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# CMS Issues Final Phase III Stark Regulations, While Also Proposing New Stark Rules

## 1. Introduction

Late this summer, the Center for Medicare & Medicaid Services ("CMS") gave with one hand, while taking with the other. Bringing a seeming finality to the Stark Law landscape, CMS promulgated the third and apparently last phase of its final regulations for the federal physician self-referral prohibition, commonly known as the "Stark Law," (72 Fed. Reg. 51012; the "Phase III regulations"). In general, this latest CMS effort continued to reflect a pragmatic and functional approach. But CMS also has made proposals for more dramatic changes to these regulations, which are in regulatory limbo.

The most critical portion of the Phase III regulations is a provision that closes a significant loophole that was created by the Phase II regulations, and was identified in our May 2004 Health Law Alert concerning the Phase II regulations [Titled: Health Law Alert - Stark Law Final Regulations: Phase II (http://www.proskauer.com/news_publications/client_alerts/content/2004_05_00_b/)]. This loophole arose from the application of the indirect compensation definition and exception, and allowed physicians who practiced in professional entities such as professional corporations and limited liability companies to avoid entirely the application of the Stark Law. CMS has now closed this loophole through a new "stand in the shoes" rule that treats the physician the same as his or her professional entity for Stark Law purposes.

The Phase III regulations are also particularly notable for tightening rules regarding physicians, in a group practice; barring the use of leased employees; eliminating the fair market value "safe harbor" for hourly rates consistent with certain surveys; and expanding the important fair market value compensation exception to cover services rendered *to* a referring physician *by* an entity (as opposed to only services rendered *by* a physician *for* an entity).

While an exhaustive analysis of the Stark Law, its regulations, and the newest changes contained in the Phase III regulations are beyond the scope of this Alert, below we emphasize the most broadly important changes implemented by the Phase III regulations. This Alert is not intended to substitute for a complete review of the current state of the Stark Law and the final regulations that implement it.

At around the same time that CMS apparently provided the industry with settled rules and expectations, CMS also decided to promulgate additional proposed Stark rules in the Physician Fee Schedule (72 Fed. Reg. 38122). These proposals would, if adopted, dramatically shift the Stark Law landscape, and require material and substantial restructuring of transactions developed under existing Stark rules. While these proposed changes may be adopted as early as October of 2007, it is important to recognize that proposals of this kind often linger for years and then are modified substantially upon adoption. Still, in an effort to keep abreast of the latest CMS thinking regarding the Stark Law, these proposed changes also are discussed briefly below.

## 2. Phase III Regulations

### Standing in the Shoes

From its adoption, CMS has struggled to apply the Stark Law to physicians whose relationships with the provider of the designated health services ("DHS"), are through an intervening professional entity. In Phase I of the final regulations implementing the Stark Law, among other things, CMS looked to the ability of the physician to control referrals from the entity. This subjective standard was replaced in the Phase II regulations by an objective definition of an "indirect compensation relationship" and a related exception. The definition excluded from covered compensation relationships any relationship

between a professional entity that employs or contracts with a physician, and the DHS provider to which the physician refers (unless the professional entity's compensation to the physician is based on referrals to the DHS provider, a very uncommon occurrence). This exclusion created a loophole that allowed compensation relationships through professional entities that would violate the Stark Law if conducted directly with the physician.

In the Phase III regulations, CMS recognizes the problem and has tried to fix it by deeming a physician and his or her physician organization ("PO") the same for purposes of Stark Law compliance.[1] Thus, the relationship between the referring physician and the PO is ignored in the above-noted example, and the relationship between the PO and the DHS provider that gets referrals from the PO is scrutinized as if the PO were the referring physician.

The indirect compensation definition and exception continue to apply as otherwise set forth in the Phase II regulations, and may apply even in the case of POs, but only after ignoring the relationship between the PO and the physician. The indirect compensation definition and exception apply: (i) in all other intermediary entity circumstances, and (ii) when the PO and the DHS provider do not directly contract, but instead rely on an intermediary entity such as an IPA. (Based upon the definition of a PO, it does not appear that an IPA or an institution that employs physicians, such as a hospital or medical school, would be deemed to be a PO.) In other words, in the structure involving a physician, a PO, an IPA, and a hospital, CMS will determine if the physician's compensation from the IPA through the PO is based on referrals of the DHS. If not, the relationship will be excluded from the Stark Law prohibition.

In sum, under the Phase III regulations, if the relationship between a physician and a DHS provider is through an intermediary PO, the relationship between the DHS provider and the physician is considered a direct relationship. Nevertheless, all other relationships remain subject to the indirect compensation definition and exception. In order to avoid prejudicing physicians deemed to have direct compensation arrangements through a disregarded intermediary PO, the Phase III regulations provide that the PO also is ignored when applying the exceptions under the Stark Law. In this way, symmetry exists between the treatment of the relationship under both the definition and the exception.

The "stand in the shoes" rule does not apply to the original term or an existing renewal term of an arrangement that met the pre-existing requirements for the indirect compensation exception.

## Rentals and Personal Service Arrangements

Historically, the Stark Law exceptions pertaining to rentals of office space (42 C.F.R. §411.357(a)), equipment (42 C.F.R. §411.357(b)), and personal service arrangements (42 C.F.R. §411.357(d)), prohibited parties to such arrangements from amending their agreements during the initial year. Moreover, if the parties terminated the agreement during the first year, they were precluded from entering into a "new" or materially amended agreement during the remainder of the original term. In the Phase III regulations, however, CMS expressly reverses this interpretation. "Parties may amend a lease agreement multiple times during or after the first year of its term, provided that the rental charges are not changed and all other requirements of the exception are satisfied." (72 Fed. Reg. 51044).[2] CMS recognizes the problems that could ensue, however, and notes that the amended agreement must still comply with "fair market value and 'volume and value of referrals' requirements" (72 Fed. Reg. 51044). In this way, while parties are free to amend the agreements to better carry out the purposes of the agreement, the parties are precluded from doing so in such a way that provides economic advantage to the referring party. It is important to keep in mind that notwithstanding this change in the regulations that implement the Stark Law, there have been no corresponding changes in the related safe harbors in the Anti-Kickback statute. Accordingly, any such amendments may cause a space or equipment rental agreement or a personal services agreement to fall outside the parameters of the applicable safe harbors, and care must be taken to assure that remuneration is not provided as a *quid pro quo* for referrals.

## Physician Recruitment

In the Phase III regulations, CMS makes several amendments to the exception pertaining to physician recruitment (42 C.F.R. §411.357(e)) (the "Recruitment Exception"). The Recruitment Exception relates to remuneration directly or indirectly provided by a hospital to a physician in order to induce the physician to relocate to the hospital's geographic area and become a member of the hospital's medical staff. The following sets forth notable changes to the Recruitment Exception:

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1 "Physician organization" is newly defined in the Phase III regulations as "a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements" for a group practice, as such term is further defined in the regulations. 42 C.F.R. §411.351. It is not clear if a faculty practice that is operated as part of an institution, such as a hospital or a medical school, meets the definition of a "physician practice."

2 CMS extended its analysis to personal service arrangements in the preamble of the Phase III regulations (72 Fed. Reg. .)

**Rural Health Clinics**

CMS extends the Recruitment Exception to include rural health clinics.

**"Geographic Area Served by the Hospital"**

In the Phase II regulations, CMS defined the "geographic area served by the hospital" to which the physician may be recruited to work as the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. For those hospitals drawing less than 75 percent of its inpatients from all of the contiguous zip codes, CMS now clarifies in the Phase III regulations that the hospital's geographic area may include all contiguous zip codes from which the hospital draws up to 75 percent of its inpatients. It also permits hospitals to ignore zip codes (such as parks or commercial districts) from which it does not draw patients. In addition, rural hospitals may take advantage of an alternative test, whereby the "geographic area served by the hospital" will be deemed to encompass the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. Rural hospitals may include noncontiguous zip codes if the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients.

**Income Guarantee**

CMS notes in the Phase III regulations that any type of income guarantee, including gross income, net income, or revenues, made by a hospital to a recruited physician involves a potential cost to the guarantor hospital and a benefit to the physician. For such guarantees given to a practice the recruited physician is joining, the costs allocated by the physician practice to the recruited physician may not exceed the actual additional incremental costs attributable to the recruited physician.

The Phase III regulations offer a more generous income guarantee under certain circumstances. In the case of a physician recruited to join a physician practice located in a rural area or HPSA to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, then the actual costs or a per capita allocation of costs (not to exceed 20%) may be guaranteed.

**Practice Restrictions**

CMS allows group practices to which a DHS provider (such as a hospital) offers support for the recruitment of a needed physician to impose certain practice restrictions that do not unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital. CMS commentary in the preamble to the Phase III regulations indicates that the following restrictions are permissible:

i) Restrictions on moonlighting;

ii) Prohibitions on soliciting patients and/or employees of the physician practice;

iii) Requiring the recruited physician to treat Medicaid and indigent patients;

iv) Requiring a recruited physician to not use confidential or proprietary information of the physician practice;

v) Requiring the recruited physician to repay losses of his or her practice that are absorbed by the physician practice in excess of any hospital recruitment payments; and

vi) Requiring the recruited physician to pay a predetermined amount of reasonable damages (that is, liquidated damages) if the physician leaves the physician practice and remains in the community.

Importantly, CMS also clarifies that reasonable non-compete provisions that comply with state law are not prohibited. In total, these changes make the recruitment exception much more appealing to groups.

**Recruiting by Rural Hospitals**

Rural hospitals may now recruit physicians to an area outside of the hospital's geographic area if it is determined through a CMS advisory opinion that the area has a demonstrated need for the recruited physician.

**Relocation Requirement**

A physician is required to relocate his or her medical practice in order to qualify for the recruitment exception. In the Phase III regulations, CMS clarifies that a physician must relocate his or her practice from outside the geographic service area to a location inside the service area. Additionally, the physician must either: (i) move his or her medical practice at least 25 miles; or (ii) have a new medical practice that derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the

physician at his or her prior medical practice site during the preceding three years, as measured on an annual basis.

CMS also creates several exemptions from the relocation requirement. Recognizing that some physicians do not have an established private medical practice that feasibly can be relocated, CMS exempts a physician who, for the 2 years immediately prior to the recruitment arrangement, was employed on a full-time basis by a Federal or State bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Department of Veteran Affairs, or facilities of the Indian Health Service. This exemption also requires that the physician did not maintain a separate private practice in addition to such full-time employment. There is also an exemption if a CMS advisory opinion determines that a recruited physician does not have an established medical practice comprised of a significant number of patients who are, or could become, patients of the recruiting hospitals.

**Recruiting Costs**

In the preamble to the Phase III regulations, CMS identifies certain recruiting costs that qualify as recruiting expenses. These recruiting costs include the actual costs of headhunter fees; air fare, hotel, meals, and other costs associated with visits by the recruited physician and his or her family to the relevant geographic area; moving expenses; telephone calls; and tail malpractice insurance covering the physician's prior practice.

## Physician Retention Payments

In the Phase III regulations, CMS has expanded the exception pertaining to physician retention payments (42 C.F.R. §411.357(f)). Specifically, the exception has been expanded to (i) permit retention payments even in the absence of a written recruitment offer; (ii) add flexibility for retention payments to physicians who serve underserved areas even by hospitals that are not in such an area; and (iii) permit rural health clinics to make retention payments.

**No Written Offer Required**

Further flexibility is provided in the Phase III regulations by permitting retention payments when a physician does not have a written offer of employment elsewhere. However, in lieu thereof, the physician must certify in writing to the entity proposing to make the retention payment (the "Retaining Entity"): (i) that he/she has a *bona fide* opportunity for future employment by a hospital, academic medical center, or PO that would require relocation of his/her medical practice at least 25 miles to a location outside the geographic area served by the Retaining Entity; (ii) details regarding steps he/she has taken to effectuate the employment opportunity; (iii) details of the employment opportunity, including the identity and location of the future employer and/or employment location, and his/her anticipated income and benefits; (iv) that the future employer is not related to the Retaining Entity; (v) the date on which he/she anticipates relocating his/her practice; and (vi) information sufficient for the Retaining Entity to verify the information included in the certification. The Retaining Entity must make a reasonable effort to verify the information.

When a physician provides such a certification rather than a *bona fide* written employment or recruitment offer, the retention payment must be the lower of (i) an amount equal to 25% of the physician's current annual income averaged over the previous 24 months using a reasonable and consistent methodology that is calculated uniformly or (ii) the reasonable costs of recruiting a new physician to join the medical staff.

When the physician has a *bona fide* written offer, the Retaining Entity may pay the lower of (i) the difference between the offer and current compensation or (ii) the reasonable costs of recruiting a new physician to the medical staff, each also for not more than 24 months.

The Phase III regulations also provide greater flexibility in that a *bona fide* written recruitment or employment offer, or an offer certified by the physician, may come from not only another hospital, but also may come from an academic medical center or a PO that is not related to the Retaining Entity.

**Underserved Areas**

As noted above, the Phase III regulations clarified lingering questions regarding whether the Retaining Entity must be located in an area of demonstrated need, or whether the physician's patients must live in the underserved area. The exception has been expanded explicitly to permit retention payments that otherwise satisfy all conditions of the exception when (i) the physician's current medical practice is located in a rural area, a HPSA, or an area of demonstrated need as determined by HHS in an advisory opinion, or (ii) at least 75% of the physician's patients reside in a medically underserved area or are members of a medically underserved population. The Phase III regulations no longer require that the Retaining Entity be located in a HPSA. Such retention payments may be made to a physician whose practice is located in a HPSA regardless of whether the HPSA has been designated for physicians in his/her specialty.

**Rural Health Clinic**

The Phase III regulations permit retention payments to be made by rural health clinics under the same terms and conditions that apply to hospitals and FQHCs in order to retain the physician's practice in a rural or underserved area.

## Fair Market Value Compensation Exception

**("FMVC Exception")**

The Phase III regulations include both a substantive and clarifying change to the FMVC Exception under 42 C.F.R. §411.357(l). The FMVC Exception originally protected compensation *from* a DHS entity *to* physicians and physician groups provided that the arrangement (a) was in a signed writing which set out the items, services and timeframe for the arrangement; (b) specified the compensation in advance (to be consistent with fair market value); (c) was commercially reasonable in furthering the legitimate business purposes of the parties; and (d) did not violate anti-kickback statutes or promote arrangements in violation of Federal and State law. The Phase III regulations substantively expand the FMVC Exception to provide that it also applies to compensation provided *to* a DHS entity *from* a physician. Though this expansion of the FMVC Exception may present providers with additional opportunities for structuring agreements, it furthers CMS's intent to restrict use of the more flexible "payments by physician" exception to only those instances "not specifically addressed by another exception."

The Phase III regulations also expressly state that it is *not applicable* to leases for office space, as CMS views such use as providing an increased risk of program and patient abuse (and reflects its aversion to "time-share" arrangements). Thus, under the new rule a space lease can only qualify if it complies with the "rental of office space" exception under §411.357(a). The Phase III regulations also explicitly exclude recruitment incentives from the protection of the FMVC Exception stating that such incentives must be structured to satisfy the requirements of the "recruitment" exception discussed above or another exception, such as that for "*bona fide* employment relationships."

## Academic Medical Centers ("AMC") Exception

The Phase III regulations include two major clarifications to the AMC exception under 42 C.F.R. §411.355(e), and illustrate CMS's intent to apply it only in supplementing the other applicable exceptions. First, CMS clarifies that the *aggregate* compensation from each AMC to a faculty physician must be set in advance and include the "compensation received from *all components* of the center." Physician compensation is not to be derived only from the component with which the physician has an employment relationship, but instead compensation must be based on the total of all components which cannot exceed fair market value for the services provided. The total compensation must be set in advance and not be determined in a manner that takes into account the volume or value of referrals from the referring physician within the AMC.

Second, in determining whether the majority of physicians on the medical staff of a hospital affiliated with an AMC consist of faculty members, "the affiliated hospital must include or exclude all physicians holding the same class of privileges at the affiliated hospital." For example, in a determination regarding physicians holding courtesy privileges, the new rule states that the affiliated hospital may choose to exclude courtesy physicians. However, in this determination the hospital must then exclude all individual physicians on staff who have the same class of privileges. Categorizing physicians by class becomes important in determining whether the majority of physicians on staff at the AMC are faculty members and consequently, whether those faculty members order the majority of admissions showing the requisite degree of integration of the hospital into the AMC.

Before conducting an analysis of whether a particular arrangement falls under the AMC exception, it is useful to first determine whether an indirect compensation arrangement exists between the referring physician and the AMC. In the absence of an indirect compensation arrangement, the Stark Law would not apply to the arrangement.

## Inadvertent Non-Compliance

The Phase III regulations provide a number of limited protections for inadvertent non-compliance. Leases and personal services arrangements may be extended on a holdover basis for a period of six months after the expiration of the agreement (as long as the terms do not change). The regulations also add a safe harbor for modest (up to 50% above the $300 allowance, plus inflation) non-monetary compensation violations, if the "excess benefit" is returned to the DHS provider by the later of year-end or 180 days after the excess payment was made, and if the exception is used not more than once every three years. Ironically, the existence of this "safe harbor" is actually indicative of the exacting nature of CMS' views on Stark Law compliance. There is virtually no margin for error in implementing this highly technical regulation.

## Miscellaneous Revisions

**Non-Monetary Compensation**

The Phase III regulations allow an annual medical staff appreciation amount in addition to the permitted $300 plus inflation payment.

**Charitable Contributions**

In the preamble to the Phase III regulations, CMS emphasizes that charitable contributions cannot be tied to or based on the value or volume of referrals to a DHS provider.

**CME for Compliance Training**

CMS has clarified that compliance training may be within the exception even if the attendees are awarded CME credit.

**Bona Fide Employment**

CMS has made clear that it is the actual manner in which a person works that determines their W-2 status, and their W-2 status that governs whether they are an employee or contractor. CMS warns against using titles and status (such as W-2 employee) that do not reflect the true nature of the relationship.

**Rural Intra-Family Referrals**

This exception now provides two different methods for measuring distance that would trigger applicability: the original distance basis of 25 miles and the new time of travel basis of 45 minutes.

**Implants in ASC**

CMS clarifies that only the ASC can bill for implants that are incidental to the ASC service, and not the surgeon or other affiliated entity.

**Professional Courtesy**

The exception no longer requires disclosure to the insurance company where a co-payment requirement is being waived. (This may, however, continue to be required as a matter of state law.)

**Incidental Services**

A hospital may give its medical staff pagers, but they cannot link the physician to his or her private patients except when the patient or the physician is in the hospital. This seems unnecessarily difficult to manage.

## Definitions

In Phase III, certain changes of the definitions in the Stark Law (42 C.F.R. §411.351) have significant implications. Some change the reach of the Stark Law and some clarify its interpretation.

**"Fair Market Value"**

In Phase II, CMS created a "safe harbor" within the definition of "fair market value" for payments to physicians for personal services based on certain hourly rates. The safe harbor provided that hourly rates that were less than or equal to either (i) the average of the 50th percentile national compensation level for physicians in the same specialty based on four of six surveys specified in the interim final rule, or (ii) the average hourly rate for emergency room physician services in the relevant market, would be considered fair market value without further scrutiny. In Phase III, CMS eliminates this safe harbor, citing the impracticability of the approved methodologies.

The elimination of the safe harbor, however, does not mean that providers should not refer to salary surveys in evaluating fair market value. In fact, the preamble expressly notes that providers may continue to refer to "multiple, objective, independently published salary surveys" in evaluating fair market value. The preamble also provides support for accounting for geographic differences in compensation levels in determining pay. Whereas the salary survey safe harbors in the Phase II definition of fair market value both looked to national compensation levels, CMS comments in the preamble to the Phase III regulations that "[u]ltimately, the appropriate method for determining fair market value for purposes of the physician self-referral law will depend on the nature of the transaction, its location, and other factors" (emphasis added). CMS notes that fair market value must take into account the nature of the task (e.g., medical or administrative), not the title of the person performing the task.

**"Physician in the Group Practice"**

The Phase II definition of "physician in the group practice" provided that an independent contractor physician could qualify as a "physician in the group practice" if he or she furnished services to patients of the group practice pursuant to "a contractual arrangement with the group practice to provide services to the group practice's patients in the group

practice's facilities." The contract also would have to meet requirements relating to restrictions on compensation and assignment.

In the Phase III regulations, CMS alters the definition to clarify that an independent contractor will not be considered a "physician in the group practice" unless the group practice contracts directly with the independent contractor. Thus, if a group practice contracts with a third party for the services of an independent contractor, the independent contractor will not be "a physician in the group practice."

This change is significant because the two key Stark Law exceptions relating to referrals within a group practice – the physician services exception and the in-office ancillary services exception – do not permit referrals to independent contractors or permit independent contractors to provide or supervise DHS unless they are "physicians in the group practice." Thus, the Phase III regulations effectively prohibit group practices from contracting with third parties (such as staffing companies or hospitals) for the services of independent contractor physicians. Similarly, as noted in the preamble, a leased employee cannot qualify as a "physician in the group practice" under the Phase III regulations since the group practice would not be contracting directly with the leased employee but rather with the lessor.

If the "stand in the shoes" rule applies in this context – and there is nothing to suggest otherwise – an agreement with a PO would be deemed a direct relationship with the physician. However, CMS has not explicitly so stated, so it may be useful to seek further guidance on the issue.

**"'Incident to' Services"**

The Stark Law allows group practices to pay physicians profit shares based on the profits of the group and/or productivity bonuses based on services personally performed by the physician and services "incident to" those personally performed services. Neither profit shares nor bonuses can be determined in a manner directly related to the volume or value of referrals.

The Phase III regulations revise the definition of "incident to" services to include supplies, such as outpatient prescription drugs, and allow a physician in a group practice to be paid a bonus based on personally performed services and services incident thereto. Under the Phase II regulations, the definition only covered services. As under the Phase II regulations, the Phase III regulations provide that services and supplies that qualify as "incident to" services must be furnished while the physician is in the office suite and immediately available, and exclude separately billable services.

Finally, CMS has clarified that "incident to" services may not be used directly as a factor in allocating profits of the group.

**"Referrals"**

In the Phase II regulations, CMS excluded from the definition of "referral" requests by a radiation oncologist for radiation therapy if (i) the request results from a consultation initiated by another physician; and (ii) the tests or services are furnished by or under the supervision of the radiation oncologist, or under the supervision of a radiation oncologist in the same group practice as the radiation oncologist. (In the 2006 physician fee schedule, this exclusion was expanded to include ancillary services necessary for, and integral to, the provision of radiation therapy.)

The Phase III regulations do not alter this provision. However, in the preamble, CMS states that it reads the provision literally to allow a radiation oncologist in the consulting radiation oncologist's group practice to supervise radiation therapy under the exclusion but not to perform it.

### Physician Security Interests in Hospital Equipment

The Stark Law regulations, 42 C.F.R. §411.354, define the financial arrangements that implicate the Stark Law restrictions on referrals. The Phase III regulations add a provision (42 C.F.R. §411.354(3)(v)) stating that where a physician sells equipment to a hospital and the hospital finances the purchase through a loan from the physician that is secured by an interest in the equipment, the security interest is not an ownership or investment interest. Instead, the security interest is deemed a compensation arrangement.

It appears that CMS made the revision relating to physician security interests in hospital equipment to resolve apparent confusion caused by conflicting statements in the Phase II regulations as to whether such an arrangement was an ownership interest. The conflicting statements caused doubt about whether such a transaction could be structured under the "isolated financial transactions" exception which only applies to compensation arrangements. The revision clarifies that such transactions may be structured under the exception.

## 3. Changes to the Stark Rules Proposed in The 2008 Physician Fee Schedule

In addition to the foregoing final regulations, there are a number of other very significant provisions that have been proposed by CMS, subject to comment. While these proposed changes, set forth by CMS in the 2008 Physician Fee Schedule (72 Fed. Reg. 38122), may be adopted as early as October of 2007, proposals of this kind often linger for years and are then substantially modified upon adoption.

The proposed changes would extend the purchased diagnostic test rule: (a) to the purchase of the professional component, and (b) to any test performed by "an outside supplier" which is defined as "someone other than a full-time employee of the billing physician or medical group." (72 Fed. Reg. 38225). Thus, under the proposals, in order to bill for a diagnostic test, a full-time employee of the physician or group would need to supervise the test. Otherwise, payment would be limited to the unit charge to the physician or the medical group by the "supplier" (e.g., any non-employee). It does not appear that a Stark Law and Anti-Kickback Law-compliant personal services arrangement would be exempted from application of the rule, nor is it clear how the net charge per test would be established if an independent contractor is paid on a fixed hourly basis as opposed to per a unit basis.

In addition, the proposed regulations provide that the DHS entity subject to the Stark Law would include either the entity that presents or causes a claim to be presented, or the person or entity that has performed the DHS. The latter deals with the circumstance where the entity performing the DHS pursuant to an agreement with the billing entity has a financial relationship with the referring physician.

The proposed regulations also would modify the special rule that allows payments to be deemed "set in advance" if the aggregate compensation is based on time or units of service, or a specific formula (generally including a percentage payment for professional services, see below) that is not modified or changed based on the value or volume of referrals during the term. However, CMS now would clarify that percentage-based compensation is not considered "set in advance" except when based on revenue directly resulting from personally performed physician services. CMS also would modify the rule to prohibit per unit of service rental charges where the unit reflects services provided to patients referred by the lessor to the lessee.

Finally, CMS proposes to make clear that whenever payment for DHS is denied on the basis that the service was furnished pursuant to a prohibited referral, the burden would be on the entity submitting the claim for payment to establish that the service was not so furnished.

These proposed changes, if adopted, would make dramatic changes to existing arrangements that were developed in accordance with existing rules, including shared space, and other arrangements with independent contractors who oversee DHS services (whether the contractor is affiliated directly or indirectly with the group). Taken together, it is fair to say that they would reflect the greatest change in the application of the Stark Law since the statute's adoption more than a decade ago.

## 4. Conclusion

In the Phase III regulations, CMS has acted in a pragmatic fashion, generally making this complex law more settled, practical, and meaningful. We applaud this effort, but, unfortunately, existing transactions will need to be reviewed for compliance (and in many cases restructured prior to any renewal). The CMS Stark Law proposals embedded in the 2008 Physician Fee Schedule, however, suggest that new transactions may require application of yet another body of new and evolving rules. If adopted, these new proposal would require health care providers to cope with yet another blunt shift in CMS's oversight of the tortuous Stark Law.

Finally, while providers have lived with the Stark Law for many years, CMS enforcement has been minimal. This soon may change. On September 14, 2007, CMS announced that it proposes to collect comprehensive information about hospital ownership and compensation arrangements from 500 hospitals, using a new form called a "Disclosure of Financial Relationships Report" (72 Fed. Reg. 52568), and that CMS will use the information to determine hospital compliance with the Stark Law and its regulations. CMS has solicited comments on its proposed information collection activity, indicating that a final version is not yet in place. However, the development clearly signals that, in a break with past practice, CMS soon will devote more intensive efforts to assessing Stark law compliance, and presumably penalizing at least some providers that run afoul of this enormously complex regulatory scheme.

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