McDermott Will & Emery

CMS Finalizes Stark Law Amendments

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SPECIAL REPORT

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On November 16, 2015, the Centers for Medicare and Medicaid Services (CMS) published the 2016 Medicare Physician Fee Schedule final rule with comment period in the Federal Register at 80 Fed. Reg. 70,886, which includes a final rule to amend CMS regulations implementing and interpreting the Stark Law, 42 C.F.R. § 411.351 *et seq*. (the Final Rule).[1] CMS published the proposed rule in the Federal Register on July 15, 2015, at 80 Fed. Reg. 41,686, 41,909–30, 41,953–58 (the Proposed Rule), which was summarized in a *Special Report*. The Final Rule will be effective on January 1, 2016 (with the exception of changes to the definition of *bona fide* investment levels for physician-owned hospitals discussed below in this *Special Report*, which will not be effective until January 1, 2017). CMS confirms, however, that many provisions of the Final Rule are "policy clarifications," and thus are intended to inform conduct that predates the effective date of the Final Rule.

According to CMS, the Final Rule "updates the physician self-referral regulations to accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance." 80 Fed. Reg. at 71,301. Notably, the Final Rule adds two new Stark Law exceptions—one for financial assistance to practices to recruit primary care non-physician practitioners and one for "timeshare" arrangements. In addition, CMS finalized the following provisions of the Proposed Rule:

- Expanding the 30-day grace period for the signature requirement of various Stark Law exceptions to a 90-day grace period (consolidating the distinct 30-day and 90-day grace periods into a single 90-day grace period);
- Extending the six-month holdover provision of various Stark Law exceptions to an indefinite holdover, provided the terms of the arrangement do not change;
- Making textual changes to clarify that signed writings need not be formal agreements or contracts for the purpose of various Stark Law exceptions; and
- Clarifying how the signed writing and volume/value standards apply when direct compensation arrangements arise from the "stand in the shoes" rule.

In the Final Rule, CMS reiterated its position stated in the Proposed Rule that the one-year term requirement of certain compensation exceptions is satisfied when an arrangement, in fact, lasts for at least one year. CMS did not respond in the Final Rule, however, to comments it solicited in the Proposed Rule on a range of topics and questions relating to physician compensation, stating that it "will carefully consider" the comments and will "determine whether additional rulemaking on these issues is necessary." *Id*. at 71,341.

A full discussion of the Final Rule follows, starting with a review of the basic terms of the Stark Law for the reader new to the subject.

The Stark Law: Basic Terms

Unless an exception applies, the Stark Law prohibits a physician from making a referral to an entity for the furnishing of designated health services (DHS)[2] that would otherwise be covered by Medicare if the physician (or an immediate family member) has a financial relationship with the entity (DHS Entity). 42 U.S.C. § 1395nn(a)(1)(A). Further, a DHS Entity may not submit a claim or bill any payor for DHS furnished pursuant to a prohibited referral, unless an exception applies. *Id*. § 1395nn(a)(1)(B). Financial

[1] The Final Rule also includes CMS's annual update to its list of CPT/HCPCS codes that define certain types of DHS (defined below). The complete list of such codes that will be effective on January 1, 2016, can be found at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html. CMS also published the non-monetary compensation and medical staff incidental benefit limits for calendar year 2016, both of which were unchanged from the 2015 limits ($392 and less than $33, respectively), according to https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates.html.

[2] The "designated health services" or "DHS" are:
1. clinical laboratory services;
2. physical and occupational therapy services;
3. radiology and other imaging services;
4. radiation therapy services and supplies;
5. durable medical equipment and supplies;
6. parenteral and enteral nutrients, equipment and supplies;
7. prosthetics, orthotics, and prosthetic devices and supplies;
8. home health services;
9. outpatient prescription drugs; and
10. inpatient and outpatient hospital services.

42 C.F.R. § 411.351.

relationships can arise from ownership/investment interests and compensation arrangements, and compensation arrangements can arise from any "remuneration," subject to certain exceptions. Financial relationships can be direct or indirect. *Id*. § 1395nn(a)(2); 42 C.F.R. § 411.354.

The Stark Law has many exceptions. For purposes of this *Special Report*, note that there are compensation exceptions for space leases, equipment leases, employment compensation, personal services arrangements, physician recruitment incentives and physician retention incentives. Generally, the compensation exceptions require that the compensation to the physician be set in advance, fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the DHS Entity.

The New Non-Physician Practitioner Recruitment Assistance Exception

Making several significant changes, CMS finalized the "non-physician recruitment" exception, found at 42 C.F.R. § 411.357(x), permitting hospitals, federally qualified health centers (FQHCs) and rural health clinics (RHCs) (Qualifying Facilities) to provide financial assistance to a physician or group to recruit a non-physician practitioner (NPP). CMS reiterated in various places throughout the preamble to the Final Rule that its policy objectives in creating this exception were to promote beneficiary access to care, address primary care workforce shortages and support the goals of healthcare delivery and payment system reform. With those policy goals in mind, CMS made various modifications to expand the exception in response to comments it received on the Proposed Rule.

A. WHO CAN BE RECRUITED AND FOR WHAT SERVICES

The exception in the Proposed Rule was limited to physician or group *employment* of the NPP to provide "only primary care services" to the physician's or group's patients. "Non-physician practitioner" was defined exclusively as a physician assistant, nurse practitioner, clinical nurse specialist or certified nurse-midwife, as defined by Medicare law.

The finalized exception was expanded to permit financial assistance for physicians or groups either employing *or directly contracting* with an NPP *on an individual basis*. Arrangements between a physician or group and a staffing agency do not fit within this exception. Also, convinced by "compelling evidence" provided by commenters, CMS expanded the types of services eligible for the exception to include mental health care services. As a result, the NPP definition now includes clinical social workers and clinical psychologists. The regulatory text does not include a specific definition of "primary care services," but the Final Rule repeats CMS' view from the Proposed Rule that general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology services are primary care services.

CMS also modified the proposed requirement that 90 percent of the NPP's services to patients of the physician's practice be primary care services to a requirement that "substantially all" (defined as 75 percent) of the NPP's services must be primary care and/or mental health care services. In addition, CMS clarified that *any* physicians or groups, including those that do not currently furnish primary care or mental health services, are eligible for the exception so long as the recruited NPP satisfies this "substantially all" test.

B. HOW THE FINANCIAL ARRANGEMENT CAN BE STRUCTURED

To qualify for the exception, the physician must engage an NPP that has not, during the year prior to the commencement of the compensation arrangement with the physician or group, practiced in the geographic area served by the Qualifying Facility or been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the Qualifying Facility, regardless of whether the NPP furnished services at the medical practice site located in the geographic area served by the Qualifying Facility. ("Geographic area served by the [Qualifying Facility]" is defined by reference to the physician recruitment exception.) This one-year limitation is much more liberal than the proposed three-year limitation. Once hired, the physician or group cannot impose practice restrictions on the NPP that unreasonably restrict the NPP's

ability to provide patient care services in the geographic area served by the Qualifying Facility.

CMS finalized the proposal that NPP recruitment assistance to the physician or group may only be provided during the first two consecutive years of the NPP's engagement, and that the exception can only be used for a physician or group once every three years. This structure essentially creates a one year "cooling off" period when the physician or group would not be eligible to receive NPP recruitment assistance. Several commenters requested that CMS eliminate this "cooling off" period and permit recruitment arrangements to last three years, arguing that it can sometimes take an extended period of time for an NPP to develop a practice that "breaks even." CMS rejected this request, contending that permitting the recruitment assistance to last three years "would permit permanent subsidies" of physician practices, which could pose a risk of program or patient abuse by being used to reward or induce referrals. CMS did, however, create an exception to the three-year rule in the Final Rule; in the event the NPP leaves the physician or group within one year of being recruited, financial assistance can be provided for a replacement NPP for the balance of the two-year assistance period.

In the Proposed Rule, CMS proposed capping the remuneration amount to not exceed the lower of 50 percent of the actual salary, signing bonus and benefits paid by the physician to the NPP or an amount calculated by subtracting all receipts attributable to services furnished by NPP from the actual salary, signing bonus and benefits paid to the NPP by the physician. In response to commenters' concerns about the feasibility of this standard, CMS instead finalized a "bright line" standard of 50 percent of the actual salary, signing bonus and benefits paid by the physician to the NPP. "Benefits" are defined in the preamble to the Final Rule as "only health insurance, paid leave and other routine non-cash benefits offered to similarly situated employees." 80 Fed. Reg. at 71,308. The remuneration may only be used to subsidize the compensation arrangement between the physician and NPP, not the NPP's ownership or investment in the practice.

The recruitment assistance agreement needs to be in writing and signed by the physician, Qualifying Facility, and NPP, and cannot be conditioned on the physician's or NPP's referrals to the Qualifying Facility. The exception contains the familiar prohibition on the remuneration taking into account the "volume or value" of any actual or anticipated referrals or other business generated by the physician or any physician in the physician's practice to the Qualifying Facility. CMS adds to this prohibition any remuneration taking into account the volume or value of referrals or other business generated by an NPP in the physician's practice, including a specific definition of "referral" to capture NPP referrals.

Finally, the exception states that the salary, signing bonus and benefits paid to the NPP cannot exceed fair market value, an element not found in the physician recruitment exception (42 C.F.R. § 411.357(e)). A fair market value requirement will unfortunately introduce an element of uncertainty for the donor DHS Entity, fair market value being so easily a subject of dispute. The exception does not, however, contain a "set in advance" requirement, which will give flexibility to adjust compensation.

The New Timeshare Arrangements Exception

CMS finalized the proposed new exception for timeshare arrangements (found at *id*. § 411.357(y)), with a few key modifications to the Proposed Rule. The new exception is intended to enable arrangements where a physician obtains the right to use premises, equipment, personnel, items, supplies or services on a limited or as-needed basis. Thus, the exception differs from the space and equipment lease exceptions in that it does not require a minimum one-year term or exclusive use and control requirements.

In the Proposed Rule, CMS had used the terminology of a "licensor" and a "licensee" to describe the parties, contrasting those terms to those of a "lessor" and "lessee." In the Final Rule, CMS abandons the licensee/licensor terminology due to concerns that those terms are confusing and may exclude non-abusive arrangements. CMS clarifies that the terminology used by the parties in the documents regarding the arrangement is not dispositive and that the fundamental question in determining whether a particular

arrangement qualifies for protection under the timeshare exception (instead of the lease exception) is whether the arrangement conveys a "possessory leasehold interest" in the office space that is the subject of the arrangement. CMS explains, "[w]here control over office space is conferred on a party such as to give that party a 'right against the world' (including a right against the owner or sub-lessor of the office space)," the arrangement is not eligible for protection under the timeshare exception and must instead meet the requirements of the lease exception. 80 Fed. Reg. at 71,329.

The Proposed Rule also limited the exception to arrangements where the user of the premises was a physician and the grantor of permission to use the premises was a hospital or physician organization. Under the Final Rule, a physician *or* hospital may be the party using the premises, equipment, personnel, items, supplies or services of a physician (or the physician organization in whose shoes the physician stands). A physician granted permission to use the premises of a physician or physician organization may not be an owner, employee or contractor of the grantor.

The Final Rule also modified the proposed requirements regarding equipment and locations. Under the Final Rule, the equipment covered by the timeshare arrangement does not need to be in the same *office suite* where the evaluation and management (E&M) services are furnished; instead, the equipment need only be in the same *building* as the office suite where the E&M services are furnished. CMS added a new requirement, however, that all locations under the timeshare arrangement, be they for E&M services or DHS, must be used on identical schedules.

CMS also responded to commenters who raised questions regarding what is meant by the term "predominantly" in the requirement that the property and services must be used "predominantly to furnish E&M services to patients of the licensee." CMS declined to offer a definition for this term, deferring to the "common meaning" of the term. However, CMS did clarify that parties may use "any reasonable, objective, and verifiable means" to measure predominance, which might include volume of patients seen, number of patient encounters, types of CPT codes billed, or the amount of time spent using the premises and services. 80 Fed. Reg. at 71,330.

With respect to the recent decision in *Council for Urological Interests v. Burwell*, which struck down CMS's prohibition on per-unit-of-service or "per click" equipment *leases*, CMS explained its view that the court's decision does not prevent CMS from restricting per-unit-of-service compensation under the timeshare exception based on its authority under section 1877(e)(1)(B)(vi) to promulgate "other requirements" by regulation as needed to protect against program or patient abuse.[3]

The requirements of the timeshare arrangements exception under the Final Rule are as follows:

1. 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;
2. The arrangement is between a physician (or the physician organization "in whose shoes" the physician stands) and either a hospital or a physician organization of which the physician is not an owner, employer or contractor;
3. The premises, equipment, personnel, items, supplies and services covered by the arrangement are used predominantly for the provision of E&M services to patients and on the same schedule;
4. The equipment covered by the arrangement is in the same building where the E&M services are furnished, is not used to furnish DHS other than those incidental to the E&M services furnished at the time of the patient's E&M visit, and is not advanced imaging equipment, radiation therapy equipment or clinical pathology laboratory equipment (other than for CLIA-waived tests);

[3] CMS stated that the prohibition on per-click equipment leases found in 42 C.F.R. § 411.357(b)(4)(ii)(B) has been remanded for further consideration in accordance with the *Council for Urological Interests v. Burwell*, *No. 13-5235, 2015 U.S. App. LEXIS 9867* (*D.C. Cir. June 12, 2015*) decision, and that it is considering its options as to how to comply with the decision. For more on the *Council for Urological Interests* decision, click here.

5. 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;

6. 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 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 using a formula based on a per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the grantor to the user;

7. The arrangement would be commercially reasonable even if no referrals were made between the parties;

8. The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission;

9. The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

Amendments and Clarifications Regarding the Signed Writing, One-Year Term and Holdover Provisions

CMS finalized its proposed regulatory revisions to (a) clarify that required signed writings need not be formal agreements or contracts for the purpose of various Stark Law compensation exceptions; (b) clarify that the one-year term requirement of certain compensation exceptions is satisfied when an arrangement, in fact, lasts for at least one year; (c) extend the six-month holdover provision of various exceptions to an indefinite period of time, so long as the terms of the arrangement do not change; and (d) expand the 30-day grace period for the signature requirement of various exceptions to a 90-day grace period. These revisions are a welcome change for the industry in seeking to comply with the technical requirements of these exceptions.

A. SIGNED WRITING REQUIREMENT

Many of the compensation exceptions require that the lease or other arrangement be set out in writing. Through administering the Self-Referral Disclosure Protocol (SRDP), CMS learned that there is uncertainty in the industry regarding whether an arrangement must be a single, formal written agreement to satisfy this requirement, particularly due to the fact that some exceptions use the term "agreement" (in the rental of office space and rental of equipment exceptions, 42 C.F.R. § 411.357(a)(1) and *id*. § 411.357(b)(1)) and others use the term "arrangement" (in the personal services arrangement exception, *id*. § 411.357(d)(1)(i)) in relation to the writing requirement. CMS clarifies that *the writing requirement is the same* for these exceptions, despite the different terminology. CMS restated its position originally stated in the Proposed Rule that:

> In most instances, a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with the applicable exception. However, *there is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract*. Depending on the facts and circumstances of the arrangement and the available documentation, *a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing*.

80 Fed. Reg. at 71, 314–15 (emphasis added.) Consistent with this stated position, CMS finalized its proposals to change "agreement" to "lease arrangement" in the space and

equipment lease exceptions, and to change "agreement" and "contract" to "arrangement" where it appears in the exceptions and special rules on compensation to clarify that a formal contract is not required (although there may be a writing requirement).

CMS did not, however, revise the term "written agreement" in the "certain group practice arrangements with a hospital" exception (42 C.F.R. § 411.357(h)) because this exception is rarely used. Further, CMS did not revise this term in the e-prescribing and electronic health records donation exceptions (*id*. §§ 411.357(v)–(w)) to avoid creating inconsistencies between these exceptions and the parallel federal anti-kickback statute safe harbors for such donations (even though CMS does not interpret "written agreement" to require a single formal contract).

CMS reiterated that substituting the word "arrangement" for "agreement" was intended to clarify and confirm its ***existing policy*** regarding the writing requirement, and that parties "considering submitting self-disclosures to the SRDP for conduct that predates the proposed rule may rely on guidance provided in the proposed rule to determine whether the party complied with the writing requirement of an applicable exception." 80 Fed. Reg. at 71,315. CMS declined to adopt commenters' recommendations that enforceability of the writing under State law should control, noting that ". . . a written contract that is enforceable under State law may not satisfy the writing requirement [of a Stark exception] if the actual arrangement differed in material respects from the terms and conditions of the written contract." *Id*. at 71,316.

In response to comments, CMS also clarified the following with respect to the signature requirement:

> For the same reason that parties do not need a *single* formal written contract to comply with the writing requirement, parties also do not need to sign a *single* formal written contract to comply with the signature requirement of an applicable exception. Nor do we expect every document in a collection of documents to bear the signature of one or both parties. To satisfy the signature requirement, a signature is required on a contemporaneous writing documenting the arrangement. The contemporaneous signed writing, when considered in the context of the collection of documents and the underlying arrangement, must clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect.

Id. CMS declined to give an example of a collection of documents that would satisfy the writing requirement, but provided examples of individual documents that could be considered as part of such a collection in determining whether the writing requirement of an exception was met, including board meeting minutes authorizing payments for specified services, written (including electronic) communication between the parties, fee schedules for specific services, check requests or invoices identifying items/services provided, time sheets, and accounts payable data, among others. CMS also declined to address what constitutes a "signature."

B. TERM REQUIREMENT

The space rental and equipment rental exceptions require that the "agreement" be for a term of at least one year. This could be interpreted to mean that the one-year term must be an explicitly stated term length of a formal agreement or contract. CMS reiterates in the Final Rule that the arrangement must in fact last for at least one year; a formal contract with an explicit term provision is generally not necessary. Rather, "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, can establish that the arrangement in fact lasted for the required period of time." *Id*. at 71,317.

Thus, CMS finalized its proposal to remove the term "agreement" in the one-year term provisions of the space and equipment rental exceptions to make it evident that a written agreement with a formal term provision is not necessary. In response to comments, CMS further modified the space rental, equipment rental and personal services exceptions to remove the word "term" and simply state that the *duration* of the arrangement must be at least one year. CMS reiterated that this statement is existing policy.

These statements do more than simply permit a DHS Entity to establish that an arrangement had a term of at least one year by referencing multiple documents; they indicate that a term of at least one year can be established simply by documentary evidence of a course of conduct *lasting* a year. Even if the parties had no particular understanding between them regarding the duration of the arrangement into which they entered, they can satisfy the one-year term requirement if they happen to perform the arrangement for at least one year. This liberalization of the one-year term requirement will not, however, appear to help parties relying on the fair market value exception to protect an arrangement with a term of *less* than one year. The fair market value exception still requires that the "writing specif[y] the timeframe for the arrangement, which can be for any period of time . . . ." 42 C.F.R. § 411.357(l)(2). The policy rationale for this distinction is obscure.

C. HOLDOVER ARRANGEMENTS

The space rental, equipment rental and personal service arrangements exceptions allow a "holdover" arrangement for up to six months following the expiration of an arrangement that lasted at least one year, as long as the arrangement satisfied the requirements of the exception when it expired, and it continues on the same terms and conditions during the holdover period. CMS finalized its proposal to amend the holdover provisions of these three exceptions to permit holdovers *indefinitely* (provided certain safeguards are met). To prevent compensation or rental charges that become inconsistent with fair market value over time, however, CMS finalized its proposal to require that the arrangement must not only satisfy the elements of the exception at the time the arrangement expires, but it must *continue* to satisfy all of the elements of the exception throughout the holdover period. CMS states that parties relying on the holdover provision must have contemporaneous documentation that the arrangement continued on the same terms and conditions as the original agreement during the holdover period.

Additionally, CMS proposed to revise the fair market value compensation exception, which currently allows for arrangements made for less than one year to be renewed any number of times as long as the terms and compensation do not change, to allow unlimited renewals of arrangements made for *any* length of time, as long as the terms and compensation do not change. Commenters requested that CMS include an indefinite holdover provision in the fair market value compensation exception, but CMS declined, indicating that no holdover provision is necessary because, even though the writing must specify a timeframe, the exception does not require that the parties renew the arrangement *in writing* (although there must be written documentation establishing that the renewed arrangement continues on the same terms and conditions). Apparently this means that, while the fair market value exception requires that the writing specify a timeframe for the arrangement, the actual renewal of this timeframe can be accomplished by course of conduct.

D. TEMPORARY NON-COMPLIANCE WITH THE SIGNATURE REQUIREMENT

Current regulations at 42 C.F.R. § 411.353(g) allow temporary noncompliance with the signature requirement of various compensation exceptions for 90 days if the failure to comply with the signature requirement is inadvertent and for 30 days if the failure to comply is not inadvertent, as long as the arrangement otherwise satisfies all other requirements of the applicable exception and is only used once every three years with respect to the same referring physician. CMS finalized its proposal to consolidate the distinct 30-day and 90-day grace periods into a single 90-day grace period, regardless of whether or not the failure to comply with the signature requirement was inadvertent.

CMS declined to adopt a similar grace period for the *writing* requirement, as it believes that a grace period for the writing requirement would not incentivize parties to document the terms and conditions of the arrangement promptly. CMS emphasizes that the grace period at *id*. § 411.355(g) only relates to temporary noncompliance with the *signature* requirement, and all other requirements of an applicable

exception (including the "set in advance" requirement) must be met as soon as a compensation arrangement is established and the physician makes referrals to the DHS Entity.

Solicitation of Comments on Perceived Need for Regulatory Revisions or Policy Clarifications Regarding Permissible Physician Compensation

CMS, in consultation with the Office of Inspector General of the U.S. Department of Health and Human Services, must deliver two reports to Congress within the next two years regarding the relationship between the fraud prevention laws and alternative care delivery and payment models. First, the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) (MACRA), enacted April 16, 2015, requires the Secretary of the Department of Health and Human Services (Secretary) to study and report to Congress on the vulnerability of alternative payment models to fraud and to examine the implications of waivers to the fraud prevention laws to support alternative payment models (the APM Report). Second, MACRA requires the Secretary to submit to Congress a report with options for amending existing fraud and abuse laws and regulations through exceptions, safe harbors or other narrowly tailored provisions, to permit gainsharing arrangements that would otherwise be illegal and similar arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency (the Gainsharing Report). To inform the APM Report and Gainsharing Report, *as well as to aid CMS in determining whether additional rulemaking or guidance is desirable or necessary*, CMS solicited comments in the Proposed Rule regarding the effect of the Stark Law on healthcare delivery and payment reform, including application of the Stark Law to performance-based and incentive compensation models. CMS made two broad requests for comments, and set forth ten specific topics or questions to "encourage robust commentary" from the industry.

In the Final Rule, CMS does not discuss the comments received, stating only the following:

> We received a number of thoughtful comments on the issues raised in the solicitation. We thank the commenters for their input, and we will carefully consider their comments as we prepare the reports to Congress required under sections 101(e)(7) and 512(b) of MACRA and determine whether additional rulemaking on these issues is necessary. We would like to note that our silence in this rule should not be viewed as an affirmation of any commenter's interpretations or views.

80 Fed. Reg. at 71,341.

Amendments to Certain Definitions

CMS amended the regulatory definitions of "remuneration" and "*locum tenens* physician," and clarified what the "stand in the shoes" rule means for the application of Stark Law exceptions to arrangements between DHS Entities and physician organizations. Finally, CMS amended to the "geographic area" definition for FQHCs and RHCs.

A. "REMUNERATION"

The Stark statute defines a "compensation arrangement" as "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C)." 42 U.S.C. § 1395nn(h)(1)(A). Subparagraph (C), in pertinent part, excludes from "remuneration" the "provision of items, devices, or supplies that are *used solely to*—(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or (II) order or communicate the results of tests or procedures for such entity." *Id*. § 1395nn(h)(1)(C). CMS regulations track this definitional language at 42 C.F.R. § 411.351. Read literally, this text arguably does not permit the item, device or supply to perform more than one of the specified functions of collecting, transporting, processing or storing specimens, or ordering or communicating results. CMS regulations track this text, but CMS indicates that it has not interpreted "used solely" so narrowly. Concerned that this language "may misleadingly suggest" that an item, device or

supply used for more than one of the six listed purposes would constitute "remuneration" creating a compensation arrangement (unless a compensation exception applied), CMS proposed to change "used solely" to "used solely for one or more of the following [six] purposes: . . ." 80 Fed. Reg. at 41,918, 41,954. CMS finalized this modification as proposed.

B. "LOCUM TENENS *PHYSICIAN*"

CMS regulations define a "*locum tenens* physician" because the regulatory definition of a "member of the group or member of a group practice" includes a locum tenens physician. The definition of a *locum tenens* physician, in pertinent part, is "a physician who substitutes (that is, 'stands in the shoes') in exigent circumstances for a physician, in accordance with applicable reassignment rules and regulations . . ." 42 C.F.R. § 411.351. Concerned that use of the phrase "stands in the shoes" potentially created an ambiguity because of the "stand in the shoes" rule within the Stark regulations, CMS proposed removing "stand in the shoes" from the definition of a *locum tenens* physician. CMS finalized this modification as proposed.

C. "STAND IN THE SHOES"

A physician who holds more than a titular ownership or investment interest in a physician organization (PO) is deemed to stand in the shoes of the PO for purposes of determining whether the physician has a direct or indirect compensation arrangement with a DHS Entity. A PO's employed or contracted physicians who are not deemed to stand in the shoes of the organization can elect to be treated as standing in the shoes of the organization. *Id*. § 411.354(c)(2)(iv). When a physician stands in the shoe of a PO, the physician is deemed to have compensation arrangements with the same parties and on the same terms as the PO. *Id*. § 411.354(c)(3).

The "stand in the shoes" concept required that CMS explain how the Stark exceptions work when multiple physicians are deemed to have the same compensation arrangement with a DHS Entity based on a compensation arrangement between the PO and the DHS Entity; the exceptions were drafted under the assumption that there would only be one physician "party" involved. CMS finalized, as proposed, additional regulatory text at *id*. § 411.354(c)(3) to confirm its intent that, with respect to the signature requirement, physicians standing in the shoes of the PO are "parties to the arrangements." Pursuant to CMS's FAQ on the issue, however, the signature of an authorized signatory for the PO would be imputed to the physicians standing in the shoes of the PO for purposes of the exceptions requiring a signed writing between the "parties." As confirmed by CMS in the preamble to the Final Rule, because all of the physicians standing in the shoes of the PO need to satisfy the signature requirement, if an arrangement between a DHS Entity and a PO needs to use the exception, *i.e*., grace period, for temporary non-compliance with the signature requirement of a compensation exception (described above), the exception cannot be used again for three years for *any* of the physicians standing in the shoes of the PO; they are all considered to have used the exception, which, by its terms, can only be used once every three years for the same physician. This is another reason why it may be preferable for DHS Entities to structure medical directorships and other personal services contracts with *individual* physicians, not POs.

CMS also finalized, as proposed, regulatory text confirming that, for purposes of all of the requirements of the direct compensation exceptions *other than* the signature requirement, including the volume or value standard, the "parties to the arrangement" include all of the PO's members, employees and independent contractors, regardless of whether these physicians stand in the shoes of the PO. Accordingly, when evaluating whether compensation paid by a DHS Entity to a PO is determined in a manner that takes into account the volume or value of the referrals or other business generated between the parties, the relevant referrals and other business generated between the parties include the referrals and other business generated by *all* the PO's members, employees and independent contractors, regardless of whether they all stand in the shoes of the PO.

D. "GEOGRAPHIC AREA" DEFINITION FOR FQHCS AND RHCS

In the Proposed Rule, CMS acknowledged that the regulatory definition of "geographic area" is contingent on *inpatient* volume, and as a result, it "provides no guidance as to the geographic area into which [FQHCs and RHCs] may recruit

a physician" since these entities only treat patients as outpatients or ambulatory patients. 80 Fed. Reg. at 41,913. Thus, although CMS intended to make the physician recruitment exception available to FQHCs and RHCs in its Stark II, Phase III rulemaking, "a concept critical for compliance with the exception's requirements" was not addressed. *Id*.

CMS proposed two alternative approaches for defining "geographic area" and finalized the more straightforward approach: the area composed of the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. This area is determined beginning with the zip code in which the highest percentage of the FQHC's or RHC's patients resides, and continues to add zip codes in decreasing order of percentage of patients.

Discrete Textual Changes Clarifying CMS Intent[4]

CMS finalized discrete textual changes regarding the phrase "takes into account" and to the text of the retention payments exception to clarify its intent and avoid confusion.

A. TAKES INTO ACCOUNT

CMS proposed to revise various exceptions to conform the language used to describe the volume/value standard. CMS was concerned that slight variations in language regarding the volume or value of referrals in different exceptions may be misunderstood to reflect a different rule than the more common phrasing, "takes into account the volume or value of referrals." CMS clarified that it views these alternative phrasings as having the same meaning as the "takes into account" language, and that it has a single, unitary understanding of the volume/value standard. CMS finalized its proposed revisions to conform the language across all exceptions. CMS did not, however, clarify whether the addition of "anticipated referrals" to the volume/value standard in only a few places in the regulations is consistent with its unitary interpretation of the volume/value standard.

B. RETENTION PAYMENTS EXCEPTION

Currently, 42 C.F.R. § 411.357(t) permits certain retention payments made to a physician with a practice located in an underserved area. This exception was first established in Stark II, Phase II and covered only retention payments made to a physician who had a *bona fide* firm, written recruitment offer. The exception was later modified in Stark II, Phase III to permit a hospital, RHC, or FQHC to retain a physician who does not have a *bona fide* written offer of recruitment or employment if the physician certifies in writing that he or she has a *bona fide* opportunity for future employment that meets the requirements at *id*. § 411.357(t)(2). In Phase III, CMS explained that a retention payment based on a physician certification may "not exceed the lower of the following: (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 in order to join the medical staff of the hospital to replace the retained physician." 72 Fed. Reg. 51,012, 51,066 (Sept. 5, 2007) (emphasis added). CMS intended the regulations to mirror the preamble language precisely, but in an apparent drafting error, the regulations at 42 C.F.R. § 411.357(t)(2)(iv) currently state the first (25 percent) alternative as "25 percent of the physician's current income (*measured over no more than a 24-month period*). . ." (emphasis added). CMS finalized its proposal to modify the regulations at *id*. § 411.357(t)(2)(iv)(A) to conform to its Phase III preamble explanation: "An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months). . ."

Physician-Owned Hospitals

A. PUBLIC WEBSITE AND PUBLIC ADVERTISING DISCLOSURE REQUIREMENT

CMS finalized, without modification, its proposed revisions to 42 C.F.R. § 411.362(b)(3)(ii)(C), which implements

[4] In addition to the discrete textual changes described in this section, CMS finalized its proposals to revise manual citations listed in the regulations that are no longer correct and to make certain typographical corrections. It appears that CMS intended to finalize its proposal to change the term "Web site" to "website" throughout the regulations, but did not actually do so. *See* 80 Fed. Reg. at 71,341, 71,373, 71,376.

requirements established in Section 6001(a)(3) of the Affordable Care Act, that a physician-owned hospital must disclose the fact that the hospital is owned or invested in by physicians on any public website for the hospital and in any public advertising for the hospital.

Public website disclosure requirement. CMS amended 42 C.F.R. § 411.362(b)(3)(ii)(C) to list examples of the types of websites that do not constitute a "public website for the hospital," namely social media websites, electronic payment portals, electronic patient care portals or electronic health information exchanges. CMS declined to explicitly include "networking websites" in the list, believing its discussion of social media websites in the Proposed Rule makes it clear that networking websites fall within the scope of social media websites. CMS also declined to give specific examples of social media or networking websites "given the pace at which technology develops." 80 Fed. Reg. at 71,337. CMS reiterated that the adopted revision is a non-exhaustive list.

Public advertising disclosure requirement. CMS amended 42 C.F.R. § 411.362(b)(3)(ii)(C) to refer to "public advertising *for the hospital*" (adding the term "for the hospital" to the existing regulatory text in order to track the statutory language), and to define the term at *id*. § 411.362(a) as "any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital." CMS also specified the types of communications that would be excluded from the definition *(i.e*., "by way of example, 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"). 80 Fed. Reg. at 71,335. CMS declined to add "search engine results" and "online listings of area hospitals" to its list of examples of communications that do not constitute "public advertising for a hospital," reiterating in the preamble to the Final Rule that the list of examples is not exhaustive, and a determination of whether a communication constitutes "public advertising for the hospital" will depend upon the facts and circumstances of the communication and not whether an individual is likely to make a medical decision based on the information provided in the communication.

Types of statements that constitute a sufficient statement of physician ownership or investment. CMS proposed to further amend 42 C.F.R. § 411.362(b)(3)(ii)(C) to specify that any language that would put a reasonable person on notice that the hospital may be physician-owned is deemed a sufficient statement of physician ownership or investment. CMS reiterates in the preamble of the Final Rule examples of statements that would meet this standard, such as "this hospital is partially owned or invested in by physicians," or a statement that the hospital is founded, managed or operated by physicians or is part of a health network that includes physician-owned hospitals. CMS stated that a hospital's name, by itself, such as "Doctors Hospital at Main Street, USA," would also put a reasonable person on notice that the hospital may be physician-owned. 80 Fed. Reg. at 71,336.

Location and legibility of disclosure statements. CMS reiterated in the preamble of the Final Rule its statement in the 2011 Outpatient Prospective System/Ambulatory Surgical Center (OPPS/ASC) Final Rule that the disclosure of physician ownership/investment should be located in a conspicuous place on the website and on a page that is commonly visited by current or potential patients, such as the home page or "about us" section. CMS also confirmed that 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 declined to prescribe a specific location or font size for disclosure statements on either a public website or public advertising, stating that "physician-owned hospitals have flexibility in determining exactly where and how to include the disclosure statements, provided that the disclosure would put a reasonable person on notice that the hospital may be physician-owned." 80 Fed. Reg. at 71,336.

Duration of period of noncompliance. CMS noted that September 23, 2011 is the date by which a physician-owned hospital had to be in compliance with the public website and advertising disclosure requirements, and therefore would be the earliest possible beginning date for noncompliance. CMS clarified that the period of noncompliance is the "duration of the applicable advertisement's predetermined initial circulation, unless the hospital amends the advertisement to satisfy the requirement at an earlier date." *Id*. (For example,

if a hospital pays for an advertisement to be included in one issue of a monthly magazine and fails to include the disclosure in such advertisement, the period of noncompliance likely would be the applicable month of circulation, even if the magazine continued to be available in the publisher's archives, waiting rooms of physician offices or other public places.) CMS declined to provide a more definitive period of noncompliance for a physician-owned hospital's failure to satisfy the public advertising requirement, as the determination will depend on the facts and circumstances of the hospital's advertisement.

B. DETERMINING BONA FIDE INVESTMENT LEVEL

CMS finalized its proposal to include non-referring physicians in the calculation of the percentage of a hospital's ownership or investment interests are held by physicians, but delays the effective date of this policy change to January 1, 2017. This change is accomplished by adding a definition of "ownership or investment interest" *for purposes of* 42 C.F.R. § 411.362 that, unlike the definition at *id*. § 411.354, is not limited to "referring" physicians. This means that a "physician" (as defined in Section 1861(r) of the Social Security Act and in 42 C.F.R. § 411.351) who is retired but stills holds his or her license to practice medicine will now be included in the calculation.

Section 6001(a)(3) of the Affordable Care Act established a requirement that the percentage of the total value of the ownership or investment interests held by physicians in a hospital, or in an entity whose assets include the hospital in the aggregate ("*bona fide* investment level"), cannot exceed the percentage held as of March 23, 2010 (the "baseline *bona fide* investment level"). The inclusion of non-referring physicians in the March 23, 2010, baseline *bona fide* investment level and subsequent calculations of bona fide investment levels is important to physician-owned hospitals because it can potentially increase the percentage of a hospital's equity that can be held by physicians. It can also, however, result in the need to divest physicians who have retired from practice but retain their medical licenses because the hospital now has to count them against the limit imposed by the baseline *bona fide* investment level.

Previously, in the 2011 OPPS/ASC Final Rule, CMS had taken the position that only referring physicians' ownership or investment would be included in the calculation of *bona fide* investment levels. CMS's policy was based on the definition of "ownership or investment interest" at 42 C.F.R. § 411.354, which limited such interests to "referring" physicians. CMS has now reversed itself, believing that the inclusion of *all* physicians in the calculation of *bona fide* investment levels is required by the statute. CMS revised its policy because (1) the statutory definition of "physician owner or investor" is broad, and if Congress had intended to limit the definition to only "referring physicians" it would have included such qualifying language; and (2) including only "referring physicians" in the definition of "physician owner or investor" for purposes of establishing the baseline *bona fide* investment level as of March 23, 2010, frustrates the purpose of an explicit December 31, 2010, deadline for physician-owned hospitals to have obtained a provider agreement. If on March 23, 2010, a physician-owned hospital was preoperational, it would not yet have a provider agreement, and *none* of its physician owners or investors would be making referrals to the hospital; it would have a baseline *bona fide* investment level of zero on March 23, 2010, making the December 31, 2010, deadline for obtaining a provider agreement meaningless for the hospital because its baseline investment level of zero would bar it from ever having any physician owners or investors.

New definition of ownership or investment interest. CMS adopted without revision its proposal to add a definition of ownership or investment interest solely for the purpose of *id*. § 411.362 that is not limited to "referring" physicians. Under the new definition, a ownership or investment interest in a hospital exists "if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor, and an *indirect* ownership or investment interest in a hospital exists if (1) between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and (2) 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," even if "the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the *precise composition* of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain." 80 Fed. Reg. at 71,340 (emphasis added). (CMS did not clarify whether an ownership or investment interest comprising a link in the chain can run any direction, or whether the interest must run towards the hospital. Presumably, CMS intended for the definition to track the Stark definition of an indirect ownership or investment interest for other Stark purposes, in which case, the ownership or investment interests must all run *towards* the hospital. For example, a physician's investment in an entity in which the hospital is also an investor would *not* make the physician an owner or investor in the hospital (*see* 42 C.F.R. § 411.354(b)(5)(iii)-(iv)).)

Delay in enforcement. CMS acknowledged the concerns of some commenters that this policy change would cause financial hardship for any non-referring or retiring physicians who would need to sell their ownership interests at the current fair market value to allow a physician-owned hospital to comply with the new policy. CMS also acknowledges that "physician-owned hospitals likely would have to restructure their governance, given the necessary ownership changes, and that such restructuring likely would be difficult and costly for the hospitals." 80 Fed. Reg. at 71,340. Accordingly, CMS is delaying the effective date of the revision for one year, to January 1, 2017.

Publicly Traded Securities[5]

Acknowledging that certain elements of the existing exception for publicly traded securities, 42 C.F.R. § 411.356(a), are antiquated, CMS undertook an investigation to determine whether the exception for ownership of publicly traded securities could be modernized by including currently existing systems that are the equivalent to the NASD's now obsolete automated interdealer quotation system. Ultimately, CMS concluded that electronic stock markets such as National Association of Securities Dealers Automated Quotation Systems (NASDAQ) and the Financial Industry Regulatory Authority's over-the-counter (OTC) market are "outgrowths and modern day equivalents to an automated interdealer quotation system." 80 Fed. Reg. at 41,920. As such, CMS proposed to revise the existing regulations "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." *Id*. In order to maintain standardization and transparency, CMS clarified that it is "not proposing to include any electronic stock markets or OTC quotation systems that trade unlisted stock or that involve decentralized dealer networks." *Id*. CMS finalized this update as proposed, having received no comments on it.

[5] CMS finalized its proposal to remove the hyphen from the phrase "publicly-traded" in the regulations.

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