PUBLICATION

Stark Updates Included in Final 2016 Physician Fee Schedule [Ober|Kaler]

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With the final Medicare physician fee schedule (PFS) for 2016, the Centers for Medicare and Medicaid Services (CMS) has made a series of updates to the Stark physician self-referral regulations. The final rule is largely similar to what CMS introduced with the proposed 2016 PFS rule in July 2015.

These updates represent the first major changes to the Stark regulations in several years. According to CMS, the updates are intended "to accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance." Based on questions received by CMS from various stakeholders and compliance issues identified through submissions to the Medicare self-referral disclosure protocol (SRDP), CMS recognized the need for clarification of certain aspects of the Stark regulations. CMS also noted a desire to expand access to needed health care services. With these goals of simplified compliance and expanded access in mind, CMS finalized a number of updates and added two new exceptions to the Stark regulations.

In this Client Alert, members of Ober|Kaler's Fraud and Abuse Team explore the updates to the Stark regulations. These updates include new exceptions for nonphysician practitioner recruitment and timeshare arrangements, clarifications to the physician recruitment exception and the physician-owned hospital provisions, and numerous technical revisions.

With the exception of certain changes related to physician-owned hospitals, the provisions of the final rule become effective on January 1, 2016. It should be noted, however, that CMS does not consider several of the updates to actually be changes. The revisions were published as a final rule with comment period [PDF] in the Federal Register on November 16, 2015.[1] Comments are due by December 29, 2015. Please contact any of the authors - or your regular Ober|Kaler attorney contact - with any questions about the final rule or for assistance in submitting comments on the final regulations.

New Exception for Nonphysician Practitioner Recruitment Assistance

Recognizing significant changes to health care delivery and payment systems, as well as projected workforce shortages in the delivery of primary care and the significant role to be played by nonphysician practitioners in addressing the projected shortages, CMS has finalized its proposed exception for assistance to recruit nonphysician practitioners (NPPs).[2]

The new exception permits hospitals, Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs) to offer recruitment assistance and retention payments to physicians (or those standing in the physicians' shoes, such as physician groups) to assist physician-employment of NPPs in the geographical area served by the hospital, FQHC, or RHC, despite the otherwise direct compensation arrangement that would implicate the Stark law. Prior to the new exception, hospitals, FQHCs, and RHCs could offer recruitment assistance to physicians only for the recruitment and retention of *physicians* into their geographic service areas.[3] Indeed, during the original physician recruitment rulemaking, CMS distinguished between payments made directly to NPPs, which would not implicate the Stark law, and payments made to a physician or physician practice for recruiting NPPs, which would in fact implicate the Stark law, and for which no exception existed.

In finalizing the current rule, CMS reiterated that the purpose of the NPP exception is "remov[ing] barriers to care that may frustrate certain goals of health care delivery system reform and to promote beneficiary access to primary care services and mental health care services, not to promote access to the services of [a] particular type of care provider (for example, an NPP)." This theme can be seen across CMS's responses to public comments. Those comments are highlighted in the following discussion of the key provisions of the finalized exception, along with notable departures from the proposed exception.

Notable Departures from Proposed Exception

The proposed rule was finalized with the following modifications:

1. CMS expanded the definition of *nonphysician practitioner* to include clinical social workers and clinical psychologists.
2. CMS expanded the types of permissible NPP services to include mental health care services in addition to primary care services.
3. CMS finalized the requirement that the NPP furnish "substantially all" primary care or mental health services to patients of the physician's practice.
4. CMS did not limit the type of compensation arrangement between the physician (or physician organization) and the NPP, but will require that such contractual relationship be directly between the physician and the NPP (barring, for example, staffing services from holding the contract).
5. CMS finalized a bright-line rule for the amount of remuneration from the hospital to the physician, limiting it to 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP.
6. CMS finalized a frequency cap on the number of times a hospital may assist the same referring physician at once every three years, with an exception in the event an NPP does not remain at the practice for at least one year.
7. CMS shortened from three years to one year the period of time that the NPP must not have practiced in the geographic area served by the hospital, FQHC, or RHC.

Key Provisions of the Exception

To be afforded protection under the exception, the recruitment activity must meet the following conditions:

8. The arrangement is in writing and signed by the hospital, the physician, and the NPP.
9. The arrangement is not conditioned on the physician's or the NPP's referrals to the hospital.
10. The remuneration from the hospital does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician (or group) to the NPP (which compensation must meet the fair market value requirement common to the Stark law).

    - At the urging of public commenters, CMS finalized a bright-line and objective rule for the remuneration cap, permitting assistance to the physician in an amount that does not exceed 50 percent of the actual aggregate compensation, signing bonus, and benefits (health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees) paid to the NPP who joins the physician's practice. That objective standard, together with the fair market value requirement, was enough for CMS to permit some flexibility and allow circumstances where the salary, signing bonus, and benefits are not set in advance. However, CMS reiterated that the exception "is not intended to provide a physician with the means to increase profit from the services of an NPP in his or her practice at the expense of a hospital, FQHC or RHC," and it will monitor the use and impact for program abuse. And, despite public comment requesting it, CMS declined to provide for a specific allocation for NPP relocation expenses. However, CMS indicated that the rule does not preclude reimbursing an NPP for relocation expenses, so long as that amount is included in the aggregate calculation of compensation as described above.

11. The remuneration may occur only during a period not to exceed the first two consecutive years of the compensation arrangement with the NPP.
12. The remuneration is not determined in a way that takes into account the volume or value of actual or anticipated referrals by the physician (or any physicians in that practice), the NPP (or any NPP in the practice), or any other business generated between the parties.
13. The NPP has not, within one year of the commencement of the NPP's compensation arrangement, practiced in the geographic area serviced by the hospital or been otherwise employed or engaged to provide patient care services by a physician or physician organization that has a medical practice site located in the geographic area served by the hospital (whether or not the NPP actually furnished services at that site within the geographic area).
14. Substantially all of the patient care services that the NPP furnishes to the physician's practice are primary care services or mental health care services.

    - CMS expanded the permissible types of services covered by the exception to include mental health services provided by the NPP based on its request in the proposed rule for comments as to whether the exception should be expanded to include more services. CMS declined, however, to expand the definition to include "specialty services," or a list of specific specialties such as neurology, urology, cardiology, surgery, or orthopedic services. CMS clarified that NPPs practicing in the areas of general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology are considered to be providing primary care services. Moreover, CMS noted that "nothing in § 411.357(x) prohibits a hospital, FQHC, or RHC from providing remuneration to a specialty physician who compensates an NPP to furnish primary care services or mental health care services to patients of the physician's practice." The emphasis is not on what the physician or physician practice may specialize in, but whether the remuneration to the physician is for the purpose of compensating an NPP for furnishing primary care or mental health care services.
    - CMS finalized "substantially all" as opposed to a second proposed alternative, "at least 90 percent," as the minimum amount of services provided by the NPP to the physician practice's patients. Drawing from the physician self-referral regulations generally, CMS noted that *substantially all* means at least 75 percent of the NPP's services to patients of the physician's practice. Thus, consistent with the regulations already in place, the *patient* care services will be measured either by (1) the total time the NPP spends on patient care services documented by reasonable means; or (2) any alternative measure that is reasonable, fixed in advance of performance of the services, uniformly applied over time, verifiable, and documented.[4]
15. The physician may not impose practice restrictions on the NPP that unreasonably restrict the NPP's ability to practice in the geographic area.
16. Records of the amount of remuneration by the hospital to the physician, and by the physician to the NPP, must be maintained for at least six years.
17. The exception may be used by a hospital, FQHC, or RHC only once every three years with respect to the same referring physician. However, this three-year limitation does not apply where an NPP is replacing an NPP who terminated his or her employment or contractual arrangement within one year of its commencement, and the remuneration provided to the physician is provided during a period that does not exceed two consecutive years from the commencement of that employment or contractual arrangement.

    - CMS finalized the three-year limitation based on a request in the proposed rule for comments on the need for such a cap.
18. Whether an employee, independent contractor, or otherwise, the compensation arrangement must be directly between the physician (or physician organization) and the NPP (barring, for example, staffing

services from holding the contract), and may not include an NPP's ownership or investment interest in the physician organization.

- CMS expanded the definition of a *compensation arrangement* to include independent contractors, employees, and "other" arrangements. Thus, the NPP need not be a bona fide employee, as specified in the proposed rule.

Definition of *Nonphysician Practitioner (NPP)*

NPP is defined to include physician assistants, nurse practitioners or clinical nurse specialists, certified nurse-midwives, clinical social workers, and clinical psychologists.

The finalized definition of *NPP* was expanded from the proposed rule to include clinical social workers and clinical psychologists, based on CMS's request in the proposed rule for comments on whether the exception should include more types of practitioners. Most commenters requested a more robust final rule applicable to even more practitioners and services. Despite comments requesting that the exception be expanded to apply to physical therapists, CRNAs, registered dieticians, and nutritional professionals, who, commenters urged, will serve to support a collaborative health care system, CMS found no "compelling need to include such practitioners in the definition of NPP for the purposes of the exception." However, in expanding the definition to include clinical social workers and clinical psychologists, CMS recognized a critical need to address the growing workforce shortage and access issues in the mental health care system.

Definition of *Referral*

A *referral by an NPP* is defined as a request by an NPP that includes the provision of designated health services for which payment may be made under Medicare; the establishment of any plan of care by an NPP that includes the provision of such a designated health service; or the certifying or recertifying of the need for such designated health services (but not including any designated health services personally performed or provided by the NPP).

The finalized exception is a positive step in the right direction to address the growing workforce shortages in the areas of primary care and mental health care. Although the rule might have been more robust in expanding the definition of NPPs to include more practitioners, or more services, the exception nonetheless should help hospitals, FQHCs, and RHCs attract and retain qualified NPPs to the geographic areas served by those facilities. Physicians and physician groups should be reassured that their recruitment efforts can be somewhat offset in the short term. Hospitals, FQHCs, RHCs, and physicians should take caution to follow the exception's recordkeeping and other requirements with earnest, as CMS intends to monitor closely these arrangements for fraud and abuse.

New Exception for Timeshare Arrangements

CMS finalized its proposed exception at § 411.357(y) for timeshare arrangements that would allow for arrangements that grant to a licensee a "personal privilege or permissive use" of a licensor's premises, equipment, personnel, items, supplies, or services.

Notable Departures from Proposed Exception

As outlined below, CMS maintained the majority of the provisions of its initial proposal, with several key modifications:

19. CMS is not dictating the roles of the parties to a timeshare arrangement. A hospital or physician organization may be a licensor or licensee.

20. CMS is revising the requirement regarding the location of the equipment covered by the timeshare arrangement. While the equipment must be located in the same building as the office suite where evaluation and management (E/M) services are furnished to the patient, it does not need to be located in the same office suite.
21. CMS is adding the requirement that all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules.
22. CMS clarified in its final rule that the exception only protects arrangements that "grant a right or permission" to use the premises, equipment, etc. It may not be used for arrangements that establish a "possessory leasehold" interest, akin to a lease.
23. CMS indicated that it was eschewing the use of the terms *licensor* and *licensee* in the exception's regulatory text, allowing for parties subject to a timeshare arrangement to use any terminology they deem appropriate.

Key Provisions of the Exception

The specific requirements of the final timeshare exception are as follows:

24. The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.
25. The arrangement is between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c) and (i) a hospital; or (ii) physician organization of which the physician is not an owner, employee, or contractor.
26. The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used (i) predominantly for the provision of evaluation and management services to patients; and (ii) on the same schedule.
27. The equipment covered by the arrangement is (i) located in the same building where the evaluation and management services are furnished; (ii) 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 (iii) not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).
28. The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.
29. The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined (i) in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; or (ii) using a formula based on (A) 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 (B) 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.
30. The arrangement would be commercially reasonable even if no referrals were made between the parties.
31. The arrangement does not violate the anti-kickback statute[5] or any federal or state law or regulation governing billing or claims submission.
32. The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

CMS also clarified in the final rule that the exception for timeshare arrangements is one option among many Stark compensation exceptions available to parties. It does not serve as a replacement.

Clarifications to Physician Recruitment Provisions

Geographic Area Served by an FQHC or RHC

The physician recruitment exception protects remuneration provided by a hospital, FQHC, and RHC to an individual physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital, FQHC, or RHC to become a member of its medical staff.[6] When the exception was expanded to include FQHCs and RHCs, however, the definition of *geographic area served by the hospital*, which was contingent on the volume of the hospital's inpatients, did not apply to FQHCs and RHCs in the same manner as it applied to hospitals. Recognizing that the existing definition did not provide guidance as to the geographic area into which an FQHC or RHC may recruit a physician, so CMS has finalized a new definition of the geographic area served by the FQHC or RHC.

Specifically, the definition now states:

The "geographic area served" by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.[7]

CMS found no potential for program or patient abuse in selecting noncontiguous zip codes to identify 90 percent of the patient base as long as there are patients in those areas. CMS similarly was not persuaded that "patients" was a more appropriate measure than "encounters" for determining service areas under this exception. CMS also recognized the need for better outreach to FQHCs and RHCs regarding the physician self-referral law and its exceptions.

Conforming Terminology

CMS finalized more consistent terminology regarding prohibitions on tying arrangements to the volume and value of referrals. Specifically, the language in several Stark exceptions contains the phrase *take into account* the volume or value of referrals, while others use the phrases *based on* or *without regard to* the volume or value of referrals. CMS is concerned that the different phrases may cause some to conclude incorrectly that there are different volume or value standards in the compensation exceptions. To clarify, CMS modified the physician recruitment exception[8] to require that the compensation provided to a recruited physician may not *take into account* (directly or indirectly) the volume or value of the recruited physician's referrals to the hospital, FQHC, or RHC providing recruitment remuneration. Similarly, CMS changed the language in the medical staff incidental benefits exception,[9] the obstetrical malpractice insurance subsidies exception,[10] and the professional courtesy exception,[11] to use the phrase *take into account* consistently.

Retention Payments in Underserved Areas

The retention payments in underserved areas exception[12] originally permitted retention payments to a physician with a practice located in an underserved area if the physician had a bona fide firm, written recruitment offer that would require him or her to move his or her medical practice at least 25 miles and outside of a geographic area served by the hospital or FQHC making the retention payments. In Stark II, Phase III, the exception was revised to permit certain retention payments made to a physician with a practice located in an

underserved area where the physician has a bona fide written offer of recruitment or employment and the physician certifies in writing that he or she has such opportunity for future employment that meets the requirements of the exception.

In Phase III, CMS explained that a retention payment based on a physician's certification may not exceed the lower of: (1) an amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months) using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician. However, the regulation did not mirror the preamble language precisely and stated that the physician's income be measured over *no more than* a 24-month period, thus allowing a retention payment that considered only part of the prior 24-month period instead of the entire period. Therefore, CMS finalized a change to correct the language and mirror the Phase III preamble language precisely.

Revised Physician-owned Hospital Provisions

The Affordable Care Act established a number of restrictions and requirements to which physician-owned hospitals must conform in order to comply with the physician-owned hospital and rural provider exceptions to the Stark law. In the final CY 2016 Physician Fee Schedule, CMS finalized its proposed revisions of two aspects of the physician-owned hospital regulations: (1) public website and public advertising disclosures[13]; and (2) determination of the *bona fide* physician investment level.[14]

Disclosure Requirements

The Affordable Care Act established the requirement that physician-owned hospitals must disclose the fact of their physician ownership or investment on any "public website for the hospital" and "public advertising for the hospital." In this final rule, CMS finalized its proposals to provide physician-owned hospitals with more certainty regarding the forms of communication that require a disclosure of physician ownership, as well as the types of language that would form a sufficient statement of physician ownership. Importantly, CMS announced it did not interpret the disclosure requirements as mandates to include specific wording.

First, CMS added a non-exhaustive list of examples of the types of websites that would not qualify as a public website for the hospital for purposes of the disclosure requirement. The regulations now state that, by way of example, social media websites, electronic patient payment and care portals, and electronic health information exchanges are not considered public websites of the hospital, and thus are not subject to the disclosure requirement. CMS highlighted its belief that even though social media sites may contain hospital communications, they should not be analyzed as public websites for the hospital because they are operated by social networking services. CMS further clarified that networking websites, "electronic patient payment portals, electronic patient care portals, or electronic health information exchanges" do not constitute public websites for the hospital because they are not readily available to the general public.

CMS was careful to note that even though a particular site may not be a public website for the hospital, depending on the facts and circumstances, the content on the website may nonetheless qualify as public advertising for the hospital which would require the appropriate disclosure.

As to the public advertising disclosure requirement, CMS amended its regulations to more closely conform to the statutory language by including the phrase *for the hospital* in reference to public advertising. CMS also finalized its definition of *public advertising for the hospital* as "any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital." From that definition, CMS carved out "communication made for the primary purpose of recruiting hospital staff (or other similar human

resources activities public service announcements issued by the hospital, and community outreach issued by the hospital." CMS emphasized that identifying a communication as public advertising for a physician-owned hospital depends on the facts and circumstances. CMS noted that it evaluates "whether the communication 'is primarily intended to persuade individuals to seek care at the hospital' and not whether an individual is likely to make a medical decision based on the information provided in the communication." Based on that, CMS refused to add "search engine results" and "online listings of area hospitals" to the list of examples.

To satisfy the disclosure requirements, CMS affirmed that physician-owned hospitals may use "any language that would put a reasonable person on notice that the hospital may be physician-owned. . . ." CMS repeated that the disclosure "should be located in a conspicuous place . . . and on a page that is commonly visited by current or potential patients. . . ." CMS continued, "the disclosure should be displayed in a clear and readable manner and in a size that is generally consistent with other text on the website."

CMS confirmed yet again that submitting disclosures to the Self-referral Disclosure Program is the appropriate way to address a failure to satisfy the disclosure requirements. CMS clarifies that the earliest possible starting point for the period of noncompliance with both the public website disclosure requirement and the public advertising requirement is September 23, 2011. For noncompliance with the public advertising disclosure requirement, the period of noncompliance would be the duration of the applicable advertisement's predetermined initial circulation.

Bona Fide Investment Level

The Affordable Care Act added a *bona fide* investment requirement to the Stark law's rural provider exception and hospital ownership exception. The requirement establishes that the "percentage of the total value of the ownership or investment interests held in a hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010." CMS refers to the ownership or investment percentage held by physicians as the "*bona fide* investment level" whereas the percentage on March 23, 2010, is called the "baseline *bona fide* investment level."

CMS codified the *bona fide* investment requirement in the CY 2011 OPPS/ASC final rule. In those regulations, CMS concluded that when calculating the baseline *bona fide* investment level, hospitals need not include the ownership or investment interests of non-referring physicians. Since finalizing those regulations, CMS has received a number of inquiries from industry stakeholders regarding the exclusion of the ownership or investment interests of non-referring physicians, and has reconsidered its position.

In the CY 2016 Physician Fee Schedule proposed rule, CMS proposed to revise its policy and amend its regulations to require that the "baseline *bona fide* investment level and *bona fide* investment level include direct and indirect ownership and investment interests held by a physician," assuming the physician meets the definition of *physician* at 42 C.F.R. § 411.351 and section 1861(r) of the Social Security Act. CMS finalized its proposed revised policy without revision. In its final rule, CMS confirmed that "a proper calculation of a physician-owned hospital's baseline *bona fide* investment level includes the ownership and investment interests held by all physicians regardless of referral status."

To accomplish those changes, CMS finalized its proposed definition of *ownership or investment interest* as: "a direct or indirect ownership or investment interest in a hospital." CMS clarified that such an interest exists when the owner or investor holds the interest without any intervening persons or entities between himself and the hospital. An indirect ownership or investment interest exists if there is an unbroken chain of persons/entities between the owner or investor and the hospital, and if the hospital "has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital."

To allow physician-owned hospitals time to comply with the revised policy, CMS delayed the effective date of the revisions to January 1, 2017.

Technical Revisions

With the publication of the final Physician Fee Schedule for CY 2016, CMS finalized numerous technical revisions to the Stark law, in an effort to reduce regulatory burden and clarify existing policy. As outlined below, the technical revisions addressed by CMS in the final rule relate to (1) writing, term, and holdover; (2) certain key definitions; (3) a modification to the exception for ownership of publicly traded securities; and (4) revisions to the temporary noncompliance with signature requirements.

Writing, Term, and Holdover

Writings

In its proposed rule, CMS sought to clarify that, to meet the writing requirement of a compensation exception, an arrangement need not be documented in a formal contract. In the final rule, CMS reiterated this stance, stating its existing policy has been and continues to be that a "collection of documents, including contemporaneous documents evidencing the course of conduct between the parties," may, dependent upon the facts and circumstances, satisfy the writing requirement of an applicable exception. In setting forth its policy, CMS noted state law contract principles are not determinative; rather, the relevant inquiry is whether the contemporaneous documents at issue would "permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made."

In line with the above comments, CMS finalized its proposal to replace the term *agreement* with the term *arrangement*, and where applicable, to replace the term *contract* with the word *arrangement*, for nearly all of the compensation exceptions that require a writing.

Signatures

Alongside its clarifying statements with respect to the writing requirement, CMS also clarified that parties do not need to sign a *single* formal written contract to comply with the signature requirement of an applicable exception. CMS noted that a collection of documents, not all of which need to be signed, may likewise allow for parties to meet the signature requirement.

However, CMS cautioned that in relying on a collection of documents for purposes of meeting the signature requirement, the contemporaneous signed writing must "clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect."

Term

In both the proposed and final rule, CMS offered clarifying statements with respect to its view on term requirements. Specifically, CMS stated that any arrangement that lasts "as a matter of fact for at least one year" will satisfy the requirement that an arrangement be at least one year as related to the rental of office space, rental of equipment, and personal service arrangements. CMS is making minor changes to the applicable exceptions to effectuate this policy clarification.

Holdover

CMS finalized its proposal to modify the current six-month "holdover" period to permit indefinite holdovers for the rental of office space,[15] rental of equipment,[16] and personal services arrangement[17] exceptions, provided that the arrangement continues to satisfy the specific requirements of the applicable exception, and that the holdover continues on the same terms and conditions as the original arrangement. CMS did not extend the holdover provisions to the fair market value exception.[18]

In finalizing its proposal, CMS commented extensively on fair market value considerations and the application of "holdover premiums" (i.e., the requirement that a lessee pay an additional amount in the event the lessee continues to hold over on an expired lease). CMS cautioned that rental payments may "cease to be consistent with fair market value in long-term arrangements." That said, and while CMS noted that a change in fair market value during a holdover period may cause the arrangement to fall out of compliance, it caveated this statement for those arrangements still within their original term. If such an arrangement was determined to be fair market value at its outset, CMS indicated that it would not have fair market value compliance concerns were the fair market value to change, so as long as the original term was commercially reasonable.

In addition, CMS noted that "the failure to apply a holdover premium that is legally required by the original arrangement" may in fact constitute a change in the terms and conditions of the original arrangement, such that the holdover provision may no longer be relied upon. CMS also noted that the non-payment of a holdover premium may constitute the "forgiveness of a debt" with the potential to create a secondary financial relationship between the parties that must also satisfy the requirement of an applicable exception.

CMS also finalized its proposal to permit renewals of arrangements of any length of time - including those arrangements that are more than one year - under the fair market value exception.

Definitions

CMS finalized its proposal to modify the definitions of the following terms:

Remuneration

CMS had proposed to revise the regulatory definition of *remuneration* to clarify that items, devices, or supplies "used solely" to collect, transport, process, or store specimens, or to order or communicate the results of tests or procedures did not constitute remuneration, and that the provision of such items, devices or supplies, for one *or more* of the above-stated purposes likewise did not constitute remuneration. CMS finalized this proposal, while also confirming that, pursuant to existing CMS policy, "split bill" arrangements, under which physicians utilize items and rely on personnel, such as nurses in a hospital, do not constitute remuneration where the physicians bill for their professional services and the hospitals bill a facility fee.

Stand in the Shoes

CMS finalized its proposal that only physicians who "stand in the shoes" of their physician organization are considered parties to an arrangement for the purposes of the signature requirements of an applicable Stark law exception. In doing so, CMS cautioned that for all purposes other than the signature requirements, physicians in a physician organization are considered parties to a compensation arrangement between the physician organization and the DHS entity, irrespective of whether they stand in the shoes of their physician organization or not. Thus, and for example, compensation between a DHS entity and a physician organization may not be determined in a manner that takes into account the volume or value of referrals and other business generated by *any* physician in the physician organization.

Locum Tenens Physician

In accordance with its proposed rule, CMS modified the definition of *locum tenens* to remove the phrase *stand in the shoes* CMS indicated that this modification is intended to remove "unnecessary verbiage" and avoid any "potential ambiguity" with respect to the stand in the shoes provisions set forth at § 411.354(c).

Exception for Ownership of Publicly Traded Securities

To "modernize" the exception for ownership of publicly traded securities, CMS finalized its proposal to revise the existing regulation to include "securities listed for trading on an electronic stock market or OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent." CMS had received no comments on its proposal.

Temporary Noncompliance with Signature Requirements

CMS finalized its proposal to allow parties an additional 90 days to obtain all required signatures. In doing so, CMS acknowledged that "it is not uncommon for parties who are aware of a missing signature to take up to 90 days to obtain all required signatures." However, CMS retained its rule that the use of the temporary noncompliance rule can be used only once every three years for the same physician.

1 80 Fed. Reg. 70886 (Nov. 16 2015).

2 42 C.F.R. § 411.357(x).

3 42 C.F.R. § 411.357(e).

4 See 42 C.F.R. § 411.352(d)(1) for additional clarity.

5 42 U.S.C. § 1320a-7b.

6 42 C.F.R § 411.357(e).

7 42 C.F.R § 411.357(e)(6).

8 42 C.F.R. § 411.357(e)(1)(iii).

9 42 C.F.R. § 411.357(r).

10 42 C.F.R. § 411.357(m).

11 42 C.F.R. § 411.357(s).

12 42 C.F.R. § 411.357(t).

13 42 C.F.R. § 411.362(b)(3)(ii)(C).

14 42 C.F.R. § 411.362(b)(4)(i).

15 42 C.F.R. § 411.357(a).

16 42 C.F.R. § 411.357(b).

17 42 C.F.R. § 411.357(d).

[18] 42 C.F.R. § 411.357(l).