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Health Law Alert

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The Stark II Phase II Interim Final Rule

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I. OVERVIEW

On March 26, 2004, the Department of Health and Human Services ("HHS"), through the Centers for Medicare and Medicaid Services ("CMS"), issued an Interim Final Rule (69 FR 16054), further implementing the physician self referral, or Stark Law, found at 42 U.S.C. § 1395nn. The Stark Law prohibits a physician from making referrals for the furnishing of certain "designated health services" ("DHS") for which payment may be made under the Medicare or Medicaid programs, if the physician or a member of a physician's immediate family has a financial relationship with a health care entity, unless an exception applies.

The Preamble informs that the Interim Final Rule is Phase II ("Phase II Rule") of a "bifurcated" final rulemaking process. Proposed regulations were first published in 1998 (63 FR 1659). Phase I regulations were published in 2001 (66 FR 856) and, with two exceptions, became effective on January 4, 2003.[1] Although CMS intended to address referrals for Medicaid-covered services in this rulemaking, it has almost completely postponed Medicaid issues until a later date.[2]

In promulgating the Phase II Rule, CMS articulates its goal of attempting to "reduce the burden and prescriptive nature of the rule while applying the statute and maintaining the integrity of the regulatory framework." Indeed, while remaining true to the Stark Law's requirements, the approach of CMS in promulgating the Phase II Rule is refreshing and helpful. In contrast to CMS' regulatory approach to interpreting the Stark Law in 1998, the Phase II Rule establishes broader, more realistic exceptions, while narrowing the Stark Law's coverage. Where "bright line" standards assist in articulating excepted relationships, such standards are often established; in instances where more flexibility in interpretation or definition would be helpful, CMS has demonstrated a willingness to adjust its approach in that direction. In the end, while physician ownership in designated health service entities remains largely impermissible, virtually every physician compensation arrangement with a DHS entity will be protected if the compensation involved is fair market value, and does not vary based on the volume or value of referrals.

A. Important Modifications to Existing Exceptions

In addition to the establishment of important new exceptions, Phase II provides mostly helpful revisions to a number of existing exceptions and criteria relating to them. Importantly, the rule serves to standardize — to the extent permitted by the statute — the criteria applicable to "core" physician compensation arrangement exceptions (e.g., the employment, personal services, academic medical center, and fair market value exceptions), by refining key definitions relating to these exceptions, including the "fair market value," "set in

1 Regulations pertaining to home health services became effective on April 6, 2001, and the effective date of the final sentence of § 411.354(d)(1), relating to the definition of "set in advance" has been delayed four times.

2 This rulemaking does, however, amend the pre-paid plans exception at § 411.355(c) to include Medicaid managed care plans.

advance," and "volume or value of referrals" terminology. In addition, important modifications were undertaken relating to the following:

Compensation Arrangement Exceptions

- Physician recruitment
- Indirect compensation arrangements
- Rental of office space and equipment
- Medicaid managed care relationships
- Risk-sharing arrangements
- Non-monetary compensation and incidental benefits
- Isolated transactions

General Exceptions

- Academic medical centers
- Group practice / in-office ancillary services

Ownership / Investment Interest Exceptions

- Publicly-traded securities
- Rural providers
- Specialty hospital ownership moratorium.

B. New Exceptions

The Phase II Rule also establishes a series of new exceptions related to:

- Professional courtesy
- Retention payments for physicians in underserved areas
- Community-wide health information systems
- Intra-family rural referrals
- Charitable donations by physicians to DHS entities
- Certain arrangements involving temporary non-compliance

C. Important Interpretations of Key Definitions and Concepts

In crafting a Rule intended to expand opportunities to avoid Stark Law violations and narrow the statute's coverage, CMS also adjusted its interpretations of a number of concepts essential to the Law's exceptions. Revisions in interpretation and/or definition were made to the following key definitions:

- referral / consultation
- "set in advance" compensation
- fair market value
- volume or value of referrals
- hospital services

D. Technical Changes to DHS Definitions

No new DHS has been added to those covered by the Stark Law, nor has any DHS category been deleted. CMS has clarified further the coverage of DHS in general, and made specific technical changes in a number of DHS categories.

E. Relaxation of Reporting Requirements

The Phase II Rule provides significant relief with respect to the reporting requirements initially set forth in the Stark Law. CMS has determined that annual or periodic reporting of Stark-related information by DHS entities would, in effect, be a costly waste of time. Relieving this burden on both itself and DHS entities, CMS has decided to impose

no formal reporting obligation. Indeed, DHS entities will simply be required to maintain records in accordance with other applicable laws and normal business practices, and provide relevant documents to CMS or the OIG upon request.

F. Left Undone: Non-Risk Based Medicaid Referrals

CMS continues to grapple with how — or whether — the Stark Law will cover the dwindling number of non-risk based Medicaid referrals. The agency has once again deferred this issue, instead expanding applicable risk-based exceptions to cover Medicaid risk-based programs.

II. ANALYSIS OF KEY COMPONENTS OF THE PHASE II RULE

A. Important Modifications to Existing Exceptions

1. Compensation Arrangement Exceptions

a. Unification of Criteria Related to "Core" Physician Compensation Arrangements

The Stark Law provides varying criteria for meeting the statutory exceptions for "core" physician compensation arrangements based on the status of the physician, i.e. whether the physician is a DHS entity employee or independent contractor, involved in a group practice, part of an academic medical center, etc. CMS itself has advanced these incongruities through oral interpretation.

In the Phase II Rule, however, responding to commentary questioning the rationality of these various criteria, CMS has sought to "equalize" the requirements for these core physician compensation exceptions. In doing so, CMS points out the "statutory preference" conferred upon group practices, and concludes that the advantages available to group practice physicians cannot, by rule, be provided to others. As regards physicians involved in the other "core" physician compensation arrangements exceptions, however — employment, personal services, fair market value, and academic medical centers — all physicians can now be paid:

- a percentage of revenues or collections for services personally performed
- productivity bonuses for services personally

performed
- based upon participation in a duly-constituted "physician incentive plan."

With regard to physicians practicing in group practices, additional compensation flexibility remains. Group practice members:

- can share in-office ancillary service revenues, or profits of the group based in part on DHS revenues, provided the allocation method is not based "directly" on individual physician referrals.
- can enjoy productivity bonuses not only for services personally performed but for "incident to" services as well.
- need not be compensated at "fair market value" nor have their compensation "set in advance" (**note**: employed physicians are also not required to meet the "set in advance" requirement).

We address below how the "core compensation" exceptions related to employment and personal services arrangement have been modified in the Phase II Rule to accommodate these interests by unifying criteria and in other ways. Thereafter, other key modifications to existing exceptions are addressed.

b. Employment Relationships

Although on its face the employment exception to the Stark rules regarding compensation arrangements technically remains unchanged, the Phase II Rule offers new interpretations in applying this exception. Specifically, CMS declined to adopt a controversial provision of the 1998 proposed rule which would have excluded from the exception productivity bonuses based on a physician's own referrals of DHS, even when personally performed. The proposed rule would have also added a restriction on compensation related to "other business generated" between the physician and the DHS entity. Both of these proposed changes were dropped from the Phase II Rule's version of the exception.

In addition, CMS has adopted a definition of "employee" that tracks the common law definition in the statute. CMS specifically declined to adopt a definition that would incorporate state law definitions of employment. Finally, CMS has endorsed certain specific payment methods as permissible under the exception. These include compensation based on a flat fee for each mid-level provider supervised by the employed physician and payments based on quality measures (so long as, in each case, such compensation represents fair market value and does not take into account referrals).

c. Personal Service Arrangements

In the Phase II Rule, CMS has modified the personal service arrangements exception in an attempt to ease compliance with the exception's requirements. While further modification would have been helpful, the revised exception represents a step in the right direction.

Most importantly, a significant amendment has been made to the regulatory definition of "fair market value" set forth in 42 C.F.R. § 411.351 as it pertains to personal service arrangements. Specifically, CMS has created two alternative "safe harbor" methodologies that may be used to calculate hourly payments for physician's personal services (*i.e.*, services performed by the physician personally, and not by employees, contractors, etc.), which calculations will result in compensation levels "deemed" to be fair market value.

Under the first methodology, fair market value is satisfied if the hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market. The flaw in

this approach appears to simply be the difficulties inherent in obtaining these data, as well as the risks in relying on the compensation levels of competitors in establishing payment rates.

As an alternative, fair market value is also deemed to exist if the hourly rate is determined by averaging the 50th percentile national compensation level for physicians within the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in at least four of the six surveys specifically identified in the regulation, and dividing by 2,000 hours. The regulation identifies the six survey sources as: Sullivan, Cotter & Associates, Inc; the Hay Group; Hospital and Healthcare Compensation Services; Medical Group Management Association; ECS Watson Wyatt; and William M. Mercer.

CMS emphasizes that compliance with these "safe harbor" methodologies is "entirely voluntary" and that entities may continue to establish fair market value through other methods. Practically speaking, however, one can assume that these methodologies quickly may become the standard in the industry for hourly rate calculations. As a result, providers should familiarize themselves now with one or both alternatives.

In other modifications, as with the office space and equipment lease exceptions (discussed *supra*), the personal service arrangements exception now explicitly permits termination with or without cause during the first year of the agreement. In order to qualify for this exception, however, the parties may not enter into the same (or substantially the same) arrangement during the first year of the original term of the arrangement being terminated.

CMS has also attempted to ease the "separate arrangements" approach first proposed in 1998. Under the Phase II Rule, a physician (or family members) may have multiple arrangements with an entity so long as either (a) the arrangements incorporate each other by reference, or (b) each arrangement cross-references a master list of contracts that is maintained and updated centrally and is available for review by the Secretary of HHS upon request. This master list is expected to identify historical as well as current agreements between the parties. There can be several master lists that are cross-referenced, or the DHS entity may even rely upon "annual or other regular financial statements (such as quarterly statements) that clearly show the parties, dates, payments, and purposes of payments separate for each personal service contract" so long as such statements are appropriately cross-referenced in the agreement. Thus, while the new revisions should ease some burdens of contract drafting, maintaining a master list will require consistent and careful administrative attention.

CMS also indicates in Phase II Rule comments, that it has reconsidered its interpretation that items and equipment cannot be included in an arrangement under the personal service arrangements exception. CMS notes, however, that it will separate services and equipment contained in a single arrangement for purposes of determining fair market value.

The Phase II Rule also clarifies that a physician or family member need not personally perform the services for which the entity has contracted. Rather, such services may be "furnished" through employees, through a wholly owned entity, or through *locum tenens* physicians. Notably, the exception does not apply to a situation in which a physician (or family member) has hired an independent contractor to perform the services for which the physician (or family member) has contracted.

d. Physician Recruitment

The Phase II Rule substantially modifies the physician recruitment exception in several respects, all of which are likely to be embraced by providers. Key modifications include the new focus of the exception on the relocation of the physician's medical practice rather than the physician's residence. As modified, a physician is deemed to have "relocated" his or her medical practice if the site of the practice is moved at least 25 miles, or at least 75% of the physician's revenues from services provided to patients (including inpatients) are derived from services provided to "new" patients (patients not seen by the physician in his or her previous practice for at least three years). For the initial "start up" year of the physician's relocated practice, the revenue test is "whether it is 'reasonable to expect' that the recruited physician will meet the 75% test."

Another important modification in the Phase II Rule allows for the recruitment of residents and physicians who have been in practice for less than one year, even if the physician or resident does not relocate. In CMS's view, these physicians do not have an established practice to relocate. The recruited physician must establish his or her practice in the hospital' s geographic area to be eligible for recruitment payments under the exception.

The Phase II Rule also ends the debate over whether the recruitment exception, or any other exception, protects payments made by a hospital to a group practice (or to a physician) when the recruited physician joins a group practice upon relocation. Indeed, the Preamble reflects CMS's recognition that there are legitimate reasons why recruited physicians prefer to join existing practices. Payments to group practices are now explicitly protected under the Phase II Rule, provided certain criteria are met. Specifically a) the agreement must be set forth in writing and signed by all parties; b) remuneration must be passed directly through to the recruited physician (except for actual costs incurred by the practice in recruiting the new physician); c) in the case of an income guarantee, the costs allocated by the practice to the recruited physician cannot exceed the actual incremental costs to the practice attributable to the physician; d) the physician must be allowed to establish staff privileges at any other hospital and, finally, e) the physician practice receiving the hospital payments may not impose additional practice restrictions on the physician (i.e., a non-compete agreement) beyond those related to quality considerations.

Finally, the Phase II rule expands the recruitment exception to cover federally qualified health centers ("FQHCs") that recruit physicians to join their medical staffs. This extension was granted in an effort to ensure that the statute "does not impede efforts by FQHCs, which provide substantial services to underserved populations, to recruit adequate staff." CMS refused to grant similar extensions to other DHS providers such as home health agencies and nursing homes, citing concerns that recruitment arrangements at such facilities could pose a risk of abuse. (*See also*, discussion of the new "Retention" exception at Section II.B.2. below).

e. Indirect Compensation Arrangements

In the Phase I Rule, CMS recognized that under the terms of the Stark Law, indirect compensation arrangements could implicate the statute's coverage. In order to address this issue at that time, CMS both defined what comprised an "indirect compensation arrangement" and established an exception for such relationships. Significant confusion resulted from what appeared to be CMS' creation of an unnecessarily complex process for first identifying and then excepting these indirect relationships. Some commenters suggested to CMS that such arrangements could simply be analyzed under existing available exceptions, e.g. if one of the

relationships in a chain met an exception, no further analysis was necessary. In the Phase II Rule, however, CMS has held its ground on the analytical need to both establish the indirect compensation arrangement definition and an analog exception. CMS expressed concern that parties might attempt to shield a compensation arrangement that was ultimately improper via an intermediary relationship that was excepted. The Phase II Rule does, however, provide some additional clarification as to how these arrangements are defined and excepted.

It is axiomatic that resort to the indirect compensation exception is required only in the event that an indirect compensation arrangement exists in the first place. Such a relationship occurs only if:

- there is an unbroken chain of financial relationships between the DHS entity and the referring physician (through ownership/investment interest or compensation arrangement);
- the aggregate compensation received by the referring physician varies based on the volume or value of referrals; and
- the DHS entity has actual knowledge of that relationship (or acts with deliberate ignorance or reckless disregard of its existence).

Importantly, the Phase II Rule makes clear that the DHS entity has no duty to inquire as to the presence of such a relationship. Thus, in arrangements with group practices, for example, DHS entities must determine whether or not to inquire beyond the direct compensation relationship as to how that group practice intends to split its revenues among its physicians. Whether a contractual representation/warranty should be sought that the group practice will not allocate compensation to its owner/employee physicians based on the volume or value of referrals is unclear. In any event, there is no requirement under the indirect compensation arrangement definition, that any inquiries be made on this point.

Assuming the existence of an indirect compensation arrangement, the exception presents a rather easy out: even if the aggregate compensation varies based on the volume or value of referrals, if the compensation paid to the referring physician is "fair market value" for the items or services provided (and, of course, assuming the relationship between the physician and the entity/person in the chain is set out in writing, is signed by the parties, specifies the services covered, and does not violate the anti-kickback statute or any billing/claims regulations), the indirect compensation arrangement will be excepted.

The most likely instance where the indirect arrangement/exception would arise would be in a situation where an equipment leasing entity, owned by a physician in a position to refer for the service involved, enters into a "per click" or "per use" lease equipment arrangement with a DHS entity. Payments to the leasing entity — and presumably, indirectly to its physician owner — would be based in part on the volume or value of referrals. Provided that the "per click" lease payment was set at "fair market value," the indirect compensation arrangement would be easily excepted.

f. Rental of Space and Equipment

CMS has made several significant — and helpful — changes to the office space and equipment exceptions to the Stark Law. First, CMS has clarified that a lease agreement for office space or equipment may be terminated with or without cause during the first year of the agreement, provided that the parties do not enter into a new agreement during the first year of the original term of the agreement. Thus, whether a potential Stark violation arises no

longer hinges on whether the "for cause" termination provision of a lease agreement has been properly exercised.

Second, both exceptions now allow for a month-to-month holdover period of up to six months so long as the lease continues on the same terms and has otherwise satisfied the exception. In other words, the technical expiration of a written, one year lease while the relationship continues will no longer immediately present a potential Stark violation. Third, CMS has clarified that "any kind" of *bona fide* lease arrangement that "in form and substance satisfies the regulatory conditions" is eligible for the office space and equipment rental exceptions.

CMS has also modified the "exclusive use" criterion to allow for subleases in most cases. "The exclusive use test will be considered met as long as the lessee (or sublessee) does not share the rented space or equipment with the lessor during the time it is rented or used by the lessee (or sublessee)." As a word of caution, however, CMS notes that "[a] subleasing arrangement may create a separate indirect compensation arrangement between the lessor and the sublessee that would need to be evaluated under the indirect compensation rules."

Finally, CMS has reiterated that "per click" rental arrangements are permitted so long as payments represent fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician. Fair market value, for purposes of a lease, continues to be defined as the value of the rental asset for general commercial purposes. The Phase II Rule further allows that declining "per click" payments are acceptable as volume increases, giving recognition to the fact that costs are likely to decrease in these arrangements over time and with increased usage.

g. Isolated Transactions

The isolated transaction exception is modified in the Phase II Rule in two significant respects. First, the definition of "isolated transaction" is modified to permit installment payments. In order to qualify for the exception, the total aggregate payment must be set before the first payment is made and must not take into account the volume or value of referrals or other business generated between the parties. In addition, the isolated transaction exception now requires that the outstanding balance be "guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to assure payment" in the event of a default by the obligated party. This last requirement was added to address CMS' concern that many installment transactions provide continuing incentives to refer. A DHS entity's need to resort to costly litigation to collect outstanding balances is, in CMS' view, insufficient protection against the continuing pressure to refer.

The second important change to this exception relates to the regulation's prior prohibition on entering into additional transactions within six (6) months of the isolated transaction, unless otherwise excepted under other Stark provisions. The Phase II Rule relaxes this restriction and allows for post-closing adjustments that are commercially reasonable and not dependant on referrals, if such adjustments are made within six (6) months of a purchase or sale transaction. With these two key modifications, the isolated transaction exception is likely to be more widely utilized.

h. Services Furnished by Managed Care Organizations to Enrollees

This exception covers services provided by a managed care organization ("MCOs") to its enrollees, either by employed or contracted health care providers. Covered MCOs will now include Medicaid prepaid inpatient health plans, prepaid ambulance health plans, health insuring

organizations and demonstration project plans. This change, long anticipated, offers Medicaid managed care organizations and their providers a protection that had already been in place for Medicare managed care companies and federally qualified HMOs. It is important to note that the contract between a Medicaid managed care organization and a participating physician could still constitute a financial relationship, so that any referrals of other Medicare or Medicaid patients (other than the excepted categories of managed care enrollees) to the MCO itself for DHS could be restricted if another exception is not available for this relationship.

i. Risk-Sharing Arrangements

CMS has confirmed that the Phase I rule's exception for risk-sharing arrangements is intended to be broad, and to cover all risk-sharing compensation arrangements, even if the physician's compensation arrangement is with an entity — even a hospital — downstream of any type of health plan, insurance company or HMO.

j. Non-Monetary Compensation and Incidental Benefits to Medical Staff

Under the Phase II Rule, the $300 limit on annual non-monetary compensation and the $25 limit on incidental benefits provided by a hospital to its medical staff will now be indexed for inflation. Additionally, changes have been made to clarify that hospitals are permitted to provide equipment, such as pagers, listings in hospital medical staff directories, and computers to be used solely for use in connection with hospital services. (Technology could also be provided for broader use as well under the new community-wide health information system exception, *see* Section II.B.4. below.)

The Phase II Rule also drops a requirement that excepted incidental benefits offered by hospitals to physicians must be of a type offered at other local hospitals or comparable hospitals in comparable regions. In addition, the Phase II Rule expands the scope of the incidental benefits exception and permits any facility with a *bona fide* medical staff to qualify for the exception, not just hospitals.

k. Compliance Training

The exception for compliance training has been expanded to cover all compliance training by any DHS entity to a physician or a physician's office staff. CME training would not qualify for this exception.

l. Special Rules on Compensation

The Phase I Rule set forth a number of special rules regarding physician compensation. Among these rules is the provision that allows physician compensation to be conditioned on the physician's referrals to a particular provider, practitioner or supplier, provided certain safeguards are in place (compensation is set in advance, consistent with fair market value, the arrangement is in writing and patient preference and best interests override the requirement to refer). In response to comments from providers expressing frustration over the competitive advantage this special rule bestowed upon integrated health system entities, CMS narrowed the scope of this rule in Phase II. Section 411.354(d)(4) now applies only to employment, managed care and other contractual arrangements that include required referrals, only to the extent those referrals relate to physician services called for under the arrangement, and the referral requirement is "reasonably necessary to effectuate the legitimate purposes of the compensation relationship."

2. Modifications to General Exceptions

a. Academic Medical Centers

Academic medical centers fared well under the Phase II Rule. The amended regulation liberalizes

aspects of the existing exception for academic medical centers. For example, hospitals or health systems that sponsor four or more approved medical education programs may now qualify as "academic medical centers," even if they do not include an accredited medical school. In addition, a referring physician can now qualify under the exception if he or she is on the faculty of an affiliated medical school or at an educational program of the accredited academic hospital.

The requirement that the referring physician be a *bona fide* employee of a component of the academic medical center is retained. The Phase II Rule clarifies that a physician who spends 20 percent of his or her professional time or 8 hours per week providing clinical teaching or academic services will satisfy the exception's requirement that the referring physician provide "substantial" academic or clinical teaching services.

With regard to faculty practice plans, according to the Phase II Rule, a majority of a medical center's medical staff physicians must be on the faculty, but they are no longer required to make a majority of their admissions to the academic medical center in order to qualify for the exception. Faculty from an affiliated medical school can also be counted in meeting the exception's requirements. Residents and non-physician professionals need not be counted.

The amended Phase II Rule removes any requirement that the faculty practice plan be tax exempt or organized in any particular manner. There can also be more than one faculty practice plan associated with a single medical center, and the plan could be affiliated with the teaching hospital, the medical school, or an accredited academic hospital.

Fair market compensation can now be determined by reference either to other academic medical centers or comparable private practice physicians. Finally, written documentation of a permitted financial relationship may be in separate writings, and could include routine financial reports showing intra-corporate transfers.

b. Group Practice Definition/In-Office Ancillary Services Exception

Group practices continue to enjoy the opportunity to share in-office ancillary service revenues. The Phase II Rule has, however, clarified the group practice definition in certain respects. In addition, while not disturbing the "supervisory" and "billing" requirements of the in-office ancillary services exception, CMS has responded to the demand for greater specificity and simplicity in the "same building" requirement by providing three specific methods for meeting the requirement.

The "Group Practice" Definition

Qualifying first as a "group practice" permits the group to utilize the in-office ancillary services exception. While no major changes were made to this definition as set forth in Phase I, the Phase II Rule offers the following:

- while group practices must continue to operate as a "unified business" the requirement that a group practice carry out "centralized utilization review" has been deleted.
- group practice physicians' profit share or productivity bonus hours may be based directly on services personally performed or on "incident to" services.
- in order to qualify as a group practice, the "primary purpose" rule now applies to its current operations, not its original purpose. Hospitals may own a group practice that meets the definition, but a hospital could not qualify its medical staff as a group practice.
- group practices will have a 12-month grace period to comply with the requirement that

at least 75% of the practice's services (a) be performed by group members, (b) be billed through the group, and (c) revenues be treated as revenues of the group when a physician is relocated to the practice (as defined in the physician recruitment exception), provided all other elements of the definition are met.

- independent contractors remain excluded from the definition of group "member," but qualify as physicians of the group for purposes of providing necessary supervision.

The In-Office Ancillary Services Exception.

Assuming a group practice exists, revenues from in-office ancillary services may be shared by the group's physicians. The exception requires, however, that (a) the ancillary services be performed by the referring physician (or other individual supervised by the referring physician) or a physician member of the group, (b) the services be billed by the physician performing or supervising the service, the group practice or a subsidiary thereof, or an entity wholly owned by the supervising or referring physician, and (c) the services must either be performed in the "same building" as the group providing physician services unrelated to the designated health service or in a "centralized building" dedicated solely to the provision of designated health services and wholly controlled by the group practice.

CMS responded in Phase II to requests that the "same building" criteria be clarified. In so doing, three specific alternatives have been established by which this requirement may be met:

- the services may be located in a building in which the referring physician or his/her group practice has an office open to patients at least 35 hours a week, and the referring physician or group practice regularly provides Medicare and Medicaid services to patients at least 30 hours a week (the "group-centric" test).
- the patient receiving the DHS service typically receives physician services in the same building, the referring physician or group practice occupies space in the building for the provision of patient services 8 hours a week and regularly provides 6 hours a week of services. The patient goes to that building to receive non-DHS services (the "patient-centric" test).
- The services are provided when the referring physician is present, the DHS is ordered in connection with a patient visit, and the 8 hour/6 hour requirements are met. The services provided during the 6 hours include physician services that are not DHS related, even though the services may lead to the furnishing of the DHS (the "specialist-centric" test).

The Phase II Rule also eliminated the requirement that the provision of the DHS not be the "primary purpose" of the patient's contact with the referring physician.

3. Modification to Ownership/ Investment Interest Exceptions

a. Publicly-Traded Securities

CMS has amended the "publicly-traded securities" exception to the referral prohibition on ownership or investment interests. Specifically, CMS has clarified that the exception applies if the securities purchased are generally available on the open market "at the time the DHS referral was made." This is helpful to providers because it means that "securities acquired by a referring physician or his or her family member prior to a public offering will fit within the exception if they are available to the public at the time of any [DHS] referral." Also helpful is CMS' reiteration of the view that it will not consider stock options received as compensation as ownership or investment interests until the time they are exercised.

b. Rural Providers

The Phase II Rule includes an exception to the referral prohibition based on ownership or investment interests for investment in a "rural provider." This exception represents an expansion of the existing exception for investment in rural laboratories and generally tracks the language in the 1998 proposed rule. The exception defines "rural provider" as "an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area…." A "rural area" is, in turn, defined as an area that is not an "urban area" as defined under the inpatient hospital PPS regulations (42 C.F.R. § 412.62(f)(1)(ii)).

Given this definition, the utility of this exception is unfortunately limited. For example, as noted in the Comments, it would seem to prevent ownership or investment in rural providers who are part of larger State-wide or regional health care systems. CMS indicated that it declined to adopt this approach so as not to create "a loophole into which virtually any provider could fit." For further discussion of changes impacting rural providers, *see* Section II.B.5. below for a summary of the new exception for intra-family rural area referrals.

c. Moratorium on Specialty Hospital Ownership

One key component of the Phase II Rule is its incorporation of the specialty hospital ownership and investment moratorium which was recently adopted by Congress as part of the Medicare Modernization Act ("MMA") (*see* 42 U.S.C. § 1395nn(d)(2) (as amended)). As a result, for an 18-month period beginning on December 8, 2003, there is no exception available for physician investments in specialty hospitals, including cardiology, surgery, and orthopedic hospitals.

B. New Exceptions

CMS demonstrated its willingness to consider the comments filed in response to Phase I and established additional compensation exceptions to cover specific narrow relationships. In CMS' view, new exceptions may be established only where there is no risk (as opposed to little risk) of abuse. Of particular note is CMS' establishment of the "temporary non-compliance" exception, long sought by the health care industry. As is the case with the other new exceptions, however, this exception is extremely narrowly drawn, and gives rise to the implication that any and all other instances of "temporary noncompliance" not covered by the exception will trigger a Stark violation.

1. Professional Courtesy

This new exception provides that an entity does not create a financial relationship when discounted health care items or services of a type that are routinely provided by the entity are offered as a professional courtesy to a physician, or a physician's immediate family member or office staff.

The entity must make the same offer to all physicians on the entity's *bona fide* medical staff without regard to the volume or value of referrals or other business generated between the parties. The entity's governing body must approve a written professional courtesy policy in advance of the provision of the courtesy. The entity may not extend the professional courtesy to a physician who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need. Moreover, the entity must assure that the applicable third-party payer is informed of any professional courtesy that involves the reduction of the recipient's co-insurance obligation.

2. Retention Payments for Physicians in Underserved Areas

This exception further demonstrates CMS' efforts to provide carve outs to the Stark Law's coverage in underserved and/or rural areas. The exception provides that a hospital or federally qualified health center does not create a financial relationship when it enters into a signed written agreement with a physician on its medical staff in order to retain the physician's medical practice in the HPSA or an area with demonstrated need (as determined by the Secretary based upon an advisory opinion) that is served by the entity, if the physician has a *bona fide* recruitment offer from an unrelated entity that would require the physician to relocate his or her practice at least 25 miles, to a location outside of the entity's service area. Neither the arrangement itself nor any remuneration may be conditioned on the referral of patients or any other business generated between the parties. The retention arrangement may not restrict the physician from obtaining staff privileges at, or making referrals to, other hospitals (unless the restriction complies with another available exception). The retention payment must be limited in amount as set forth in the Phase II Rule formula for calculating the payment amount based on the physicians' current and potential income if the recruitment offer were accepted. Further, the retention arrangement must match any obligations and restrictions on repayment or forgiveness of indebtedness contained in the *bona fide* recruitment offer. The entity may not enter into a retention arrangement with the same physician more than once every 5 years.

3. Certain Arrangements in Temporary Noncompliance

A new exception has been established for situations when a financial relationship between a DHS entity and a referring physician that fully complied with an exception for at least 180 days immediately preceding noncompliance, and became noncompliant for reasons beyond the control of the entity, provided the entity promptly seeks to rectify the noncompliance. The entity may bring the relationship into compliance or unwind it (and should structure arrangements such that unwinding is feasible in the event of noncompliance).

The DHS entity may bill for DHS referrals from the party to the relationship only for the period of time it takes the entity to rectify the noncompliance, which cannot exceed 90 days following the initial date of noncompliance. This exception may be used with respect to a referring physician only once every 3 years. The exception does not apply to noncompliance with exceptions for non-monetary compensation or medical staff incidental benefits.

4. Establishment of Community-Wide Health Information Systems

The Phase II Rule establishes an exception for entities that provide items or services of information technology to a physician, which items or services allow access to, and sharing of, electronic health care records and drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners. The items or services must be available as necessary to enable the physician to participate in a community-wide health information system, must be principally used by the physician as part of the community-wide health information system, and may not be provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician. The community-wide health information system(s) must be available to all providers, practitioners, and residents of the community who desire to participate.

5. Intra-Family Rural Referrals

Under this new exception, an entity may bill for services provided pursuant to a referral from a physician to the physician's immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if the patient resides in a rural area (an area that is not an urban area as defined in 42 C.F.R. § 412.62(f)(1)(ii)) and if no other provider is available within 25 miles of the patient's residence to furnish the services in a timely manner. The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS within (but not beyond) 25 miles from the patient's residence. The exception also applies without regard to whether other providers are located within 25 miles of the patient's residence if services are furnished to patients where they reside and cannot otherwise be provided in a timely manner.

6. Charitable Donations by Physicians to DHS Entities

Bona fide charitable donations made by a physician (or immediate family member) to a tax-exempt DHS entity do not create a financial relationship with the entity if the entity does not solicit the donation and the donation is not made in a way that takes into account the volume or value of referrals or other business generated between the physician and the entity.

C. Important Interpretations of Key Definitions and Concepts

A number of key definitions and interpretations permeate CMS' articulation of covered and excepted relationships. In the Phase II Rules, CMS has largely interpreted these key terms in ways that expand the coverage of the Stark Law's exceptions, thereby narrowing the applicability of the Law itself. As a general rule, most physician ownership/investment interests in DHS entities remain covered by the law while virtually any compensation arrangement, based on fair market value and which is not based on the volume or value of referrals will be excepted. Adjustments in the interpretations of the following terms demonstrate CMS' efforts to achieve its goal of narrowing the Stark Law's applicability.

1. Referral

While Phase II makes no major changes to the definition of "referral," it does clarify some issues. The rulemaking clarifies that no referrals occur when a physician personally performs a service, regardless of whether the physician bills the program directly or another entity bills under assignment from the physician. However, technical components associated with services personally performed by a physician in a hospital are referrals to which the Law applies. As regards the services that are performed "incident to" a physician's personally performed services, or those that are performed by other licensed professionals employed by the physician, CMS states that it will not stray from its initial determination that such "incident to" services are referrals within the meaning of the Act. Many such services, however, will fall within the in-office ancillary services exception.

2. Consultation

The Stark Law created a narrow exception to the definition of "referral" for certain services provided or ordered by particular specialists in accordance with a "consultation" requested by another physician. This exception applies to pathologists requesting clinical laboratory or pathological examination services; radiologists requesting diagnostic radiology services; and radiation oncologists requesting radiation therapy. To qualify for the exception, services must be furnished by, or under the supervision of the pathologist, radiologist, or radiation oncologist in accordance with a consultation.

The Phase II Rule makes various clarifications and modifications with respect to consultations. First, CMS clarifies that the level of supervision required for radiological and other procedures is that "otherwise required by the applicable Medicare payment and coverage rules for the specific service." CMS also makes clear that the necessary supervision may be provided by a physician in the same group practice as the consulting physician. In addition, the exception for radiation oncologists who, in turn, request radiation therapy services, is modified to protect services that are "integral and necessary" to the provision of radiation therapy, such as CT scans, MRI, and ultrasound.

Finally, in response to various comments, CMS draws a distinction between situations where ordering and interpreting a procedure is the physician's primary specialty, such as where a radiologist orders a diagnostic radiology test, and situations where a service is "ancillary" to the physician's primary medical practice, such as where a cardiologist performs an echocardiogram. CMS finds that the former example is acceptable under the statutory exception for consultations while the latter is not.

3. Fair Market Value

The definition of the term "fair market value" is amended in the Phase II Rule to address hourly payments made to physicians. The new definition "deems" certain hourly payments for services personally performed by a physician, to be at fair market value if they are established using one of two prescribed methodologies. The first methodology relies upon the average hourly rate for emergency room services in the "relevant physician market" to determine fair market value, while the second utilizes a formula based upon physician compensation data set forth in national surveys. For additional discussion of the modifications to the "fair market value" definition, refer to Section II.A.1.c. above.

4. Volume or Value of Referrals

As a general rule, compensation may not take into account the volume or value of referrals. In the context of unit-based or time-based arrangements, i.e. "per click" leases, which CMS sanctioned in Phase I of the Stark II regulations, aggregate compensation in most cases will vary based upon the volume or value of referrals. Under the Phase II Rule, such compensation will be deemed not to take into account the volume or value of referrals if the unit fee or per click payment is at fair market value at the inception of the agreement, and does not change during the term of the agreement.

In the Phase I regulations, CMS also determined that the volume or value standard would not be implicated by an otherwise acceptable compensation arrangement for the sole reason that the arrangement required the physician to refer to a particular provider as a condition of payment. (S*ee* § 411.354(d)(4)). In response to comments that this exception competitively disadvantaged certain providers, CMS in Phase II narrowed the applicability of the exception. Section 411.354(d)(4) now applies only to employment,

managed care and other contractual arrangements that include required referrals, only to the extent those referrals relate to physician services called for under the arrangement, and the referral requirement is "reasonably necessary to effectuate the legitimate purposes of the compensation relationship."

5. Set in Advance

Independent contractor physicians are provided some relief in the Phase II Rule through CMS' modification to its interpretation of the term "set in advance." Prior interpretations of the term prohibited percentage compensation payments. Commenters noted that the set in advance requirement is not present in the group practice definition or employment exception, while it does appear in the personal services and fair market value exceptions – exceptions frequently relied upon when structuring independent contractor arrangements with DHS entities. The Phase II Rule clarifies that CMS now permits certain percentage compensation arrangements provided that the compensation methodology is set in advance and does not change over the course of the arrangement in a manner that reflects the volume or value of referrals or other business generated by the referring physician.

D. Changes To DHS Definitions

No new designated health services or regulatory exceptions for DHS were added by the Phase II Rule. CMS did reiterate, and carry out, its intention to draw bright line definitions of the various DHS categories, by defining these services with reference to specific CPT an HCPCS codes. Sources for these code-based definitions include the CMS website, the physician fee schedule final rule, and the Phase II Rule Appendix.

CMS also makes clear in Phase II that the DHS definitions include both the physician service and technical service components. The physician services may, of course, fall into a relevant exception, for example, the physician services exception. Following is a summary of the technical changes to various DHS categories:

1. Physical Therapy Services

The Phase II rule removed the following CPT codes from the list of "physical therapy services":

- CPT code 94762 (measure blood oxygen)
- CPT code 92505 (speech/hearing evaluation)
- CPT code 92510 (rehab for ear implant)
- CPT code 92601 (cochlear implant f/up exam <7)
- CPT code 92602 (reprogram cochlear implant <7)
- CPT code 92603 (cochlear implant f/up exam 7>)
- CPT code 92604 (reprogram cochlear implant 7>)

The Phase II rule added the following CPT codes to the list of "physical therapy services":

- CPT code 97601 (removal of devitalized tissue from wound without anesthesia)
- CPT code 97602 (non-selective debridement)

2. Occupational Therapy Services

No changes.

3. Radiology and Certain Other Imaging Services

CMS clarified that the only services that constitute "radiology and certain other imaging services" are those identified by the CPT and HCPCS codes. Services that are specifically excluded from the

definition of "radiology and certain other imaging services" are listed below:

- Diagnostic nuclear medicine procedures;
- Radiology procedures integral to the performance of, and performed during a nonradiological medical procedure;
- Radiology services performed immediately after a procedure in order to confirm the placement of an item during the procedure; and
- X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe.

The Phase II Rule also expands the consultation exception in the definition of "referral" to permit supervision of the service by another physician in the same radiology group, so long as the request is initiated by another physician and the other criteria of the exception are met.

4. Radiation Therapy Services and Supplies

"Radiation therapy services and supplies" are exclusively identified by the CPT and HCPCS code lists. The regulatory definition of "radiation therapy services and supplies" was unchanged by the Phase II rulemaking. CMS continues to exclude nuclear medicine procedures from this definition.

5. Durable Medical Equipment (DME) and Supplies

No changes.

6. Parenteral and Enteral Nutrients, Equipment and Supplies

No changes.

7. Prosthetics, Orthotics, and Prosthetic Devices and Supplies

No changes.

8. Home Health Services

No changes.

9. Outpatient Prescription Drugs

The Phase I Rule defined "outpatient prescription drugs" as those covered under Medicare Part B. In the Phase II Rule, CMS seeks comments on how to redefine "outpatient prescription drugs" in light of the definition of "covered Part D drug" under the MMA.

10. Inpatient and Outpatient Hospital Services

In the Phase I Rule, CMS declined to treat lithotripsy differently than other inpatient or outpatient hospital services, noting that Congress did not intend for CMS to make service-by-service decisions on whether a service is a DHS based on the service's potential for over-utilization. In Phase II, CMS again declined to change the regulatory definition, but conceded that, based on legislative history, lithotripsy is not an "inpatient or outpatient hospital service" for purposes of section 1877 of the Act. CMS emphasized that a contractual arrangement regarding lithotripsy, such as rental arrangement, would create a financial relationship.

E. Reporting Requirements

The Stark Law requires entities (except those furnishing 20 or fewer covered services annually) to "report information concerning their financial relationships with physicians," such as the services furnished and the nature of the financial relationships. Since enacted, however, CMS has not implemented the specific statutory reporting requirements, and no reporting has been required. CMS has struggled with the practicalities of adhering to the statutory requirements, while not imposing unduly heavy reporting burdens on either itself or the health care industry. The Phase II Rule resolves this tension. The Rule concludes that "information" need not be reported annually or on any periodic basis. Rather, entities must supply relevant information as required by law and make such information available "upon request." Entities will be given at least 30 days from the date of the request to respond. Failure to submit information upon request may result in a civil money penalty of up to $10,000 per day. This clarification will come as a relief to providers, and perhaps to CMS as well.

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