Overview of Phase III Final Rule for Federal Physician Self-Referral (Stark) Law

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On September 5, 2007, the Centers for Medicare & Medicaid Services (CMS) published the “Phase III” Final Rule to the Federal Physician Self-Referral Law (Stark Phase III). Stark Phase III finalizes, and responds to public comments regarding, the 2004 Phase II interim final rule with comment period. It also comes more immediately on the heels of the Proposed Physician Fee Schedule Rule for CY 2008 (PFS Proposed Rule), which put forth a number of significant and potentially sweeping changes to the existing Stark Law. With the exception of the implementation of a new “stand in the shoes” provision, relevant to the analysis of financial relationships with group practices, Stark Phase III primarily clarifies previously published regulations or makes changes only at the edges. CMS has specifically left for further study the several more significant changes it set up to address in response to public comments submitted on the PFS Proposed Rule. A final rule based on those proposals it not expected until next year. Stark Phase III will be effective on December 4, 2007. Set forth below is a summary of Stark Phase III, organized to track the text of the Final Rule. For a short summary of highlights, see our Healthcare Alert dated September 6, 2007.

I. General Comments and Definitions (§ 411.351)

Anti-Kickback Law Requirement. Not surprisingly, as it previously and repeatedly has done, CMS rejected the objections of numerous commenters regarding the requirement, which appears in a number of Stark exceptions, that arrangements must not violate the Federal anti-kickback statute.

“Employee.” CMS confirmed that in order to qualify as an employee of a group practice, “the actual conduct of the relationship is determinative.” In other words, the common law rules would apply when considering whether someone is an

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5. 72 Fed. Reg. at 51,013; Section 1128B(b) of the Social Security Act (42 U.S.C. § 1320-7b(b)).
6. Id. at 51,014.
employee. “[R]eceipt of a W-2 from an entity and the written terms of the arrangement are relevant,” but neither one controls.7

“Entity.” Although CMS did not make any changes to the definition of “entity” in Stark Phase III, it has proposed a change in the PFS Proposed Rule (see below). For the present, CMS contented itself with reiterating its concern over certain services furnished “under arrangements,” specifically, those “arrangements structured so that referring physicians own leasing, staffing, and similar entities that furnish items and services to entities furnishing [designated health services (DHS)] . . . but do not submit claims.”8 In CMS’s view, physician-owned companies selling DHS items and services to hospitals (e.g., lithotripsy, imaging and outpatient surgery), “raise significant concerns under the fraud and abuse laws and would appear contrary to the plain intent of the” Stark Law9 and “appear highly suspect under the anti-kickback statute.”10 CMS was similarly strident in expressing its concerns in the PFS Proposed Rule about these arrangements.11 In the PFS Proposed Rule, CMS proposed revising the definition of “entity” so that a DHS entity includes the person or entity that performs the DHS as well as the person or entity who submits claims or causes claims to be submitted to Medicare for the DHS.12 In Stark Phase III, CMS notes that any change to address its concerns, whether through the definition of “entity” or otherwise, would be made in a separate rulemaking (such as the PFS Proposed Rule) that is subject to public comment.13

“Fair Market Value.” CMS has eliminated the safety zone for calculating the “fair market value” of a compensation arrangement that relied on published compensation surveys.14 Among other objections, industry had complained that the surveys identified in the old rule were too prescriptive and did not accurately capture significant regional differences.15 According to CMS, use of “multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value,” but CMS also recognized that the appropriate method for determining fair market value “will depend on the nature of the transaction, its location, and other factors.”16

7 Id.
8 Id.
9 Id.
10 Id. at 51,014-15.
11 See id. at 38,186 (noting that CMS has received anecdotal reports of hospital and physician joint ventures that provide hospital imaging services under arrangements that formerly were provided by the hospital directly; “there appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services”).
12 Id. at 38,187.
13 Id. at 51,104.
14 Id. at 51,015, 51,081 (to be codified at § 411.351).
15 Id. at 51,015.
16 Id.
“Incident to Services.” CMS confirmed that it did not intend to distinguish between “services” and “supplies” furnished “incident to” a physician’s professional services.17 Accordingly, CMS revises the definition of “incident to” services in Stark Phase III to clarify that the term includes both services and supplies (such as drugs) that meet the applicable requirements.18

“Physicians in a Group Practice.” The Stark Law permits physicians to make referrals for DHS within their group practices, provided that certain requirements are met. Stark Phase III modifies the definition of “physician in the group practice,” which is relevant to both the physician services exception19 and the in-office ancillary services exception,20 to clarify that an independent contractor must furnish patient care services for the group under a contractual arrangement directly with the group practice.21 This is to effectuate CMS’s belief that it is “appropriate to consider an independent contractor physician a ‘physician in the group practice’ only when he or she is performing services in the group practice’s facilities and, thus, has a clear and meaningful nexus with the group’s medical practice.”22

“Radiology and Certain Other Imaging Services” and “Radiation Therapy.” CMS made no changes to the definition of “radiology and certain other imaging services.” In general, “radiology and certain other imaging services” exclude radiology services that are integral to the performance of a nonradiological medical procedure and performed (1) during the nonradiological procedure or (2) immediately following the nonradiological services when necessary to confirm placement of an item placed during the procedure.23 In declining to expand this exclusion to cover CT scans taken 6 weeks after prostate brachytherapy, CMS emphasized its position that only under circumstances where the radiology procedure is performed “immediately after the nonradiology procedure to confirm placement of an item”24 is there no risk of program or patient abuse. While CMS noted that a CT scan or other imaging ordered after prostate brachytherapy may qualify as “necessary and integral” ancillary services, which could come within the consultation exclusion from the definition of referral (discussed further, below),25 CMS questioned whether a CT scan or other type of imaging performed as late as 6 weeks after the brachytherapy could ever be considered “necessary and integral” to the original procedure.”26

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17 Id. at 51,016.
18 Id. at 51,016, 51,081 (to be codified at § 411.351).
19 42 C.F.R. § 411.355(a).
20 Id. at § 411.355(b).
21 72 Fed. Reg. at 51,017.
22 Id.
23 42 C.F.R. § 411.351.
25 Id.
26 Id.
“Referral.” Although CMS made no changes to the definition of “referral,” it clarified some apparent confusion regarding whether there is a “referral” when antigens are prepared and furnished by a physician or when a physician orders a refill for, and personally refills, an implantable pump. CMS confirmed that there would be no “referral” in either case, but cautioned that it could only imagine a “few, if any” situations in which a referring physician would be enrolled in Medicare as a durable medical equipment (DME) supplier, personally perform all DME supplier obligations, and furnish DME and supplies to a patient.\textsuperscript{27} Apparently, a number of commenters asked for a clarification of, or an expansion to, the “consultation exclusion” to the referral definition.\textsuperscript{28} Although CMS did not expand the exclusion, it clarified that (a) the consultation exclusion would protect only radiation oncology services personally performed or supervised by the radiation oncologist or (b) supervised by a radiation oncologist in the same group practice.\textsuperscript{29} As such, the exclusion from the definition allows a radiation oncologist in the consulting radiation oncologist’s group practice to supervise the radiation therapy, but not to perform it.\textsuperscript{30}

“Rural Area.” Stark Phase III moves the definition of “rural area” to Section 411.351 and defines it as an area that is not an urban area (as defined in 412.63(f)(1)(ii)).\textsuperscript{31}

II. Group Practice (§ 441.352)

Stark Phase III does not make any substantive changes to the all-important definition of a group practice. For physician groups, compliance with this regulatory definition is an essential threshold requirement for furnishing DHS to Medicare beneficiaries under the Stark Law’s in-office ancillary services exception. Moreover, unlike other DHS entities, group practices may compensate their physicians through profit shares and productivity bonuses that indirectly take into account the volume or value of in-office DHS referrals. While the Phase I and Phase II rules devoted significant attention to group practice issues, Stark Phase III provides only a few relatively minor clarifications to the group practice definition, including the following:

- The “special rule” in Section 411.352(i)(1) – which allows group practices to pay productivity bonuses for services personally performed by their physicians – is revised to make clear that “incident to” services need not be personally performed by a physician to be included in bonus calculations,

\textsuperscript{27} Id.
\textsuperscript{28} Id. at 51,020
\textsuperscript{29} Id. at 51,020-21. A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services and requests by a radiologist for diagnostic radiology services are treated similarly. Id. at 51,021.
\textsuperscript{30} Id. at 51,020.
\textsuperscript{31} Id. at 51,021, 51,084 (to be codified at § 411.351).
provided that the physician supervises the provision of those services in accordance with the Medicare incident to requirements (i.e., the physician is present in the office suite and immediately available when the services are furnished). 32

- In response to comments, CMS makes clear that hospital-formed entities, nonprofit medical foundations, and faculty practice plans all may qualify as group practices and use the in-office ancillary services exception if, in each case, all the requirements of the regulatory definition are satisfied.33

- Under certain circumstances, a tax-exempt, nonprofit group practice may have a majority of its board composed of disinterested representatives of the community.34

III. Prohibition on Certain Referrals by Physicians and Limitations on Billings (§ 411.353) (Inadvertent Violations)

In Stark Phase III, CMS declines to make a number of suggested changes to certain regulatory provisions intended to address potentially harsh results from inadvertent violations of the Stark Law. Those provisions currently permit payment to DHS entities that either (1) did not have actual knowledge of, or acted in reckless disregard or deliberate ignorance of, a prohibited financial relationship,35 or (2) submitted claims during a period of temporary noncompliance of up to 90 days.36 In particular, CMS rejected suggestions that the 90-day period of temporary noncompliance be measured from the date of discovery (rather than the date of noncompliance) or that it eliminate the requirement that an arrangement must have been in compliance with an applicable exception for at least 180 days before it may qualify for the temporary noncompliance exception.37

IV. Financial Relationship, Compensation, and Ownership or Investment Interest (§ 411.354)

A. Ownership

Security interest in loans. In Phase II, CMS had indicated that loans or bonds secured by, or otherwise linked to, a particular piece of equipment or the revenue of a department or other discrete hospital operations would be considered an ownership interest in part of a hospital.38 In addition, CMS stated that a one-time sale of property (which could be equipment), using installment payments that are

32 Id. at 51,022, 51,085 (to be codified at § 411.352(i)(1)).
33 Id. at 51,022.
34 Id. at 51,023
35 42 C.F.R. § 411.352(e)
36 Id. at § 411.352(f).
appropriately secured, for example, by a security interest taken in the property, could qualify for the isolated transaction exception in Section 411.357(f) if all other requirements of the transaction were satisfied. Stark Phase III changes this to establish that a security interest taken by a physician in equipment sold to a hospital will be treated as a compensation arrangement, not an ownership interest by a physician in a component of the hospital. However, loans or bonds secured by or otherwise linked to the revenues of a hospital department or other discrete hospital operations will continue to be treated as ownership interests that will not qualify under the exception for “whole hospital” ownership.

Retirement plans. CMS reiterates its concerns, stated in the PFS Proposed Rule, that the exemption of retirement funds from the definition of ownership interest is not intended to allow physician retirement funds to invest in DHS. CMS points out that, at present, such arrangements may need to satisfy the exception for indirect compensation arrangements, and may violate the anti-kickback law, and suggests that future rulemaking may narrow the definition of retirement plan to eliminate this loophole.

Bonds. Stark Phase III rejects the request by some commenters (primarily the promoters of so-called participating bond transactions) to exempt ownership in tax-exempt bonds from the definition of ownership or investment interest.

B. Compensation

“Stand in the shoes.” The most significant change to the definition of financial relationships in Stark Phase III is the addition of the “stand in the shoes” provision, under which physicians will now be deemed to “stand in the shoes” of their “physician organizations.” As a result, arrangements between physician organizations and DHS entities (e.g., hospitals) will now be viewed as creating direct compensation arrangements with the physicians within such organizations, and will have to meet a direct (as opposed to the potentially more forgiving indirect) compensation exception. For purposes of applying the various exceptions, these physician organizations include professional corporations, a physician practice, or group practices, but apparently do not include a physician-owned leasing or management company (although this may require clarification from CMS). The rule will grandfather arrangements entered into prior to September 5, 2007, for the

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39 Id. at 16,098.
40 72 Fed. Reg. at 51,027. (to be codified at § 411.354(b)(3)(v)).
41 Id. at 51,027.
42 Id. at 51,027 citing 72 Fed. Reg. at 38183-84 (proposing changes to 42 C.F.R. § 411.354(b)(3)(i)).
43 Id. at 51,027.
44 See id. at 51,083 (to be codified at 42 C.F.R. § 411.351 (physician organization)); 51,087 (to be codified at 42 C.F.R. § 411.354(c) (compensation arrangements)).
45 Id. at 51,028.
46 Id. at 51,028, 51,083 (to be codified at § 411.351).
now current contractual term of such arrangements, after which the arrangements will have to qualify for one of the exceptions for direct compensation arrangements.47

“Otherwise reflect.” CMS reiterates that a lump-sum payment may “otherwise reflect” the volume or value of referrals or other business if it is not fair market value.48

Required referrals. Stark Phase III clarifies that if certain conditions are satisfied, a DHS entity may condition physician payment under an employment, managed care, or personal services contract on making referrals only to approved providers, repeating the example that a hospital may require such physicians to refer to a hospital-owned home health agency.49 According to CMS, such required referrals do not violate the Medicare requirement to provide discharged hospital patients with a choice of home health agencies, because one condition is that the referral requirement does not apply if the patient expresses a different preference.50

C. Special Rules on Compensation

Percentage compensation. CMS clarifies that while percentage-based compensation may satisfy the “set in advance” component of the compensation exceptions, it also must satisfy the other standards of fair market value and not be based on the volume or value of referrals or other business generated.51

V. General Exceptions to the Referral Prohibition Related to Both Ownership and Compensation (§ 411.355)

Physician services. CMS declined to take the position that referrals within a group practice to independent contractor pathologists who perform services for the group in off-site “pod labs” can never meet the physician services exception. However, CMS noted that it is continuing to study these issues and observed that “the provision of off-site services by group practices raises significant concerns under the anti-kickback statute.”52 In the PFS Proposed Rule, CMS has proposed an “anti-markup” provision on both the technical component and professional component of diagnostic tests, which would address some of the commenters’ concerns.53

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47 Id. at 51,028, 51,087 (to be codified at § 411.354(c)(3)(ii)).
48 Id. at 51,029.
49 Id. at 51,030, 51,088 (to be codified at § 411.354(d)(4)).
50 Id. at 51,031.
51 Id. at 51,031-32.
52 Id. at 51,032.
53 Id. at 38,180.
In-office ancillary services. Stark Phase III did not make any substantive changes to the in-office ancillary services’ exception, although it did provide clarification with respect to some requirements. For example:

- With respect to the requirement stating that physicians must provide “some” physician services in the “same building” that are unrelated to the furnishing of DHS, CMS declined to provide a quantitative measure of what “some” non-DHS means. However, CMS stated that it will take into account the nature of the group’s overall practice (for example, the specialties of the group’s physicians) and the referring physician’s full range of practice. Where physicians provide DHS to their patients in a shared space in the same building, the physicians “must control the facility and the staffing . . . at the time the designated health service is furnished to the patient.” CMS observed that “per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the anti-kickback statute.” Note that this statement is consistent with CMS’s proposal in the PFS Proposed Rule, whereby space and equipment leases would not be permitted to include unit-of-service based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by the physician to the entity.

- CMS emphasized that the operation of the arrangement, not its form on paper, will determine compliance with either the “same building” or “centralized building” tests.

- CMS stated that it will address possible additional requirements to qualify as a centralized building (which were proposed in the Physician Fee Schedule for 2007) in a separate rulemaking in order to respond to criticisms that this element of the rule permits numerous abusive arrangements.

- CMS also clarified that the physician self-referral rules do not supersede or alter Medicare payment and billing rules and policies, including rules

54 Id. at 51,033.
55 Id.
56 Id.
57 Id.
58 Id.
59 Id. at 38,183.
60 Id. at 51,033.
61 Id.
on reassignment, supervision, or purchased diagnostic tests.\(^{62}\)

- Finally, in response to the large number of comments from the physical and occupational therapy profession regarding the detrimental effect the exception has on their practice, CMS echoed its statements in the PFS Proposed Rule that it is considering requests for modifications to the exception.\(^{63}\)

**Services furnished by an organization (or its contractors or subcontractors) to enrollees.** No notable changes or comments regarding the exception for services furnished by an organization to enrollees.

**Academic medical centers.** To qualify under the Stark Law’s academic medical center (AMC) exception, an AMC must consist of, among other things, one or more affiliated hospitals in which a majority of physicians on the medical staff consists of physicians who are faculty members of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital.\(^{64}\) Stark Phase III clarifies that, for purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (e.g., physicians holding courtesy privileges).\(^{65}\) Stark Phase III also clarifies that the total compensation to referring physicians need not be set in advance, and it is sufficient if the contribution of each component of the AMC to the aggregate compensation uses a methodology that qualifies under Section 411.354(d).\(^{66}\) Similarly, payment by each AMC component must be set in advance and not take into account the volume or value of referrals or other business generated by the referring physician within the AMC.\(^{67}\) However, CMS confirmed, and modified the exception to make clear, that the compensation paid by each AMC component to the referring physician is not required to satisfy a fair market value test; rather, only the aggregate compensation paid by all AMC components must reflect fair market value.\(^{68}\) Finally, CMS reminded parties that failure to satisfy the AMC exception does not prevent the parties from seeking to satisfy the exception for indirect compensation arrangements.\(^{69}\)

**Preventive screening tests, immunizations, and vaccines.** No notable changes or comments regarding the exception for preventive screening tests, immunizations, and vaccines.

\(^{62}\) *Id.* at 51,034

\(^{63}\) *Id.* at 51,032.

\(^{64}\) 42 C.F.R. § 411.355(e).

\(^{65}\) 72 Fed. Reg. at 51,037, 51,090 (to be codified at § 411.355(e)(2)(iii)).

\(^{66}\) *Id.* at 51,037.

\(^{67}\) *Id.*

\(^{68}\) *Id.* at 51,037, 51,090 (to be codified at § 411.355(e)(1)(ii)).

\(^{69}\) *Id.* at 51,038.
Eyeglasses and contact lenses. No notable changes or comments regarding the exception for eyeglasses and contact lenses.

Implants furnished by an ambulatory surgical center. CMS clarifies that the exception for implants furnished by an ambulatory surgery center (ASC) applies only where the ASC bills for the implanted device (and not where the physician bills for the implant during an ASC procedure).\(^\text{70}\)

EPO and other dialysis-related drugs furnished in or by an end-stage renal disease facility. CMS refused to expand the exception for Epoetin and certain other dialysis-related outpatient prescription drugs furnished in or by an end-stage renal disease (ESRD) facility, rejecting calls to expand the current exception to include all drugs furnished as part of a dialysis treatment (whether in a home or at a facility).\(^\text{71}\) According to CMS, expanding the list as suggested by the commenter would “creat[e] a risk of program or patient abuse” and “may lead physicians to order intravenous administration of a drug when oral administration is as effective, or to not choose the most cost-effective appropriate drug.”\(^\text{72}\)

Intra-family rural referrals. In general, the exception for certain referrals from a physician to his or her immediate family member for DHS requires that the patient reside in a rural area and that there is no other person or entity available to furnish the DHS, either: (i) at the patient’s residence (in the case of home health services or other DHS required to be furnished in the patient’s home), or (ii) within 25 miles of the patient’s residence.\(^\text{73}\) Stark Phase III revises this exception to include a test based upon transportation time from the beneficiary’s residence. Specifically, the alternative provider must not be within either 25 miles of the patient’s residence or 45 minutes’ transportation time from the patient’s residence. Referring physicians are free to choose either the distance or transportation time tests when determining whether a DHS referral may be made to an immediate family member.\(^\text{74}\) Thus, the revised regulation may permit some intra-family referrals when the distance to the closest alternative provider is less than 25 miles from the patient’s residence and the transportation time test may result in intra-family referrals being permitted at one time (e.g., in winter months when snow covers mountain roads and limits access) but not at a different time. CMS recommends that physicians using the transportation time test should maintain documentation of the information used in determining the transportation time, such as Mapquest and published weather reports.\(^\text{75}\)

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\(^{70}\) Id.

\(^{71}\) Id. at 51,039.

\(^{72}\) Id.

\(^{73}\) 42 C.F.R. § 411.355(g).

\(^{74}\) 72 Fed. Reg. at 51,040.

\(^{75}\) Id.
VI. Exceptions to the Referral Prohibition Related to Ownership or Investment Interests (§ 411.356)

Publicly traded securities and mutual funds. No notable changes or comments regarding the exception for publicly traded securities and mutual funds.

Hospitals located in Puerto Rico. No notable changes or comments regarding the exception for hospitals located in Puerto Rico.

Rural providers. CMS clarifies that where an entity furnishing DHS qualifies for the rural ownership exception, no other exception must be satisfied for a referring physician’s ownership or investment interest. Any related compensation arrangement would have to meet a separate compensation arrangements exception, such as the in-office ancillary services exception.

Ownership interest in a whole hospital. CMS declined to extend the exception for ownership interest in a whole hospital to separately licensed subsidiary providers and suppliers such as a hospital’s wholly owned home health agency, skilled nursing facility, or DME supplier. As explained in the section on Ownership, above, CMS also confirmed that a security interest in equipment sold to a hospital by a physician and financed through a loan to the hospital by the physician is not an ownership interest in the hospital, but, rather, a compensation arrangement. In addition, a security interest in the hospital itself is an ownership interest in the hospital and an indirect ownership interest in any subsidiary owned by the hospital.

VII. Exceptions to the Referral Prohibition Related to Compensation Arrangements (§ 411.357)

Rental of office space and equipment. Although Stark Phase III made no substantive changes to the rules regarding the exceptions for rental of office space and equipment, CMS addressed a number of comments and questions. Among CMS’s clarifications:

- Parties may change rental charges during a lease agreement only if they terminate the lease and enter a new agreement, but this can be done only after the first year of the original lease term, regardless of the length of the original term. Otherwise, leases may be amended multiple times.

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76 Id. at 51,043. CMS does not believe Congress intended to create a blanket exemption for physician ownership in for-profit hospital conglomerates, which would intensify rather than diminish the incentive to refer due to increased profit opportunities. Id.
77 Id.
78 Id.
79 Id. at 51,044.
during or after the first year of the agreement (presuming all other requirements of the exception are met).80

- Changes to terms that are material to the rental charges, such as the amount of space leased, may cause the rental charges to fall out of compliance with the fair market value and volume and value of referrals’ requirements.81

- With respect to the requirement that an office space lessee have exclusive use of the leased space or equipment when being used by the lessee, CMS confirmed that the ability for several physicians and/or groups to share facilities equipment is limited.82 Under the exception, sublessors and sublessees of space may share common areas — foyers, central waiting rooms, break rooms, vending areas, etc. — to the extent that the areas are, in fact, used by the sublessee (i.e., “the sublessee cannot pay rent for a break room that it will never use”).83 Common areas also may include equipment so long as it is limited to the type that is not usually separately leased, such as scales.84 Common areas do not include exam rooms.85

- With respect to tenant improvements, if a lessor provides improvements for the benefit of a physician lessee that are unlikely to be chargeable to a subsequent tenant, the lessor should allocate the entire cost of these improvements to the lessee, for whose unique benefit they are made.86 Improvements that the lessor reasonably expects would be chargeable to a subsequent lessee may be allocated over their expected useful life.87

- Lessors can charge a holdover rental premium, provided that the amount of the premium was set in advance in the lease agreement (or renewal) at the time of its execution, and the rental rate and premium remain consistent with fair market value and do not take into account the volume or value of referrals or any other business generated between the parties.88 However, CMS declined to permit the holdover grace period to last for the length of time that the landlord is taking steps to evict the tenant, stating that the existing 6-month holdover period permitted in the regulations is sufficient.89

80 Id.
81 Id.
82 Id. at 51,045.
83 Id.
84 Id.
85 Id.
86 Id.
87 Id.
88 Id.
89 Id.
Personal services arrangements. Stark Phase III modified the personal services arrangements exception to permit a holdover personal service arrangement of up to 6 months, similar to the holdover provisions in the exceptions for the rental of office space and equipment, and CMS noted that a personal service contract can be amended in the same manner as an office space or equipment lease. CMS declined to permit incentives to physicians for their services in connection with fee-for-service patients, whether or not such incentives fit the general structure of the exception. However, compensation related to patient satisfaction goals or other quality measures unrelated to the volume or value of business generated by the referring physician or unrelated to reducing or limiting services would be permitted under the personal services arrangements exception (assuming all requirements of the exception are satisfied). Because CMS now considers a physician to “stand in the shoes” of his or her group practice or physician organization, if a hospital contracts with a group practice for the provision of services, a physician in that group is deemed to have a direct relationship with the hospital, and the physician must meet an exception in order for the physician to be able to refer patients to the hospital. As of the effective date of Stark Phase III, when a group practice physician stands in the shoes of a group practice with which a medical foundation has contracted, the medical foundation may apply the personal services arrangements exception to the arrangement between it and the group practice in order to protect referrals from the physician.

Physician recruitment. Although retaining the basic principles with respect to permissible and impermissible compensation arrangements for physician recruitment into a “geographic area served by the hospital,” Stark Phase III makes some significant changes to the procedure for meeting these exceptions. For example:

- Rural health clinics are now able to utilize the exception.
- Rural hospitals may take advantage of a new method of determining the “geographic area served by the hospital.”
- Groups in a rural area or health professional shortage area (HPSA) that recruit a physician to replace a retired, deceased, or relocated physician may allocate the actual incremental costs of additional overhead for the recruited physician or the lower of a per-capita allocation or 20% of the

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90 Id. at 51,047, 51,092 (to be codified at § 411.357(d)(1)(vii)).
91 Id. at 51,047.
92 Id. at 51,048.
93 Id.
94 Id. at 51,047.
95 Id. at 51,049, 51,093 (to be codified at § 411.357(e)(6)).
96 Id. at 51,050, 51,093 (to be codified at § 411.357(e)(5)).
aggregate overhead costs.\textsuperscript{97}

- Certain practice restrictions, such as non-compete agreements, are now permitted, so long as they do not “unreasonably restrict the recruited physician’s ability to practice medicine in the geographic area served by the hospital.”\textsuperscript{98}

**Isolated transactions.** Stark Phase III did not modify this exception, under which an isolated transaction, such as a one-time sale of property or a medical practice, is not considered to be a compensation arrangement for purposes of the prohibition on physician referrals if certain conditions are met. CMS, however, clarifies the circumstances under which installment payments may be used for an “isolated transaction” and that each separate transaction involving related parties must satisfy all of the requirements of the isolated transaction requirement.\textsuperscript{99}

**Remuneration unrelated to designated health services.** No changes were made to the exception for remuneration unrelated to DHS by Stark Phase III. However, CMS’s comments again emphasized that remuneration would be considered related to DHS not only if it directly related to the provision of DHS services, but also compensation relationships related “in any way to the furnishing of DHS.”\textsuperscript{100}

**Group practice arrangements with a hospital.** No notable changes or comments regarding the exception for group practice arrangements with a hospital.

**Payments by a physician.** No notable changes or comments regarding the exception for payments by a physician.

**Charitable donations by a physician.** Stark Phase III amends the exception for \textit{bona fide} charitable donations made by a physician (or his or her immediate family member) to a tax-exempt organization furnishing DHS to provide that, not only may the entity not solicit the donation, the physician may not offer the donation, in any manner that reflects the volume or value of referrals.\textsuperscript{101}

**Nonmonetary compensation.** Two substantive changes to the exception for nonmonetary compensation that does not exceed $300 per year were implemented as part of Stark Phase III:

- First, physicians may repay certain excess nonmonetary compensation within the same calendar year to preserve compliance with the exception.

\textsuperscript{97} \textit{Id.} at 51,052, 51,093 (to be codified at § 411.357(e)(4)(iii)).

\textsuperscript{98} \textit{Id.} at 51,054, 51,093 (to be codified at § 411.357(e)(4)(vi)).

\textsuperscript{99} \textit{Id.} at 51,055.

\textsuperscript{100} \textit{Id.} at 51,056.

\textsuperscript{101} \textit{Id.} at 51,057, 51,094 (to be codified at § 411.357(j)(2)).
Under this new provision, nonmonetary compensation will be deemed to be within the regulatory limit if the entity has inadvertently exceeded the limit by no more than 50% during a calendar year, and the physician repays the excess compensation within the earlier of the end of the calendar year or 180 days from the date on which the excess compensation was received.102

- Second, the revised exception allows entities, without counting against the dollar limit, to provide one medical staff appreciation function (such as a holiday party) for the entire medical staff per year. The comments explain that allowing one annual, local social event for the entire medical staff — i.e., all physicians and other medical practitioners who order hospital services for patients — would not create a risk of program or patient abuse.103

CMS’s comments to the nonmonetary compensation clarify that the aggregate limit is to be calculated on a calendar-year basis and that small services arranged as “tokens of appreciation” for physicians, are to be included.104 CMS also again emphasized that hospitals and other DHS entities that wish to use the exception should take steps to ensure the implementation of effective compliance systems, including appropriate tracking and valuation mechanisms.105

Fair market value compensation. The exception for fair market value compensation arrangements — protecting fair market value compensation from a DHS entity to a physician, immediate family member of a physician, or a group of physicians, for the provision of items or services by the physician or group to the DHS entity — has been amended in Stark Phase III to provide that it may also apply to compensation provided to a DHS entity from a physician.106 In addition, the CMS amended the rule to clarify that the exception is not applicable to leases for office space, which must comply with the exception for the rental of office space at Section 411.357(a).107

Medical staff incidental benefits. No notable changes or comments regarding the exception for medical staff incidental benefits.

Risk-sharing arrangements. No notable changes or comments regarding the exception for risk-sharing arrangements.

102 Id. at 51,058, 51,094 (to be codified at § 411.357(k)(3)).
103 Id. at 51,059, 51,094 (to be codified at § 411.357(k)(4)).
104 Id. at 51,059.
105 Id. at 51,058.
106 Id. at 51,059, 51,094-95 (to be codified at § 411.357(l)).
107 Id.
Compliance training. Stark Phase III opens the compliance training exception to protect compliance training programs that offer continuing medical education (CME) credit, “provided that compliance training is the primary purpose of the program.”108 (Presumably, this means at a minimum that the compliance training elements occupy more than 50% of the program’s time.) CMS cautions that programs offering CME credit have “substantial value to the physician, who is required to obtain such CME credit for State licensure purposes,” and that CME programs do not meet the exception “merely because they contain a compliance training component.”109

Indirect compensation arrangements. The exception for indirect compensation arrangements is retained but, in light of the new “stand in the shoes” provision, is now relatively limited. As noted previously, under the new provision, if the party between the individual physician and the DHS entity is a group practice, under Stark Phase III, there is a direct, as opposed to an indirect, compensation relationship between the physician and the DHS entity; accordingly, the relationship must satisfy an exception for direct compensation instead of the indirect compensation arrangement. Arrangements existing as of the publication date of the Stark Phase III rule are grandfathered until the end of their original or current renewal term.110 If an arrangement is, as defined under Stark Phase III, an indirect compensation relationship, the exception for indirect compensation relationships can be used to protect that arrangement and no other protection (i.e., for the other links in the chain of relationships) would be needed. CMS, noting that it depends “on how the actual collections progress,” declined to confirm that a contract based on percentage of collections could satisfy the requirement in the indirect compensation arrangement exception that the compensation be fair market value and not determined in a manner that takes into account the volume or value of referrals or other business generated for the DHS entity.111

Referral services. No notable changes or comments regarding the exception for referral services.

Obstetrical malpractice insurance subsidies. Although Stark Phase III makes no notable changes or comments regarding the exception for obstetrical malpractice insurance subsidies, in the PFS Proposed Rule, CMS suggested modifying the exception to make it less restrictive and sought comments and recommendations concerning a number of potential safeguards against program or patient abuse when remuneration is provided by a hospital to a physician in the form of an obstetrical malpractice insurance subsidy.112

108 Id. at 51,061, 51,095 (to be codified at § 411.357(o)).
109 Id. at 51,061.
110 Id. at 51,061, 51,087 (to be codified at § 411.354(c)(3)(ii))...
111 Id. at 51,063.
112 Id. at 51,063-64; see also 72 Fed. Reg. at 38,182-83.
Professional courtesy. The professional courtesy exception was modified to remove the requirement that an entity notify the applicable insurer when the professional courtesy involves reduction of any coinsurance obligation. The exception was also clarified to indicate that it applies only to entities, such as hospitals, with formal medical staffs, and not to suppliers, such as laboratories or DME companies.

Retention payments in underserved areas. In addition to allowing rural health clinics to take advantage of the exception for retention payments in underserved areas, CMS modified the retention exception in a number of ways. Of particular note:

- Stark Phase III now permits a hospital, rural health clinic, or federally qualified health center to offer assistance to a physician who does not have a *bona fide* written offer of recruitment or employment, in limited circumstances. Specifically, the physician must certify, among other things, that he or she has a *bona fide* opportunity for future employment by a hospital, academic medical center, or physician organization that would require relocation of his or her medical practice at least 25 miles to a location outside of the geographic area served by the hospital, rural health clinic, or federally qualified health center. Where the retained physician provides a written certification, rather than a *bona fide* written offer of recruitment or employment, the retention payment may not exceed the lower of (1) an amount equal to 25% of the physician’s current annual income or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area to recruit the retained physician. Where the physician has a written offer, that offer may be matched. In addition, a *bona fide* written offer (or certification of an employment opportunity for which no written offer has been received) now includes an offer not only from a hospital, but also an academic medical center or a physician organization (as defined in Stark Phase III).

- Stark Phase III also expanded the exception to permit retention payments when the physician’s current medical practice is located in a rural area or a HPSA, or where at least 75% of the physician’s patients either reside in a medically underserved area or are members of a medically underserved area.

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113 72 Fed. Reg. at 51,065, 51,096 (to be codified at § 411.357(s)).
114 *Id.*
115 *Id.* at 51,065, 51,097 (to be codified at § 411,357(t)(5)).
116 *Id.* at 51,066, 51,096 (to be codified at § 411.357(t)).
117 *Id.* at 51,066, 51,096 (to be codified at § 411.357(t)(2)).
118 *Id.* at 51,066, 51,096 (to be codified at § 411.357(t)(2)(iv)).
119 *Id.* at 51,066, 51,096 (to be codified at § 411.357(t)(1)).
120 *Id.* at 51,066, 51,096 (to be codified at § 411.357(t)(1)(i)).
population.\textsuperscript{121}

- CMS clarified that retention payments may not be paid to group practices,\textsuperscript{122} may be applied by the physician to malpractice insurance premiums,\textsuperscript{123} and that the amount of a retention payment may take into account the experience, training, and length of service in the area as well as both direct and indirect costs of a replacement, provided that they are actual costs.\textsuperscript{124}

Community-wide health information system. No notable changes or comments regarding the exception for community-wide health information systems.

VIII. Reporting Requirements (§ 411.361)

Other than revising the reporting requirements to reflect the transition from the Unique Physician Identification Number (UPIN) to the National Provider Identifier (NPI), there were no notable changes or comments regarding the reporting requirements.\textsuperscript{125}

\textsuperscript{121} Id. at 51,066, 51,096 (to be codified at § 411.357(t)(3)).
\textsuperscript{122} Id. at 51,067.
\textsuperscript{123} Id.
\textsuperscript{124} Id.
\textsuperscript{125} Id. at 51,068, 51,098 (to be codified at § 411.361(c)).