Health Law Alert

January 31, 2001

PHASE I FINAL RULE ISSUED UNDER STARK

Introduction

On January 4, 2001, HCFA published the long-awaited final rule for implementing that portion of the Ethics in Patient Referrals Act (the "Stark Law" or "Law") relating to those ten (10) designated health services ("DHS") added to the Law's coverage in 1995. 66 Fed. Reg. 856 ("Final Rule"). As envisioned by HCFA, the Final Rule was developed to:

- establish "bright line" standards to aid physicians and health care providers achieve compliance with the Stark Law
- avoid micro-managing the medical care business by providing more organizational flexibility, and prohibiting only those compensation and referral relationships that clearly violate the Law's statutory terms and Congress' intent
- connect Stark Law definitions with payment rules and supervisory requirements set forth in Medicare billing policies to definitions utilized in the Stark Law
- avoid interfering with the medical needs of federal health care beneficiaries.

We believe that HCFA has for the most part achieved these goals. The Final Rule does:

- narrow and clarify HCFA's interpretation of the Law's prohibitions
- provide more flexible approaches for meeting the Law's existing exceptions and
- add helpful additional new exceptions for avoiding a Stark violation.

In addition, the Final Rule properly provides protection for health care entities who file claims that would otherwise be illegal, where the entity did not know or could not reasonably have known the referral source, or that the referring physician had an impermissible indirect financial relationship with that entity.

On the other hand, we believe HCFA has inartfully crafted other important portions of the Rule to make them almost indecipherable. Most notably, HCFA's approach to creating a new exception for certain "indirect compensation arrangements" is difficult to comprehend, much less apply. In any event, on balance, the Final Rule offers new opportunities – and challenges – for physicians, providers, and health plans.

I. STATUTORY AND REGULATORY CONTEXT OF THE FINAL RULE

A. Legislative Highlights

The Omnibus Budget Reconciliation Act of 1989 added Section 1877 to the Social Security Act. This law prohibited a physician from referring a patient to an entity for clinical laboratory services, for which Medicare might otherwise pay, if the physician (or an immediate family member) had a "financial relationship" with the entity.[1] A "financial relationship" was defined as one existing through either an "ownership/investment interest" or through a "compensation arrangement" with the entity.

The statute provided certain exceptions to this prohibition; some exceptions applied to both "ownership/investment interests" and "compensation arrangements"; other exceptions applied to one or the other type of financial relationship. Sanctions and reporting obligations were also included in the law, which was eventually codified at 42 U.S.C. § 1395nn, and became effective January 1, 1992. ("Stark I")

The Omnibus Budget and Reconciliation Act of 1993 significantly modified Stark I by expanding the Law's referral prohibitions to ten (10) new designated health services.[2] The 1993 amendments to the Law also changed several statutory exceptions, and added new exceptions. These amendments ("Stark II") became effective on January 1, 1995. (Stark I and Stark II will be referred to hereafter as the "Stark Law.")

B. Relevant Regulatory History

On August 14, 1995, HCFA issued a "final rule with comment period" intended to implement Stark I and those components of Stark II relating to clinical laboratory services. 60 Fed. Reg. 41914. These "Stark I regulations" (set forth at 42 CFR § 411.350 et seq.) while technically relevant only to clinical laboratories, remain instructive as to how HCFA would interpret the Stark Law with respect to all "designated health service" relationships.

On January 8, 1998, HCFA published a proposed rule intended to formally interpret and implement the Stark Law as regards those designated health service relationships not covered by the Stark I regulations. 63 Fed. Reg. 1659 ("Proposed Rule"). This Proposed Rule added numerous new definitions and revised others, provided additional detailed HCFA interpretations of the Law's coverage and proposed the addition of several new regulatory exceptions.

HCFA received almost 13,000 public comments to the Proposed Rule. Many commenters expressed concern regarding the Proposed Rule's perceived inappropriate and unnecessary impact on numerous benign business relationships. Among the complaints received were that the Proposed Rule:

- unnecessarily intruded into the organization and delivery of medical care within physician office settings
- ran counter to (or was inconsistent with) other long-standing Medicare policies on payment coverage and clinical care
- failed to provide "bright line" guidance which, given the "strict liability" standard in the Law, left those unclear as to the

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[1] In addition to prohibiting the referral, the statute also prohibited the entity providing the clinical laboratory services from presenting a Medicare claim or bill for services provided as a result of a prohibited referral, and required that any such payment be refunded.

[2] The ten additional "designated health services" included: (1) physical therapy services, (2) occupational therapy services, (3) certain radiology services, (4) radiation therapy services and supplies, (5) durable medical equipment and supplies, (6) parenteral and enteral nutrients, equipment, and supplies, (7) prosthetics, orthotics, and prosthetic devices and supplies, (8) home health services, (9) outpatient prescription drugs and (10) inpatient and outpatient hospital services.

Law's strictures exposed to serious consequences for innocent acts

- was administratively impractical and costly for health care providers seeking to achieve compliance. 66 Fed. Reg. 860.

Now, some three years later, this Final Rule has been published.

II. CURRENT LEGAL IMPORT OF THE FINAL RULE

In contrast to HCFA's generally commendable efforts to set forth specifics within the Final Rule to clarify "what the law is," in electing to publish a Rule which is "final but not effective," HCFA has raised broader issues as to the overall legal applicability of the Rule itself. Specifically, though published on January 4, 2001 the Final Rule will not be "effective" until January 4, 2002.[3] While this delay was apparently well-intended (HCFA sought to provide some time for businesses to conform to the Rule's requirements), such a delay seems inappropriate under the circumstances.

The Final Rule is not newly-burdensome or proscriptive – it does not in general impose new obligations upon physicians and health care entities. Rather, the Rule: 1) articulates new regulatory interpretations of existing law and 2) provides broadened and new opportunities for excepting relationships from the Law's purview. In this context, a delayed effective date is not helpful, and instead adds murkiness – not clarity – to the current contours of the Stark Law.

[3] The Bush administration has apparently postponed the effective date of the Final Rule, along with all other new regulations published in the Federal Register, but which have not yet taken effect, by 60 days, to provide new appointees an opportunity to review the regulations. (White House Memorandum on Regulatory Review Plan dated January 20, 2001). It is not clear whether this Memorandum will ultimately carry any legal effect.

In light of the delayed effective date of the Final Rule, then, the most reasonable view of how the Stark Law is to be currently applied is as follows:

- the Stark statute of course applies to all physician/designated health service relationships – including all the statute's prohibitions, exceptions, definitions, etc.

- the Stark I regulation (42 CFR § 411.350 et seq.), which technically relates only to clinical laboratory relationships, continues to apply to those relationships

- for relationships involving other DHS entities, HCFA's new interpretations of statutory definitions, as set forth in the Final Rule, may be relied upon as the government's current position as to how the Law is to be applied; parties acting in reliance on these interpretations can do so with assurance that the federal government will view arrangements or activities relying thereon as benign

- relationships which now conform with newly-broadened existing exceptions or newly-established exceptions will also be exposed to an extremely low risk of federal prosecution

- in contrast, qui tam relators seeking to establish a False Claims Act violation through use of the Stark Law will not necessarily be constrained to follow federal enforcement policy, and those entities operating under Corporate Integrity Agreements will force difficult choices in meeting CIA obligations to report "illegal activities."

III. PHASE I AND PHASE II OF A FINAL RULE-MAKING PROCESS

It is also important to place the Final Rule in its proper perspective as involving only Phase I of an intended two-phase final rule-making process. In the

January Phase I publication, HCFA focused its rule-making efforts on three primary targets: 1) the Stark Law's prohibitions (§ 1395nn(a)); 2) those exceptions to the Law that apply to both the ownership/investment interest and compensation arrangement arms of the "financial relationship" definition (§ 1395nn(b)); and 3) those definitions in the Law that relate to these considerations (§ 1395nn(h)) (to be fair, the Final Rule also includes the addition of a number of new "compensation arrangement" exceptions as well).

The Final Rule was published with a 90-day comment period. Thereafter, HCFA intends to publish Phase II of the two-part final-rulemaking "shortly." Phase II will deal with exceptions to the two specific types of "financial relationships," finalize regulatory reporting requirements, and address Medicaid referrals.

There is wide skepticism, however, about this timetable and as to what impact Phase II will have. Most of the important concepts in the Law have been addressed in Phase I; the new "fair market value" and "indirect compensation" exceptions render further tinkering with the compensation arrangement exceptions almost moot; and in any event, the Stark I rule of course remains in place should HCFA simply wish to default back to that rule for matters not addressed in Phase I. Nonetheless, as with its unwillingness to render the Final Rule itself "effective," HCFA's decision to take on some, but not all the final Stark rulemaking at this time injects additional uncertainty into the future status of the Law.

IV. THE FINAL RULE'S EFFECT ON THE SCOPE OF THE STARK LAW'S PROHIBITIONS

Reduced to its very simplest elements, the Stark Law prohibits a physician from "**referring**" a patient to a "**designated health service**" entity if that physician (or a family member) has a "**financial relationship**" with that entity (unless an exception applies). In the Final Rule, HCFA has effectively chosen to limit the Law's applicability through a number of important changes.

A. Important Changes Relating to "Referrals"

1. "Self-Referrals" Are No Longer Covered by the Stark Law

The Final Rule now excludes from the definition of referral the request by a physician for, or ordering of, "any designated health service personally performed or provided by the referring physician. . ." § 411.351. This recognition of the incongruity of a physician "referring" a patient to him or herself will be most welcome by group practices. Heretofore, group practices were unable to directly reward their member physicians for any designated health services "referrals" – even when the "referring" physician provided the services. The Final Rule will carve out the revenues produced by a physician performing those designated health services himself from these concerns.

2. Claims May Be Made for Payment Based on Impermissible Referrals, if the Claiming Entity "Does Not Know" From Whom the Referral Came

The Final Rule acknowledges the practical difficulty health care entities sometimes have in tracking the source of referrals from a physician through a series of intervening parties. To alleviate this burden, the Rule now permits entities to be paid for claims made as a result of otherwise illegal referrals, if the entity "does not know" or "did not act in reckless disregard of" the identity of the physician who made the referral. 42 CFR §411.353(e). While this relief has been billed as an "indirect referral exception," this is a misnomer. An entity may submit a claim for services based on any referrals where the entity does not meet the scienter element described above.

The Rule does make clear that a referral made by a physician's group practice, its members, or its staff may be imputed to a physician if the referral is "di-

rected" by the physician or if the physician otherwise "controls" the referral through his or her influence. This clarification of what constitutes a referral, however, has no bearing on the central point of this exception. Absent "knowledge" or "reason to know" the identity of the referring physician, a claim for payment may be made by the entity receiving the illegal referral – however the referral has occurred.

The availability of this exception raises important questions of how vigilant a hospital or other provider entity needs or ought to be in tracking referral activity. While HCFA suggests that "reasonable inquiries" should be made, this obligation goes well beyond the test of what is required to demonstrate the absence of sufficient scienter under, for example, the False Claims Act. In addition, in this section and others where a "knowledge" element has been added to the Rule, HCFA has demonstrated its willingness to convert a "strict liability" law to one where tougher calls as to the level of scienter must be made. In this instance, a blurring of the Law's "bright lines" has likely occurred.

B. Important Changes Involving "Designated Health Services"

The Final Rule clarifies the definitions of those "designated health services" covered by the Law. Numerous commenters to the Proposed Rule expressed frustration with HCFA's confusing and often inconsistent applications of clinical terminology as they sought to fit the Stark Law's "designated health services" into relevant Medicare payment codes. In response, HCFA reached a practical, "bright line" solution by defining certain designated health services (clinical laboratory, physical therapy, occupational therapy, radiology and other imaging and radiation therapy services) by simple reference to a specific list of CPT and HCFA Common Procedure Coding System (HCPCS) codes appended to the Rule itself. §411.351.

HCFA has also undertaken efforts to focus and narrow the scope of certain other "designated health services" covered by the Law:

- The Rule now excludes from Stark's coverage a) implants used in ambulatory surgical centers, b) preventive screening and immunizations (including mammograms, bone density screenings, PSA testing, and flu vaccines), c) eyeglasses and contact lenses provided after cataract surgery and d) erythropocietin provided by end stage renal disease facilities. §411.355(f) – (i).

- HCFA has also explicitly excluded from Stark Law coverage those designated health services that are included in composite payment rates paid to ambulatory surgery centers or skilled nursing facilities under Part A (but not Part B). §411.351. Note that Part B nursing home services (physical therapy, for example), are <u>not</u> excluded. Thus a physician who holds an ownership or some other financial relationship with a skilled nursing facility will find it difficult to take advantage of the "Part A exception" when referring a patient whom he reasonably anticipates will also require Part B services.

C. Important Changes Involving "Financial Relationships"

1. Clarification of What Constitutes An Ownership/Investment Interest

The Final Rule clarifies that loans or bonds <u>secured</u> by an entity's property creates an "ownership" interest in the entity, §411.354(b)(1), while <u>unsecured</u> loans, etc., comprise a compensation arrangement only (for which a compensation arrangement exception might apply). §411.354(b)(3)(iii). On the other hand, retirement plan interests, stock option arrangements (while the option remains unexcepted), and "under arrangement" contracts have been excluded from the definition of "ownership or investment interest." §411.354(b)(3).

2. Indirect Financial Relationships and the "Knowledge" Element

In several areas, the Final Rule takes steps to eliminate the impact of an unknown "indirect" financial relationship between a physician and a designated health service entity on the ability of entities to claim payment for services. Until the Final Rule's publication, HCFA made no regulatory distinction between "direct" and "indirect" financial relationships for purposes of applying the Law. Acknowledging the potential harshness of such a viewpoint - especially on entities who find it impossible (or cost prohibitive) to trace the flow of remuneration through multiple pass-through levels - HCFA has arrived at a more reasonable approach. For the first time, HCFA has defined "indirect" ownership or investment interests and "indirect" compensation arrangements independently from "direct" financial relationships, and has established new rules for dealing with them.

An "indirect ownership" relationship exists where there is an "unbroken chain" of persons or entities with ownership or investment interests between the entity and the referring physician, and where the DHS entity has actual knowledge of, or acts in reckless disregard of that relationship (although the entity need not know the precise nature of each relationship in the chain). §411.354(b)(5).

An "indirect compensation arrangement" exists when a) between the referring physician and the DHS entity there is an unbroken chain of persons or entities with financial relationships between them, b) the referring physician (or immediate family member) receives aggregate compensation from the person or entity with which he has a direct financial relationship that varies with, or otherwise reflects, the "volume or value of referrals" [4] or "other business generated" by the referring physician to the DHS entity, and c) the DHS entity has actual knowledge or acts in reckless disregard or deliberate ignorance of the existence of the relationship. [5] §411.354(c)(2).

By defining both "indirect" relationships to include a scienter element, HCFA has narrowed the coverage of Stark's "strict liability" law to prohibiting claims only when an entity "knew or should have known" of the indirect financial relationship. This carve-out for unsuspecting entities addresses complaints regarding previous HCFA interpretations of the "strict liability" Stark Law, that is, the virtual impossibility for health care entities to be confident that referrals are not "somehow, somewhere" tainted by an inappropriate physician ownership interest relationship over which it has no control.

As with the new "referral" scienter requirement, this permissive approach raises similar questions as to what "due diligence" is required of a DHS entity in

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4 As will be discussed in more detail below, HCFA's new definition of the "volume or value" prohibition would except "per use" or "per procedure" relationships where the compensation is set at "fair market value" even if the physicians providing the service, equipment, etc., could influence the quantity of services or uses through referrals.

5 If a physician's relationship between him and the entity directly preceding him in the "chain" is an ownership relationship, the "volume or value" analysis is "bumped up" the chain toward the DHS entity to the next compensation arrangement. §411.354(c)(2)(ii).

order to demonstrate it has not "ignored" or "disregarded" the potential that a tainted financial relationship exists somewhere between it and a referring physician. It also turns the notion of a "strict liability" law on its head.

3. The New Indirect Compensation Arrangement Exception

Aside from the "knowledge" carve-out described above, HCFA noted additional concerns relating to indirect compensation relationships in the Final Rule. On the one hand, HCFA sought to assure that the Law reached indirect compensation arrangements that violated the statute's intent. At the same time, HCFA recognized that the current exception framework did not protect "benign" indirect relationships.

For example, HCFA wished to address the type of "indirect compensation arrangement" that arises through a contract between a hospital and a group practice whereby the group practice agreed to furnish emergency room coverage through its physicians (which physicians referred to the hospital). Depending on how it was structured, this relationship could be either benign or violative of the Stark Law. Yet, since the relationship involved only an "indirect" compensation arrangement between the hospital and the physicians, the relationship was not previously covered by an exception. HCFA's solution was to first establish "indirect compensation arrangements" as a unique category of financial relationship (see above), and then to create an indirect compensation arrangement exception in an effort to protect harmless relationships.

Before describing the "indirect compensation arrangement" exception, it should first be pointed out that in order to have an indirect compensation relationship in the first place, the "chain" must involve a series of "financial relationships". Under the statute, a "financial relationship" is defined as one that does not meet an exception. Therefore, if at any point in the "chain" an excepted financial relationship exists, the chain is broken and an "indirect compensation arrangement" no longer exists. See 42 U.S.C. § 1395nn(a)(2)(A) and (B).

HCFA's newly crafted antidote to otherwise prohibited "indirect compensation" arrangements consists of an exception based on three criteria:

- the compensation paid to the referring physician must be fair market value for services and items provided and not take into account the volume or value of referrals
- the compensation arrangement must be set out in writing, and
- the arrangement may not violate the anti-kickback statute or any other law.

Turning to the case of the emergency room coverage contract, the "indirect compensation" analysis evolving from the concepts described above requires ultimate focus on the "direct" compensation arrangement between the hospital and the group (since the physician ownership of the group "bumps" the analysis up the chain). If the hospital-group practice relationship is not based on the "volume or value of referrals" (remembering that under the new definition even "per use" or "per procedure" compensation arrangements could so qualify), then an "indirect compensation arrangement" with the physicians does not exist and the exception is not needed. On the other hand if the arrangement with the group is based on the "volume or value of referrals" an impermissible indirect compensation relationship exists, and the exception, when applied, appears to be of no assistance.

What may be concluded from this analysis is that the indirect compensation exception was intended to cover only indirect compensation relationships that comprise "fair market value", and that do not take into account the "volume or value of referrals" generated. If this was HCFA's intended outcome, the "fair market value" compensation exception appears to present a much simpler approach to achieving the same goal.

V. THE FINAL RULE EXPANDS AND CLARIFIES EXISTING STARK LAW EXCEPTIONS

The Final Rule demonstrates that for the most part HCFA finally "got it" when considering the comments submitted regarding the Proposed Rule. The Final Rule provides helpful new opportunities for physicians, hospitals and other providers, and health plans to fashion financial relationships which meet mutual business interests without stumbling upon a potential Stark violation. HCFA focussed first on offering broader parameters to existing exceptions to the ownership and compensation arrangement prohibitions.

A. HCFA Expanded the Coverage of the "In-Office Ancillary Services" Exception and the "Group Practice" Definition

The "biggest news" concerning the Final Rule is that HCFA has recognized that it need not micro-manage how physician group practices are organized in order to assure enforcement of the statute. After years of stumbling over petty concepts such as what constitutes a "building," how to parse the Law's restrictions when a physician "refers" to himself, etc. HCFA has in this Final Rule presented a simpler, more reasonable framework within which physicians may safely organize a group practice while continuing to benefit from the revenues generated by designated health services provided therein.

1. The "Group Practice" Definition

The definition of "group practice" is of central consideration for many physicians seeking to avoid the Stark Law's prohibitions. Qualifying an organization as a "group practice" permits physicians (or whomever owns the group practice) to take advantage of the Law's "physician services" and "in-office ancillary services" exceptions, which in turn permits the group practice to retain and distribute revenues generated from most designated health service referrals.

Before publication of the Final Rule, HCFA perceived a great potential for mischief within "loosely connected" physician groups, and thus construed the requirements for meeting the "group practice" definition quite strictly. As a result of widespread criticism of this approach, however, HCFA has modified its views considerably. Professing to be no longer interested in micro-managing how physicians organize, HCFA has established a number of significant changes to the "group practice" definition in the Final Rule, including the following:

- the type of arrangements that may qualify as a group practice now include "multi-entity legal structures" and those owned by a single physician group practice; HCFA also has clarified again that group practices may be owned by any party - including health care facilities or other entities. §411.352(a).

- independent physician contractors, which are not included in the statutory definition of group practice "member," are nonetheless now permitted to provide the "physician supervision" necessary for the group to meet the in-office ancillary "supervision" requirements (see below), and may now also be paid a productivity bonus or profit share by the group.

- a group practice will be considered to function as the requisite "unified business," even if its accounting methods allocate compensation to physicians under a cost center or location-based accounting method under certain circumstances.

- "productivity bonuses" paid to physicians in the group may be paid from the group's entire profits derived from DHS payable by Medicare without relating directly to the volume or value of referrals, provided that the division and nature of such revenues meet certain requirements. Physicians may also receive productivity bonuses for the services

they personally provide so long as the bonus does not directly relate to the volume or value of referrals. §411.352(i).

- what constitutes "patient care services" for measuring whether "substantially all" of a group practice physician's services are performed within the group (a statutory definition requirement) has been expanded. §411.352(d).

- the group practice attestation requirement has been dropped.

The "kinder, gentler" HCFA Final Rule even goes so far as to provide specific examples of the types of group practice "productivity bonus" and "profit share" arrangements which will not be considered to be impermissibly "directly" related to the "volume or value of referrals."

2. The "In-Office Ancillary Services" Exception

The in-office ancillary services exception (§411.355(b)) protects revenues earned from most designated health services[6] provided within a group practice, if these services meet certain criteria related to a) the identity of the person furnishing the services, b) the physician supervision involved, c) the location of the service, and d) the identity of the entity submitting the bill. By far the most complicated of these criteria are the "supervision" and "location" criteria. The Final Rule provides clarity – and some additional leeway – for meeting these criteria:

- physician supervision – the nature and extent of supervision involved for any specific services will be governed by Medicare payment and coverage rules – not by potentially-conflicting Stark Law requirements. In addition, as noted above, independent physician contractors (who by definition are not group practice "members") may provide the physician supervision required to meet this criteria under certain circumstances.

- location – the Final Rule now permits physician groups to share a designated health service facility in the same building they also provide "substantial physician services." The Final Rule clarifies that such "same building" health services need not be provided directly in the physician office so long as it is provided in the "same building." (For purposes of the Rule, the "same building" means the same post office address.) The Final Rule also continues to permit group practices (but not solo practitioners) to provide in-office ancillary services at other locations (even in a van or trailer) provided the other "centralized" location is owned or leased on a full time basis by the practice. Left unprotected are shared off-site locations and part-time rental arrangements.

B. The Addition of a "Risk-Sharing" Exception and Modification of the "Pre-Paid Plan Exception"

Another opportunity is provided in HCFA's newly created broad exception for "risk sharing arrangements." A qualifying "risk sharing arrangement" will not be a "financial arrangement" for Stark Law purposes. Such arrangements will, therefore, not provide the basis for a prohibition on referrals between the involved parties for the covered enrollees or other persons. The exception covers risk sharing arrangements between a managed care organization ("MCO") or an independent physicians association ("IPA") and a physician for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback law or any billing or claims submission law.

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6 HCFA has added crutches, walkers, canes and other ambulation aids, as well as blood glucose monitors, to the DME which may qualify for in-office ancillary service protection.

Risk sharing includes but is not limited to withhold, bonus, and risk pool arrangements. Health plans are particular categories of entities that furnish or arrange by agreement with health care providers to furnish health care services to enrollees, or furnish insurance for such services, in return for a premium or a fee.

The covered categories are organizations acting in accordance with a contract with HCFA or a state health care program, such as Medicaid; insurers, HMOs and preferred provider organizations whose premium structures are regulated by state law; employer and union welfare fund plans; and state licensed third party administrators ("TPAs") serving other qualified organizations for a fair market fee. The MCO's or IPA's arrangement with the physician may be direct or via a subcontractor. "Subcontractor" is not specially defined.

The Commentary on the new exception explains that the risk sharing arrangement must be "*bona fide,*" but the Commentary does not explain whether any demonstration of "bona fide" status is intended other than meeting the specific relational requirements listed above.

The new risk sharing exception ameliorates a range of concerns by MCOs and providers about the Stark Law's potential to interfere with traditional and legitimately innovative forms of risk-based contracting. Whereas numerous other exceptions under the Stark Law are premised on compensation not varying on account of the volume or value of referrals between the parties or on the compensation levels being set in advance, this new exception does not contain either of these requirements. There remain some possible ambiguities, such as treatment of contracting activities of TPAs that are not licensed by any state.

Except as indicated, the new exception also does not include a fair market value requirement. The anti-kickback law remains available, though, to deal with abusive practices that might be entitled to Stark Law protection under this new protective umbrella. The Final Rule also confirms the breadth of the separate prepaid health plan exception to the Stark Law's referral prohibition. Adding clarifying language to confirm HCFA's intent, the revised exception permits all referrals for services furnished by certain prepaid health plan entities to their enrollees either directly or through their contractors or subcontractors.

The protected organizations are Medicare + Choice plans; HMOs or competitive medical plans with Medicare risk or cost contracts; Medicare health care prepayment plans; entities paid on a prepaid basis under Medicare demonstration contracts, and federally qualified HMOs. Phase II of the Stark regulation process will expand this list to include various types of Medicaid managed care organizations.

This exception protects referrals for the provision of services to enrollees in the specified programs. However, the financial arrangement for the managed care patients can still be the basis for prohibiting referrals of other patients, such as Medicare or Medicaid fee for service patients, unless another exception is available. The new risk sharing exception described above should help greatly on this score.

The Final Rule also clarifies that if a provider reassigns to a health plan, managed care organization, IPA or physician-hospital organization the provider's right to Medicare payment, this will not be a basis for prohibiting referrals by the physician to the health plan or managed care entity even if the physician has a financial relationship with it. On the other hand, where the managed care entity is itself a provider of designated health services, a Medicare or Medicaid referral to the entity for designated services from a physician with a financial interest in the entity could still be prohibited if the arrangement or referral did not qualify for any exception.

VI. THE FINAL RULE ADDS NEW EXCEPTIONS TO AVOID STARK'S PROHIBITIONS

HCFA has postponed until Phase II of this rulemaking any modifications to the existing list of "compensation arrangement" exceptions (including, e.g., the physician recruitment exception). The Final Rule does, however, provide a number of new "final but not effective" exceptions of significant note. In addition to the "indirect compensation arrangement" exception and "risk-sharing exception" previously addressed, several simple exceptions relating primarily to medical staff relationships have been added:

- an exception for "non-monetary" compensation to physicians of up to $300 (per year) 42 CFR 411.357(k)
- an exception for a hospital's "medical staff incidental benefits" (e.g., meals, parking, etc.) 42 CFR 411.357(m)
- an exception for a hospital's providing "compliance training" to physicians practicing in the hospital's community or service area. 42 CFR 411.357(o).

Of more complexity are two additional exceptions, the academic medical center exception applicable to both ownership/investment interests and compensation arrangements, and the fair market value compensation arrangement exception.

A. The Academic Medical Center Exception

The new "academic medical center" ("AMC") exception was established in response to many public comments that the existing compensation arrangement exceptions for personal services arrangements and employment relationships did not adequately address the complex manner in which AMCs were organized, how referrals flowed through multiple entities within these centers, and how faculty physicians were compensated. An AMC is defined to include organizations consisting of 1) an accredited medical school, 2) an affiliated non-profit faculty practice plan, and 3) a hospital, in which a majority of the medical staff consists of physicians who are faculty members, and where a majority of the admissions are made by these physicians.[7]

Under the exception, AMCs may compensate referring physicians who are "bona fide employees" of a component of the AMC and who provide substantial academic or clinical teaching services, provided the total compensation is set in advance, the aggregate fees do not exceed fair market value, and the compensation paid is not based on the volume or value of referrals or other business generated.

This exception will be helpful to many complex AMC organizations that heretofore could not technically squeeze its faculty physician relationships into a particular exception. However, the "set in advance" requirement would appear to leave unprotected "percentage of compensation" arrangements, which relationships are quite common between medical centers and faculty practice plans.

B. The "Fair Market Value" Exception

HCFA has included a "fair market value" exception to the compensation arrangement prohibitions in the Final Rule. This exception covers virtually any written compensation arrangement for items or services provided by a physician to a DHS entity (but not the reverse), requires that the compensation involved in the arrangement be set in advance, be consistent with fair market value, and not take into account the volume or value of referrals or other business generated by the referring physician.

HCFA's promulgation of this broad exception is of significant import: entities seeking to "except" a physician compensation arrangement will no longer

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[7] The AMC must also comply with other more technical financial and organizational requirements.

need to shoehorn the relationship into the precise criteria set forth in any other particular compensation arrangement exception. Even if another exception could theoretically apply, the fair market value exception is available for use.

In combination with the "indirect compensation arrangement" exception (depending upon how this exception ultimately becomes clarified), the "fair market value" exception provides great opportunities for achieving Stark compliance. Care must still be taken, however, in understanding and properly applying various definitions relating to these exceptions, such as "volume or value of referrals," "set in advance" and "fair market value."

VII. OTHER KEY DEFINITIONAL MODIFICATIONS

A. The "Volume or Value of Referrals"

As noted previously, compensation arrangements which take into account the "volume or value of referrals" usually will not fit within a Stark exception. Such arrangements can serve as an incentive for physicians to maximize referrals based on financial incentives – precisely the evil the Stark Law was intended to eliminate.

In the Proposed Rule, HCFA took the position that even when fair market value compensation was paid to a physician for some other item or service – such as a hospital's rental of physician-owned lithotripsy equipment, if the physician-owner could influence the amount of service generated (and compensation paid) by his or her DHS referrals (such as when a physician's referrals would increase the number of procedures generated by lithotripsy equipment leased on a "per click" basis). This type of lease arrangement would be considered a "volume of referral"-based arrangement, and thus would not fall within any exception.

The Final Rule relaxes this interpretation. Under the Rule, "per procedure" or "per interval" compensation arrangements (including personal service arrangements) will not be deemed to be based on the "volume or value of referrals," provided the arrangement is otherwise "fair market valued" even if the number of procedures, amount of services, etc., is influenced by a physician's referral activity. Of course, the "fair market value" terms on which the arrangement is based may not themselves vary during the course of the agreement in any manner that takes into account the volume or value of referrals.

B. "Set in Advance" Arrangements

In a companion piece to its adjustment of its "volume or value" interpretation, HCFA also expanded on its view of what constitutes an acceptable "set in advance" compensation arrangement. HCFA has clarified in the Final Rule that "set in advance" does not require that the actual aggregate payment amount be set in advance. Instead, in the case of a "per use" or "per service" relationship, the per use rate must be set in advance.

Regrettably, however, HCFA responded negatively to a commenter's inquiry as to whether "percentage of gross revenues, collections, or expenses" arrangements would meet the "set in advance" requirement. HCFA opined that these types of relationships would not. HCFA reasoned that "aggregate amounts" could not be discerned in such relationships, inasmuch as the bases for the percentage compensation involved "fluctuating or indeterminable measures."

Because the term "set in advance" appears in most, but not all, compensation arrangements, parties wishing to utilize "percentage of revenues" and similar arrangements will need to seek out an exception which does not contain the troublesome "set in advance" language. (For example, the new "indirect compensation" exception does not contain this phrase). By recognizing such detailed distinctions, and choosing applicable exceptions wisely, DHS entities/physicians may be able to achieve business

goals under the Final Rule that heretofore had been elusive.

C. "Fair Market Value"

The Final Rule defines fair market value as "the value, in an arm's length transaction consistent with the price that would result from bona fide bargaining between well-informed parties who are not otherwise in a position to generate business with each other." This is not a new concept. The Commentary to the Final Rule does offer direction however as to how to determine whether "fair market value" is present in a commercial relationship.

While emphasizing that any commercially reasonable valuation method may be employed, reliance on comparable transactions in the market place, or appraisals from an independent expert, will typically be satisfactory. To remove the potential that the valuation be based on the "volume or value of referrals," however, HCFA cautions against measuring financial terms against other relationships also involving referring physicians. Similarly, office lease terms may not reflect any additional value for the physician – related to the convenience or proximity of the location to the recipient of that physician's referrals.

CONCLUSION

The January 4, 2001 Stark II Final Rule for the most part offers additional "bright line" opportunities for physicians and designated health service entities to fashion acceptable financial/referral relationships. In some cases however – especially in its handling of "indirect" referral, financial interest, and compensation relationships, the Rule continues to present some difficult interpretative challenges.

Since the Rule is not yet "effective," some minor risks remain in embarking upon efforts to take advantage of the Rule's new opportunities at least until January of 2002. However, the potential benefits attendant to revising existing relationships or establishing newly-excepted relationships to permit the free flow of designated health service referrals and revenues can be extremely significant. All physicians, health care providers, and plans affected by the Stark Law should therefore take this opportunity to evaluate their current financial and referral relationships in light of what new permitted alignments could prove to be most beneficial to their mutual business goals, and to take appropriate steps to create more helpful relationships.

The discussion contained in this Health Law Alert is not intended to provide legal advice. Readers should seek specific legal counsel before taking any action with regard to the matters discussed. For further information related to your own situations and any specific legal questions you may have contact your regular contact at Crowell & Moring or one of the following attorneys:

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