whether or not the physician stands in the shoes of the organization.

#### *Definition of “Locum Tenens” Physicians*

CMS has removed the phrase “stand in the shoes” from the definition of a “locum tenens” physician to emphasize that this definition is separate and distinct from the “stand in the shoes” requirement applicable to certain compensation arrangements.<sup>[16]</sup> This definition is located at 42 C.F.R. § 411.351.

#### *Publicly Traded Securities*

The existing exception allows a physician who owns publicly traded securities in a DHS entity to refer to that entity when the securities are, among other possibilities, traded under an automated interdealer quotation system operated by the National Association of Securities Dealers (NASD). As NASD no longer exists and it is no longer possible to purchase stock through the automated interdealer system that NASD formerly operated, CMS has revised the publicly traded securities exception to include securities listed for trading on an electronic stock market or an OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.<sup>[17]</sup>

#### *Physician-Owned Hospitals*

The Affordable Care Act (ACA) eliminated the former “whole hospital” Stark Law exception, except for certain grandfathered physician-owned hospitals, and imposed new requirements on those grandfathered hospitals. Those requirements include, among others, a requirement that a physician-owned hospital disclose the fact that it is partially owned or invested in by physicians in any public advertising for the hospital, including on the hospital’s website, and a limit on the percentage of physician investment in a physician-owned hospital to its March 23, 2010 level. The new Stark Law regulations include important clarifications regarding both requirements.

*First*, CMS provides more certainty regarding the type of statements that would be sufficient for a physician-owned hospital to disclose its physician ownership or investment.<sup>[18]</sup> The new regulations include a non-exhaustive list of the types of websites that CMS does not consider to be a “public website for the hospital.” Notably, social media websites, including an individual hospital page on a social media website, will not be considered a “public website for the hospital.” Also excluded are electronic patient payment portals, electronic patient care portals, and electronic health information exchanges.

CMS likewise clarified its definition of “public advertising for the hospital,” noting that it includes public communications that are paid for by the hospital and primarily intended to persuade patients to seek care at the hospital. It does not include, as an example, communications related to recruitment of staff or public service announcements.

*Second*, the new regulations clarify how to calculate the percentage of physician investment (the “*bona fide* investment level”) in physician-owned hospitals.<sup>[19]</sup> Importantly, CMS established a new definition of “ownership or investment interest” specific to this exception. Under this new definition, all physician owners and investors, regardless of whether they refer patients to the hospital, are included for purposes of calculating the *bona fide* investment level of a physician-owned hospital. Moreover, direct (i.e., without any intervening persons between the hospital and the physician) or indirect (i.e., “an unbroken chain” of persons having ownership or investment interests between the hospital and the physician) ownership or investment interests will be considered for purposes of calculating the *bona fide* investment level.

The new regulations also clarify that a hospital’s actual knowledge of a specific indirect ownership or investment interest is not required to determine that such an interest exists. Notably, an indirect ownership or investment interest exists even if the hospital does not know, or acts in reckless disregard of, the precise components of the “unbroken chain.”

CMS recognized that some physician-owned hospitals may have relied on its earlier commentary concerning non-referring physicians and the *bona fide* investment level as part of its Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011.<sup>[20]</sup> Because the new regulations may cause some hospitals that relied on this earlier guidance to no longer be in compliance with the exception, CMS is postponing the effective date of these changes until January 1, 2017 to allow those hospitals to come into compliance with the new regulations.

## **Conclusion and “Take-Aways”**

The new exceptions, relaxation of certain technical requirements, and interpretive guidance provided by the new regulations may be helpful to avoid some violations of the Stark Law. However, the Stark Law is a strict liability statute and providers must remain vigilant in seeking to ensure compliance with its exceptions. With that in mind, we provide some compliance “take-aways” below.

### *New Recruitment and Retention of Non-Physician Practitioners Exception*

- Hospitals and physicians looking to take advantage of the new exception need to keep in mind that it only applies to the recruitment of nurse practitioners, clinical nurse specialists, physician assistants, certified nurse-midwives, clinical social workers, and clinical psychologists.
- The exception only protects direct employment or independent contractor arrangements between a physician and a NPP. It does not extend to arrangements between a physician and an agency or other company that provides NPP services.
- The remuneration offered to a physician is limited to 50% of the NPP’s actual aggregate compensation and benefits. Additionally, providers should keep in mind that there is a two-year limit imposed on assistance given for a particular NPP.

### *New Time-Share Arrangements Exception*

- The new exception applies only to time-share arrangements between physicians and hospitals or physician organizations. Other entities receiving a physician’s DHS referrals, such as

independent diagnostic testing facilities, cannot rely on this exception. However, the existing lease of office space exception would still be available for such arrangements.

- Parties to a time-share arrangement must ensure that the compensation formula under the arrangement is consistent with fair market value and does not rely on a “per-click” formula.

#### *Relaxed Technical Requirements*

- Providers should not relax their disciplined contracting processes aimed at ensuring that valid signed contracts are in place to support any payments to physicians. Although the “writing” and “one-year” requirements can be satisfied by multiple writings, it is unclear exactly what contemporaneous documentation will be sufficient to show satisfactory compliance in a given scenario. As CMS observes in its final rule, a single written contract documenting the details of an arrangement will continue to provide the “surest and most straightforward” means to establish compliance with an applicable exception.
- To avoid being in the position of having to rely on the 90-day signature grace period, it is still a best compliance practice to execute all agreements with physicians prior to the effective date of the arrangement.
- Because a holdover arrangement must continue to satisfy the elements of an applicable exception, including that the compensation or rent paid under the arrangement is at fair market value, the new indefinite holdover period does not absolve parties of the need to periodically review arrangements. In particular, parties should be wary of allowing arrangements to continue as holdover arrangements for significant periods of time as the compensation or rental rates may fall out of fair market value over time, causing the entire arrangement to fail to meet a needed Stark Law exception. Rather, providers should maintain discipline over their review of contracts nearing expiration, and renew any such contracts as needed.
- CMS states that its clarifications to the writing requirement are not a change in policy. As a result, providers can use the guidance provided by CMS in its commentary to the new Stark Law regulations to evaluate their historical arrangements, including when considering submitting a self-disclosure to the SRDP. Indeed, providers may find that CMS’ guidance allows them to avoid self-disclosure in many cases.

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[1] A discussion of the implications of CMS' proposed regulations is *available at* <http://www.reedsmith.com/en-US/The-Implications-of-CMS-Proposed-Stark-Law-Regulations-07-24-2015/>.

[2] 72 Fed. Reg. 51012 (Sept. 5, 2007).

[3] 80 Fed. Reg. 70886, 71301-71311.

[4] 80 Fed. Reg. 70886, 71325-71332.

[5] 80 Fed. Reg. 70886, 71314-71317.

[6] 80 Fed. Reg. 70886, 71317-71318.

[7] See 42 C.F.R. §§ 411.357(a)(7), (b)(6), and (d)(i)(vii).

[8] 80 Fed. Reg. 70886, 71318-71321.

[9] 80 Fed. Reg. 70886, 71333-71334.

[10] *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 792 F.3d 364 (4th Cir. 2015).

[11] *Available at* <http://www.reedsmith.com/en-US/The-Implications-of-CMS-Proposed-Stark-Law-Regulations-07-24-2015/>.

[12] 80 Fed. Reg. 70886, 71313-71314.

[13] 80 Fed. Reg. 70886, 71321-71322.

[14] See 42 C.F.R. § 411.354(c).

[15] 80 Fed. Reg. 70886, 71322-71324.

[16] 80 Fed. Reg. 70886, 71324.

[17] 80 Fed. Reg. 70886, 71324.

[18] 80 Fed. Reg. 70886, 71335-71337.

[19] 80 Fed. Reg. 70886, 71337-71340.

[20] 75 Fed. Reg. 71800 (Nov. 24, 2010).

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