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*Practice Group:*  
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## CMS Finalizes Two New Exceptions and Other Modifications to the Stark Law

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On October 30, 2015, the Centers for Medicare and Medicaid Services (“CMS”) posted a final rule, which was published in the *Federal Register* on November 16, 2015 (“Final Rule”), modifying the regulations implementing the federal physician self-referral law (“Stark Law”).<sup>1</sup> In the Final Rule, CMS finalized regulations previously proposed in July 2015 (the “Proposed Rule”) (please see our earlier Alert for greater detail — [here](#)), with several additional expansions and revisions, as highlighted below. These new regulatory provisions will be generally effective on January 1, 2016, with the exceptions of a few clarifying changes of existing policy, and the amended definition of “ownership or investment interest,” which will be effective January 1, 2017.

### Two New Stark Law Exceptions Finalized

*Assistance to Compensate a Nonphysician Practitioner.* CMS finalized the new regulatory exception that permits the provision of remuneration from a hospital, federally qualified health center (“FQHC”) or rural health clinic (“RHC”) to a physician or physician organization for the purpose of recruiting certain primary care nonphysician practitioners (“NPP”) into the geographic area served by the hospital, FQHC or RHC.<sup>2</sup> In the Final Rule, CMS recognized the significant changes in health care delivery and payment systems, the “alarming trends” in the projected primary care workforce shortage and the increasing demand for primary care.<sup>3</sup> In light of the expectation that the supply of primary care physicians will not keep pace with the need for primary care services, and due to the increasing role for NPPs in evolving care delivery models, CMS finalized the new exception to allow hospitals, FQHCs and RHCs to assist physicians in the recruiting and hiring of nonphysician practitioners. Highlighted requirements of the new exception include:

- The arrangement must be set out in writing and signed by the hospital, physician and the NPP. The definition of “nonphysician practitioner” for the purposes of the exception will include physician assistants, nurse practitioners, clinical nurse specialists and certified nurse-midwives. The definition of NPP in the Final Rule was expanded to include clinical social workers and clinical psychologists.
- Substantially all of the services provided by the NPP to the physician’s or physician organization’s patients must be primary care services or mental health services, and no practice restrictions may be imposed on the NPP that unreasonably restrict its ability to provide patient care services in the hospital’s geographic area.

<sup>1</sup> “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016,” 80 Fed. Reg. 70886 (Nov. 16, 2015) (to be codified in 42 C.F.R. pts. 405, 410, 411, et al.).

<sup>2</sup> 42 C.F.R. § 411.357(x).

<sup>3</sup> 80 Fed. Reg. at 71,301.

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- The remuneration from the hospital, FQHC or RHC to the physician or physician organization shall not exceed 50% of the actual aggregate compensation, signing bonus and benefits paid to the NPP for a period not to exceed the first two consecutive years of the compensation arrangement between the physician or physician organization and NPP.
- The NPP must not have practiced, within one year, in the geographic area serviced by the hospital, or been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice site in the geographic area, regardless of whether the practice site was in the geographic location of the hospital.
- The arrangement must not be conditioned on the physician's or NPP's referrals to the hospital, and the compensation, signing bonus and benefits to the NPP must not exceed the fair market value of the NPP's services. The arrangement must not otherwise violate the federal anti-kickback statute or any federal or state billing and claims submission regulations.
- Assistance may only be provided to the same referring physician no more than once every three years, unless the NPP is replacing a NPP who terminated the contractual arrangement with a physician or physician organization within the first year. The two-year assistance period, in this case, is still measured from the commencement of the original arrangement.

*Timeshare Arrangements Exception.* CMS also finalized a new regulatory exception for timeshare arrangements for the use of premises, equipment, personnel, item, supplies or services.<sup>4</sup> In the Final Rule, CMS acknowledged the unique nature of timeshare arrangements, which can be structured more as a license to use office space, property and personnel of the licensor than a lease of space, which requires the arrangement to provide for the exclusive use of the premises, and a duration of at least one year to fit within the Rental of Office Space Exception.<sup>5</sup> Specifically, CMS stated that through the administration of the Self-Referral Disclosure Protocol ("SRDP"), CMS has discovered such legitimate arrangements for the use of another person or entity's premises, equipment, personnel, items or services by physicians who are not interested in a traditional office space lease, such as a specialist physician providing services in a rural community that needs specialty services but whose need is not great enough to support a full-time practice.<sup>6</sup> The Final Rule creates an exception to protect these arrangements. The Final Rule states that the new exception will provide flexibility for a hospital or local physician practice to ask a specialist from another community to provide services in space owned by the hospital or practice on a limited or as-needed basis.<sup>7</sup>

In order to fit within the new exception, the arrangement must be between a physician (or the physician organization in whose shoes the physician stands) and a hospital or physician organization of which the physician is not an owner, employee or contractor (regardless of which party grants and which party receives use of the space). The Final Rule also requires the following to satisfy the new exception:

<sup>4</sup> 42 C.F.R. § 411.357(y).

<sup>5</sup> 80 Fed. Reg. at 71,325.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

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- The arrangement must be set out in writing, signed by the parties, and must specify the premises, equipment, personnel, items, supplies and services covered.
- The premises, equipment, personnel, items, supplies and services covered by the arrangement must be used predominantly for the provision of evaluation and management services to patients, and on the same schedule.
- The equipment covered by the arrangement is:
  - located in the same building as where the evaluation and management services are furnished;
  - not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and
  - not advanced imaging equipment, radiation therapy equipment or clinical or pathology laboratory equipment (other than equipment used to performed CLIA-waived laboratory tests).
- The arrangement is not conditioned on the referral of patients.
- The compensation over the term of the arrangement is set in advance, consistent with fair market value and not determined:
  - In a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; or
  - Using a formula based on:
    - A percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies or services covered by the arrangement; or
    - Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies or services covered by the arrangement to the party to which the permission is granted.
- The arrangement would be commercially reasonable even if no referrals were made between the parties.
- The arrangement does not violate the federal anti-kickback statute or any federal or state law or regulation governing billing or claims submission.
- The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

### Revisions Offering Providers Additional Flexibility with Stark Law Compliance

*Writing Requirement.* CMS finalized the Proposed Rule's revisions and clarified the writing requirement in many Stark Law regulatory exceptions by substituting "arrangement" for the terms "agreement" and "written contract" throughout the regulatory text. In doing so, CMS acknowledged that the Stark Law regulations do not require that an arrangement be

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documented in a single, formal contract, but that a collection of contemporaneous documents evidencing the conduct between the parties may satisfy the writing requirement. CMS provided a non-exhaustive list of documents that may demonstrate whether a compensation arrangement complies with the writing requirement, such as board meeting minutes, hard copy and electronic communications, fee schedules for services, check requests or invoices detailing items or services provided and relevant dates and rates, time sheets documenting services performed, call coverage schedules, accounts payable or receivable and checks issued.

Additionally, in order to avoid differing standards, CMS declined to adopt commenters' suggestions that state contract law principles determine whether an arrangement is set out in writing. In relation to the signature requirement of applicable exceptions, CMS clarified its existing policy that the arrangement must be signed by the parties to satisfy the exception, and that a signature is required on a contemporaneous writing documenting the arrangement. CMS also emphasized that the temporary noncompliance grace period (discussed below) only applies to the signature requirement, and that the writing requirement must be satisfied before the physician makes referrals to the DHS entity.

*Term Requirement.* For Stark Law regulatory exceptions requiring a term of at least one year, CMS clarified that a written contract with a formalized term provision is not necessary. CMS also stated that an arrangement that lasts as a matter of fact for at least one year satisfies the term requirement, and revised the regulations to clarify this existing policy. Therefore, CMS removed the word "term" from the Rental of Office Space Exception,<sup>8</sup> Rental of Equipment Exception<sup>9</sup> and Personal Services Exception,<sup>10</sup> and revised the regulatory exceptions to state that the *duration* of the arrangement must be at least one year. It should be noted that CMS retained the qualifying condition in each of these exceptions that if the arrangement is terminated prior to a year, the parties may not enter into a new arrangement for the same space, equipment or services during the first year of the original arrangement.

*Holdover Arrangements.* CMS finalized its proposal for an indefinite holdover provision in the Rental of Office Space Exception, Rental of Equipment Exception and Personal Services Exception. CMS also finalized its proposal to amend the Fair Market Value Compensation Exception<sup>11</sup> to allow arrangements of any time frame to be renewed for any number of times (as long as the arrangement continues to comply with the other requirements of the exception). Previously, the Fair Market Value Compensation Exception referred to renewals of arrangements made for less than one year.

Of note, CMS also indicated that while nothing in the Fair Market Value Compensation Exception requires the renewals to be in writing, the parties must be able to produce written documentation which establishes that the arrangement was renewed on the same terms as the original arrangement. In regard to the indefinite holdover provisions, CMS indicated the following:

- Parties relying on the holdover provision must continue to have contemporaneous documents establishing that the holdover continued on the same terms and conditions as the immediately preceding arrangement.

<sup>8</sup> 42 C.F.R. § 411.357(a).

<sup>9</sup> 42 C.F.R. § 411.357(b).

<sup>10</sup> 42 C.F.R. § 411.357(d).

<sup>11</sup> 42 C.F.R. § 411.357(l).

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- If an arrangement falls outside of the range of fair market value during a holdover period, it would no longer comply with the requirements of the applicable exception. On a related point, CMS also cautioned providers by noting that the Rental of Office Space Exception requires rental payments to remain consistent with fair market value during the entire term of the lease and, thus, parties should consider this when entering into arrangements with long terms.
- If the original agreement required a holdover premium charge, but the parties fail to apply the holdover premium, such a failure to apply the charge may constitute a change in the terms and conditions of the original arrangement. CMS acknowledged that such an analysis is contingent on the facts and circumstances of the arrangement in question.

*Temporary Noncompliance with Signature Requirements.* CMS finalized its proposal without revision to allow an entity 90 days to obtain required signatures, regardless of whether or not the noncompliance was inadvertent.<sup>12</sup> Previously, an entity only had use of a 30-day grace period to comply if the failure was not inadvertent. Entities still may only use this exception once every three years per physician or physician group.

### Revisions to Stark Law Definitions and Other Clarifying Changes

CMS finalized all of the Proposed Rule's revisions to regulatory definitions without modification (please see our earlier Alert for greater detail — [here](#)). This includes, but is not limited to, the following revisions:

*Stand in the Shoes.* CMS finalized the proposed revisions to clarify that a physician who is standing in the shoes of his or her physician organization has satisfied the signature requirement of an applicable exception when the authorized signatory of the physician organization has signed the writing. For purposes other than the signature requirement, all physicians in a physician organization are considered to be "parties" to the compensation arrangement. It appears that CMS intended this to mean that compensation between a DHS entity and physician organization may not be determined in a manner that takes into account the volume or value of referrals or other business generated by *any physician* in the physician organization, including physicians who do not stand in the shoes of the physician organization.<sup>13</sup>

*Geographic Area Served By FQHCs and RHCs.* CMS finalized the regulatory definition of the geographic area served by an FQHC or RHC as the area composed of the lowest number of contiguous and noncontiguous zip codes from which it draws at least 90 percent of its patients on an encounter basis.<sup>14</sup>

### Physician-Owned Hospitals

As contemplated in the Proposed Rule, CMS finalized regulations regarding the calculation of ownership or investment interests in a physician-owned hospital to require that the investment level include interests held by both referring and non-referring physicians.<sup>15</sup> The

<sup>12</sup> 42 C.F.R. § 411.353(g).

<sup>13</sup> 42 C.F.R. § 411.354(c)(3)(i).

<sup>14</sup> 42 C.F.R. § 411.357(e)(6).

<sup>15</sup> 42 C.F.R. § 411.362(a).

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Final Rule delays implementation of the revised policy to January 1, 2017, to allow physician-owned hospitals time to become compliant.

CMS also finalized changes regarding the Public Website and Public Advertising Disclosure requirements for physician-owned hospitals.<sup>16</sup>

### Summary

Entities and providers should consider situations in which the new Stark Law exceptions may apply when contracting, and whether any new arrangements are possible given these new protections. The Final Rule also provides greater flexibility in meeting certain Stark exceptions; however, as CMS reiterates, a current, signed contract remains the easiest method of demonstrating compliance. In light of the additional flexibility provided in the Final Rule, providers may want to consider contacting legal counsel to discuss the potential impact of these new rules on pending SRDP submissions to CMS and possibly amending previously submitted SRDPs.

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<sup>16</sup> 42 C.F.R. § 411.362(b)(3)(ii)(C).