Honigman Miller Schwartz and Cohn's *March 2001*

HEALTH LAW FOCUS

A Periodic Newsletter Published by The Health Care Department of Honigman Miller Schwartz and Cohn

IRS ISSUES TBOR2 TEMPORARY REGULATIONS

By: Gerald M. Griffith

On January 10, 2001, the Internal Revenue Service released temporary regulations relating to excise taxes on excess benefit transactions under Section 4958 of the Internal Revenue Code. These taxes apply to Disqualified Persons (at rates of up to 225%) and Organization Managers (10% rate up to $10,000 per transaction). All transactions by 501(c)(3) and 501(c)(4) health care organizations have been subject to the IRS' intermediate sanctions regime since the Code was amended, retroactively, in 1996 in the Taxpayer Bill of Rights 2 ("TBOR2"). These temporary regulations replace the proposed regulations published August 4, 1998, and are effective as of January 10, 2001 for a period of three years while the IRS works on refinements for final regulations. The IRS also requested written comments on the temporary regulations, with comments due by April 10, 2001. Inasmuch as these regulations were effective prior to January 20, 2001, they were not postponed by the Executive Order delaying certain regulations.

Overview. The temporary regulations generally, though not universally, provide some additional flexibility, constructive guidance and helpful examples for tax-exempt organizations. They continue to place a premium, however, on adequate documentation for, and a reasonable approach to, transactions. Issuance of the new regulations also may increase the likelihood of active enforcement by the IRS.

Disqualified Persons. Disqualified Person status is often based on ability to exercise substantial influence. The temporary regulations limit, but do not eliminate, the extent to which a person's control over a department or revenue generating activity affects whether he or she is a Disqualified Person. With respect to managerial authority, the factors tending to show substantial influence over the affairs of the organization have been revised to include management authority over a discrete segment or activity of the organization that represents a significant portion of the activities, assets, income or expenses of the organization, as compared to the organization as a whole. The temporary regulations also eliminate as a factor tending to show substantial influence the fact that a person serves as a key advisor to a manager. In addition, the temporary regulations add as factors tending to show a lack of substantial influence (a) the fact that the direct supervisor of a person is not a Disqualified Person, and (b) the fact that a person does not participate in any management decisions affecting the organization as a whole or a substantial discrete segment or activity of the organization.

Initial Contracts. The temporary regulations reverse the IRS' former view that no one should receive a "free first bite" at the apple for their initial contract. The temporary regulations provide that Section 4958 does not apply to any payment made to a person pursuant to an initial contract with an exempt organization (i.e., a binding written contract between the exempt organization and a person who has no prior relationship with the organization), so long as the amount or formula for such payment is fixed in the agreement, the agreement is not materially modified, and the person substantially performs his or her obligations under the contract. Non-fixed (i.e., discretionary) payments pursuant to initial contracts will continue to be subject to scrutiny under Section 4958. The temporary regulations contain eleven examples illustrating the application of the initial contract rule.

Correcting Excess Benefit Transactions. The temporary regulations clarify that correction of an excess benefit transaction to avoid the 200% penalty excise tax requires that a Disqualified Person must pay to the tax-exempt organization an amount equal to the value of the excess benefit (the "correction amount"), plus interest at the applicable Federal rate. With the agreement of the exempt

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organization (in its unfettered discretion), the temporary regulations also allow a Disqualified Person to make a payment by returning specific property previously transferred in the excess benefit transaction. The value of such payment, however, must equal the lesser of the fair market value of the property on the date the property is returned or the date the excess benefit transaction occurred. To the extent the value of such payment is less than or greater than the correction amount, the shortfall is to be paid by the Disqualified Person or the excess may be refunded by the organization, respectively. Correction also may include performing additional services at no charge under an ongoing contract. In addition, the temporary regulations provide five new examples that illustrate acceptable forms of correction.

Organization Manager. An Organization Manager is defined in the temporary regulations as an officer, director or trustee of the exempt organization or any individual with similar powers or responsibilities. An Organization Manager is someone who regularly exercises general authority to make administrative or policy decisions on behalf of the organization and to implement, not merely recommend, administrative or policy decisions. Anyone who is not otherwise an Organization Manager will become an Organization Manager by serving on a committee reviewing transactions to establish a rebuttable presumption of fair market value. Independent professional advisors such as attorneys and accountants, however, are not Organization Managers when acting in that capacity.

Safe Harbors for Management. A new safe harbor for Organizational Managers has been included in the temporary regulations. This safe harbor provides that a manager (who is not a recipient of the excess benefit) will not be subject to personal tax liability as a participant in an excess benefit transaction if the manager relies on the fact that the rebuttable presumption review procedure outlined in the temporary regulations was followed in establishing proof of fair market value in advance of the transaction. The rebuttable presumption review procedure requires that three steps be taken prior to making any payment to a Disqualified Person: (1) the arrangement must be reviewed and approved by the organization's board or committee, and none of the members thereof have a conflict of interest with respect to that arrangement, (2) the board or committee must rely on appropriate data as to comparable arrangements prior to making its determination, and (3) the board or committee must adequately and timely document the basis for its decision in the minutes. The temporary regulations also retain the safe harbor for Organizational Managers based on reliance on a reasoned, written opinion of an attorney or other appropriate professional, if such opinion concludes that the transaction is not an excess benefit transaction and is based on a full disclosure of all of the facts regarding the transaction. Appropriate professionals now include independent valuation experts who hold themselves out as appraisers or compensation consultants, perform on a regular basis and are qualified to make relevant valuations and provide written certification of the foregoing in their opinion.

Indirect Payments. The temporary regulations provide additional guidance with respect to how indirect payments through affiliates (i.e., controlled entities or intermediaries) may run afoul of TBOR2, including four new examples that illustrate different fact patterns under which economic benefits are provided indirectly to a Disqualified Person through a controlled entity or an intermediary. In providing that all consideration and benefits exchanged between a Disqualified Person and the exempt organization, its controlled entities and its intermediaries are taken into account in determining whether there has been an excess benefit transaction, the temporary regulations clarify that an economic benefit is provided indirectly through an intermediary when (a) the organization provides such benefit to the intermediary, (b) the intermediary provides economic benefits to the Disqualified Person, and (c) there is an oral or written understanding that the transfer will occur or the intermediary lacks a significant business or exempt purpose of its own for engaging in such a transfer.

Revenue Sharing. The temporary regulations do not provide any new guidance regarding revenue sharing arrangements. In fact, the temporary regulations do not even retain the provisions regarding revenue sharing arrangements set forth in the proposed regulations. Accordingly, revenue sharing arrangements will continue to be judged under TBOR2 strictly based on fair market value while the IRS resolves the many comments received in response to the revenue sharing arrangement standards set forth in the proposed regulations. Any regulations governing excess benefits from revenue sharing arrangements will be enforced only after they are published in final regulations; however, they may apply to certain pre-existing transactions. In addition, even before final regulations are issued, revenue sharing arrangements that disproportionately reward insiders (compared to the value they provide) or give them the equivalent of a profit interest in a tax-exempt entity may jeopardize that entity's tax-exempt status under existing law.

Other Changes. Other significant modifications or clarifications in the temporary regulations include:

- Competitive bids received from unrelated third parties have been added as recognized comparability data for property transfers, similar to competing offers for services. Many examples from the proposed regulations illustrating appropriate comparability data have been revised and several new examples have been added.
- The provision that reasonable expenses of attending meetings of the governing body may be disregarded for Section 4958 purposes has been replaced by a more general rule that all fringe benefits excluded from income under Section 132 of the Code (except for certain liability insurance premiums, indemnity payments or reimbursements) are disregarded.
- In determining the reasonableness of compensation, the same standards that apply to deductability for for-profits also apply to nonprofit compensation reasonableness. The fact that a bonus or revenue sharing arrangement is subject to a cap is a relevant factor in a determination of reasonableness.
- The number of comparables small organizations (annual gross receipts under $1 million) must obtain to satisfy the special rule applicable to them has been reduced from five to three.
- The authorized body of an entity controlled by an exempt organization may establish the rebuttable presumption, at least where such entity provides economic benefits to a Disqualified Person.
- A Disqualified Person must correct an excess benefit transaction even if the applicable organization has ceased to exist or is no longer tax-exempt under Section 501(c)(3) or (4).
- Instead of providing clear and convincing evidence of its intent to treat benefits provided to a Disqualified Person as compensation for services, an organization now must provide "written substantiation that is contemporaneous with the transfer of benefits at issue."
- Records documenting a board's or committee's basis for fair market value determination of a transaction must be prepared by the later of the next meeting of such body or 60 days following final approval of the transaction.

NEW MATH FOR REFERRALS: STARK II PHASE I REGULATIONS

By: Gerald M. Griffith, Carey F. Kalmowitz and Patrick LePine

The purpose of this article is to alert readers to key points of Phase I of the final Stark II regulations issued by HCFA on January 4, 2001. The Stark Law generally prohibits a physician from making referrals for Medicare/Medicaid designated health services ("DHS") to any entity with which the physician or family member has a direct or indirect financial relationship (compensation or ownership), unless an exception applies.

Effective Date and Scope. The regulations comprise the first of two phases of HCFA's rulemaking to implement prior amendments to the Stark Law. Phase I focuses on the general referral prohibition, services-based and some compensation exceptions, and definitions that are used throughout the Stark Law. The Phase I regulations generally become effective on January 4, 2002. HCFA reiterated that until then, the August 1995 final rule covering referrals for clinical laboratory services remains in effect. In a number of respects, the Phase I regulations differ substantially from that rule and the January 1998 proposed rule. These changes generally fall into three areas: definitional clarifications; expansion of the in-office ancillary services exception; and new exceptions. To the extent providers wish to provide additional input on the regulations, HCFA is accepting written comments through at least April 4, 2001.

Referral Prohibition. The Phase I regulations make three significant modifications to the basic scope of prohibited referrals. First, any referrals by mid-level providers that are directed or controlled by a physician will be attributed to that physician (but a physician's financial interest will not be attributed to his/her group practice). Second, there will be a limited exception to allow billing for claims that do not comply with the Stark Law if the entity billing those DHS did not have knowledge of (or deliberately disregard) the violation. Third, HCFA defined "referral" to exclude any DHS personally provided by the referring physician (i.e., self-referred). The net effect of these changes should be to reduce the number of potential Stark Law violations and increase the flexibility for designing personal productivity compensation models for physicians based on services they actually perform (though "incident to" services generally would not fit that model outside of a group practice).

Definitions. There are a number of other significant definitional changes in the regulations.

DHS. Whereas neither the statute nor the proposed regulations provide certainty as to whether specific services constitute DHS for purposes of the Stark Law, the Phase I regulations define certain services (clinical laboratory services, physical therapy, occupational therapy, radiology and certain other imaging services, and radiation therapy services) by reference to specific lists of Current Procedural Terminology ("CPT") and HCFA Common Procedure Coding System ("HCPCS") codes. In those cases, the published list of codes will be controlling. Thus, with respect to the above-referenced categories of DHS, the Phase I regulations afford providers the opportunity to determine with greater certainty whether a referral by a physician for a particular service falls within the scope of the Stark Law. Further, to the extent that the CPT or HCPCS code for a particular service that is covered by the CPT/HCPCS list (i.e., thus a DHS) includes a professional as well as a technical component, the professional component also will constitute a DHS. The Phase I regulations also provide that services which constitute DHS, by themselves, but are subsumed or "bundled" within another service category and are paid by Medicare as part of a composite payment for a group of services as a separate benefit category (e.g., services that are paid at the ASC rate), are not DHS for purposes of the Stark Law.

Entity: The Phase I regulations clarify that an "entity" does not include the referring physician himself or herself, but does include his or her medical practice. Therefore, when a physician refers to himself/herself, that act does not constitute a referral to an "entity" for purposes of the Stark Law. By contrast, when the physician orders a service which is furnished by another group practice member or the practice's staff, that act would be a "referral" to the physician's practice. Also, the Phase I regulations clarify that a person or entity is considered to be furnishing DHS (the "DHS entity") if it is the person or entity to which HCFA makes payment for the DHS, except that if the person or entity has reassigned its right to payment under certain circumstances, then the DHS entity is the person or entity to which payment has been reassigned.

Fair Market Value. Consistent with the Proposed Regulations, the Phase I regulations define "fair market value" as the "value in arm's-length transactions, consistent with the general market value." Under this formulation, fair market value requires that the compensation or price terms (1) be the product of bona fide bargaining (2) between well-informed parties (3) who are not otherwise in a position to generate business for each other. Usually, fair market value will be consistent with (a) the purchase price paid in connection with similarly situated sale transactions, and (b) the compensation paid in connection with similar service agreements. HCFA adopts a relatively flexible position with respect to establishing that a transaction involving the payment of compensation for assets or services is fair market value. Specifically, HCFA is willing to accept any commercially reasonable method which provides evidence that the compensation is comparable to what is ordinarily paid for an item or service in the relevant location, by parties in arm's-length transactions who are not in a position to refer to one another. Although not required, HCFA suggests that it will give greater deference to independent valuations and surveys.

Indirect Financial Relationships. The Phase I regulations clarify the scope of indirect financial relationships that implicate the Stark Law.

Indirect Ownership or Investment Interest. To establish an "indirect ownership or investment interest," two elements must be present: (1) there must be an unbroken chain of persons or entities having ownership or investment interests between them, and (2) the DHS entity must either have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician has some ownership or investment interest in the DHS entity, albeit indirect (i.e., there are one or more parties interposed between them in the ownership chain). For purposes of this provision, the "knowledge" element does not require knowledge as to the specific composition of the referring physician's ownership or investment, only knowledge or reason to suspect that the referring physician has some ownership or investment interest in the DHS entity (directly or through one or more other entities).

Indirect Compensation Arrangements. The most sweeping changes introduced by the Phase I regulations with respect to financial relationships relate to indirect compensation arrangements, the establishment of which require: (1) an unbroken chain of persons or entities with financial relationships between them (i.e., each link in the chain must have either an ownership or investment interest in, or compensation arrangement with, the preceding link); (2) the aggregate compensation received by the referring physician from the person or entity with which the physician has a direct financial relationship (the "directly compensating

entity") varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the DHS entity; and (3) the DHS entity has actual knowledge that the referring physician's aggregate compensation varies with, or otherwise reflects, the volume or value of his or her referrals, or otherwise acts in reckless disregard or deliberate ignorance of the existence of such relationship. Where the financial relationship between the physician and the directly compensating entity is an ownership or investment interest, the determination as to whether his or her aggregate compensation varies with or otherwise reflects the "volume or value" of referrals is measured by the terms of the compensation arrangement closest in the chain to the referring physician. Significantly, for the purpose of determining whether an indirect compensation arrangement exists, the Phase I regulations include a formulation of the "volume or value" standard that differs from, and is broader than, the standard applied in connection with other exceptions (including the exception for indirect compensation arrangements). Thus, an arrangement potentially might implicate the "volume or value" standard used for the definition of an indirect compensation arrangement (i.e., "varies, or otherwise reflects, the value or volume ..."), but the compensation under that same arrangement nonetheless might not be considered to "take into account the value or volume ..." and thus not implicate the standard for purposes of exceptions, such as the indirect compensation arrangement exception. The Phase I regulations do not expressly define the terms, but read in context it appears that "otherwise reflects" means any effect, even indirect, on the total amount of payments. By contrast, the other undefined term "takes into account" appears to mean any variation in the rate of payment (e.g., whether the per-click charge is the same regardless of the volume or value of referrals).

Volume or Value Standard and Variable Payments. The Phase I regulations adopt consistent definitions of three key terms that are relevant in a variety of incentive compensation plans.

"Volume or Value." HCFA's interpretation of the "takes into account the volume or value of referrals standard" under the Phase I regulations (which, according to the commentary, will be applied consistently for all exceptions and definitions using that term) may enable entities to enter into certain contractual relationships with physicians that the proposed regulations would have prohibited. In particular, the Phase I regulations differ from the proposed regulations in two significant respects. *First*, provided that the compensation (a) is fair market value for services or items actually provided, and (b) does not vary during the agreement's term in any manner that takes into account referrals of DHS, then a contractual arrangement pursuant to which a physician's compensation is established on a fixed time-based or per unit of service-based amount (e.g., an equipment rental arrangement with payments on a "per-click" basis) will not violate the volume or value standard, even if the compensation received by the physician includes amounts that relate to his or her referrals. For example, if a physician were to lease to a hospital an item of equipment on a "per-click" basis, it would be permissible for the hospital to make rental payments to the physician-lessor, even for units of service performed on patients that he or she referred, provided that the "per-click" rental payment is consistent with fair market value, remains fixed over the lease term, and the arrangement otherwise qualifies for the rental exception. *Secondly*, the conditioning of a physician's compensation on his or her referring patients to a particular provider or supplier will not be considered to take into account value or volume of referrals, so long as (a) the terms governing the referral obligations are memorialized in a signed agreement, (b) the payment is both fixed in advance for the term of the arrangement and fair market value for the services performed (i.e., the payment does not take into account the volume or value of the anticipated or required referrals from the physician), (c) the arrangement otherwise complies with the requirements of an applicable Stark Law exception, and (d) the arrangement expressly provides exceptions to enable the physician to refer to a non-designated provider in certain circumstances (e.g., patient choice, the physician's independent medical judgment about the patient's best medical interest, etc.). Under the proposed regulations, by contrast, if the amount a physician could receive was fixed but whether or not he or she could receive it was dependant on whether or not referrals were made to a particular provider, the arrangement potentially would have violated the volume or value standard.

"Other Business Between the Parties." HCFA offers two substantive clarifications of the phrase, "business generated between the parties." First, the agency interprets the phrase to mean business generated for the entity by the referring physician. Second, the Phase I regulations specifically provide that compensation (including time-based or per unit of service-based compensation) will be deemed to not take into account "other business generated between the parties" so long as (a) the compensation is fair market value, and (b) the compensation does not vary during the term of the agreement in any manner that takes into account

referrals or other business generated by the referring physician. For purposes of this standard, "other business generated" expressly includes "private pay health care business" that the referring physician generates. It remains to be seen whether this broader concept will be applied to the employment exception in Phase II of the regulations.

"Set in Advance." To fit within several exceptions under the Stark Law, compensation under the arrangement must be "set in advance." HCFA uses this term interchangeably with "fixed in advance," which requires essentially that the compensation terms must be fixed and objectively verifiable, and may not fluctuate during the term of the agreement. In addition, to qualify as "fixed in advance," the amount of the payment must be consistent with fair market value for the services (or items) that the referring physician actually provides, and cannot take into account the volume or value of referrals or other business generated by the referring physician. Also, the definition of the term expressly excludes percentage arrangements "in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser." As a result, most percentage compensation arrangements will not be deemed to be "fixed in advance'' because the percentage compensation is measured by reference to a single standard that does not remain constant throughout the term. In the commentary, HCFA indicates that payments based upon a percentage of either (a) gross revenues, (b) collections, or (c) expenses will not be considered to be fixed in advance. If, however, a physician were to be paid a percentage of a single fee schedule (i.e., the hospital does not accept different amounts from different payors), the arrangement would qualify as "fixed in advance."

Group Practice. The Phase I regulations set forth nine standards for what constitutes a group practice. These standards generally track the statute and the thrust of the proposed regulations, but with added flexibility for subpooling and productivity bonuses, as well as elimination of the group practice attestation requirement. Not all of the group practice provisions in the Phase I regulations, however, are provider-friendly. For example, HCFA clearly states its position that the group practice entity must be established for the primary purpose of providing physician services and a hospital with employed physicians can not qualify as a group practice. If the hospital division, however, is separately incorporated it can qualify as a group practice (whether owned by the hospital or organized as a captive or friendly PC). In any case, regardless of ownership, to qualify as a group practice requires at least two physicians who are either owners or full-time employees of the group and who are practicing in the group.

Unified Business. The Phase I regulations also note HCFA's view that so-called "group practices without walls" and other loose confederations formed primarily to share ancillary referrals do not qualify as group practices. Likewise, a PC that already conducts a medical business itself cannot own an entity that is a group practice. These views are reflected in a "unified business" standard for qualifying as a group practice. That standard requires: (1) centralized decision-making by a representative board with effective control over the group's assets and liabilities, including budgets and compensation from all sources (not just DHS); (2) consolidated billing, accounting and financial reporting; and (3) centralized utilization review (i.e., group-wide UR function).

Independent Contractors. As with the proposed regulations, independent contractors would not qualify as members of the group. They may, however, be counted for some supervision purposes and they may be treated similarly to members for compensation purposes if they are providing services under contract to the group's patients. Leased employee physicians also would not be "members of the group," but on-call and bona fide locum tenens physicians can qualify as members if their services are billed by the group.

Time Spent in Group. Substantially all (i.e., 75%) of the total patient care services (including consulting and certain administrative services) provided by group practice members must be provided through the group practice and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. This test is calculated as an average and looks to the services of the physicians in any setting, with two limited exceptions (groups providing services in a HPSA and newly formed groups for up to a 12 month start-up period if they make a reasonable good faith effort to meet the test as soon as practicable). As a default standard, patient care services are measured based on actual time spent, which must be documented (e.g., by time cards or appointment books). Groups also may use any alternative measure that is reasonable, fixed in advance (before the services are performed), uniformly applied, verifiable and documented (e.g., personal schedules or billing records).

Set in Advance. The regulations clarify the requirement for a group practice's compensation methodology to be set in advance. To qualify as a group practice, the group's income and overhead expenses must be distributed according to a compensation methodology determined before the receipt of payment for the services (meaning prior to payment from patients or third parties and not just prior to payment of compensation to physicians). The regulations also allow prospective adjustments in the compensation methodology as often as the group deems appropriate, subject to the limits on productivity bonuses.

Productivity Bonuses. Group practices still may pay productivity bonuses to their physicians based directly on personal productivity (including services that are incident to those personally performed services but are not themselves DHS). Compensation for physicians in a group practice need not also fit within the employee or personal services exception as long as all of their services fit one of the service exceptions discussed below. The Phase I regulations do not permit groups to pay their physicians productivity bonuses based directly on the volume or value of referrals of DHS performed by someone else, but those revenues may be indirectly reflected in physician compensation in a group practice setting. A productivity bonus for personally performed services (and services incident to such personally performed services) would satisfy the volume or value standard if it is determined in a manner that meets any one of the following four conditions: (1) bonus based on physician's total patient encounters or relative value units (RVUs); (2) bonus based on the allocation of physician compensation attributable to services other than DHS payable by any Federal health care program or private payor; (3) revenues from DHS constitute less than 5% of the group's total revenues and the portion thereof allocated to each physician in the group constitutes 5% or less of his/her total compensation from the group; or (4) bonus calculated in any reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. In addition to the added flexibility for specialty- or location-based compensation, this safe harbor is significant as HCFA's first express recognition of the use of RVUs as an acceptable means of allocating incentive compensation and it is not limited to groups of at least five physicians. HCFA also noted that it believes capitation payments are unlikely to lead to increased utilization and, therefore, capitation payments may be allocated by any reasonable selected by the parties.

Subpooling. The regulations substantially reduce the restrictions on subpooling and would allow division of profits from Medicare or Medicaid DHS derived not only by the group as a whole but also by any component of the group consisting of at least five physicians if the profits are divided in a manner that satisfies the volume or value standard and the allocation methodology is documented. The volume or value standard would be satisfied in any of the following circumstances: (1) profits are divided per capita; (2) the Medicare/Medicaid DHS revenues are distributed based on the distribution of the group's revenues from services other than Medicare, Medicaid or private pay DHS; (3) revenues from DHS constitute less than 5% of the group's total revenues and the portion thereof allocated to each physician in the group constitutes 5% or less of his/her total compensation from the group; or (4) profits are divided in any other reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.

Services Exceptions. Several exceptions addressed in the regulations operate to exclude certain categories of services from the reach of the Stark Law. In effect, services that are described in these exceptions are not treated as DHS for purposes of the Stark Law. Thus, both exceptions protect both ownership and compensation arrangements.

Physician Services Exception. The regulations revise the physician services exception to apply to services provided by or under the supervision of a member of the group or an independent contractor physician in the same group practice (meeting the contracting requirements discussed above). HCFA also incorporated compliance with other applicable Medicare supervision requirements as part of the physician services exception and clarified that this exception includes incident to services only if they are also physician services under Section 410.20(a) of the Medicare regulations. All other incident to services (e.g., diagnostic tests, physical therapy) are excluded from this exception. Accordingly, as HCFA notes in the preamble, the physician services exception may be of only limited utility.

In-office Ancillaries Exception. HCFA also made several changes of note both to provide additional flexibility for in-office ancillaries in traditional groups and to restrict the expansion of this exception to nontraditional settings such as group practices without walls or other arrangements to essentially share in off-site laboratories or other DHS facilities. These changes are reflected in HCFA's interpretation of the three basic requirements for this exception: personally performed or supervised services;

located in the same building as the practice or a centralized building for a group practice; and billed by the referring physician, group practice, its wholly-owned subsidiary or an independent billing company. This exception continues to be relevant for both solo practitioners and group practices. Although solo practitioners are limited to the "same building" location standard, the exclusion of many self-referred services from the definition of "referrals" should reduce significantly the disparity in permitted referrals between group practices and solo practitioners.

Personally Provided or Supervised. The services must be furnished personally by the referring physician or another physician member of the same group practice, or furnished under the supervision of the referring physician or another physician in the same group practice (i.e., members and certain independent contractors). HCFA removed the separately defined direct supervision requirement for this exception in favor of simply requiring compliance with the general Medicare rules for supervision of ancillary services.

Location - Same Building. HCFA adopted a bright line test for defining "same building" by looking to whether the locations share a single street address assigned by the U.S. Postal Service. Only usable professional office space and common areas are included and all exterior spaces, parking garages, mobile vehicles, vans and trailers are excluded. Under this location standard, the ancillary services must be furnished in the same building (though potentially a different, non-adjacent part of the building) as the referring physician or other group member furnishes substantial physician services unrelated to the furnishing of DHS (Medicare, Medicaid or private pay) even if they lead to the ordering of DHS. Obtaining DHS can not be the primary reason that the patient comes into contact with the group or the referring physician. If an independent contractor supervises (but does not directly provide) the ancillary services, they must meet the "same building" requirement rather than be provided at a centralized location. For home health services provided by a physician whose principal practice consists of treating patients in their homes (not including a nursing home or other facility), the location requirement will be met if the referring physician or an accompanying nurse or technician provides the DHS contemporaneously with a physician service that is not a DHS provided by the referring physician.

Location - Centralized Building. Group practices could have more than one centralized building for DHS and would not be required to centralize all non-lab DHS in a single location. Under HCFA's definition, a group need not use the whole building. A "centralized building" also would include a mobile unit, but only if owned or leased on a full-time basis by and used exclusively by a group practice, 24/7 for a term of at least six months. If space in a building or mobile unit, however, is shared by the group with any other group or provider, it would not qualify as a centralized building even if rented serially for consecutive exclusive periods (e.g., a mobile van moving from site-to-site outside the group). Although shared labs and other shared facilities may be possible under the "same building" standard, the exclusivity requirement for the centralized building standard would preclude treatment of a shared facility as a centralized building for any group (whether as lessor or lessee).

Billing. The general description of the billing requirement is substantially similar to the proposed regulations. HCFA makes it clear, however, that a group practice may have and bill under multiple Medicare billing numbers subject to any applicable Medicare program restrictions.

Laboratory Subsidiaries and Joint Ventures. The ancillaries need not be provided through the same entity that employs the physicians. A group practice can itself own one or more subsidiaries for purposes of providing services to the group practice. For example, a group practice could wholly own a laboratory entity that provides laboratory services to the group or other patients. Those laboratory services could qualify for the in-office ancillary services exception if the supervision, location and billing requirements are met. In the preamble, however, HCFA notes that joint ventures only partially owned by group practices likely could not satisfy the billing requirement because it would not be wholly owned by the group. Presumably a joint venture entity also would not qualify as an "independent" billing company; however, it could hire an independent billing company to do the billing.

Ancillaries Included. The regulations also clarify the scope of ancillaries included in the exception. HCFA provided more flexibility by expanding the range of DME covered in the exception to address circumstances where patients need the DME items to ambulate from the physician's (an objectively verifiable need), and eliminating the restriction on marking up items such as crutches. On the other hand, HCFA also noted that DHS provided "under arrangement" with a hospital would be considered inpatient or outpatient hospital services and not covered under the in-office ancillary services exception. Exclusion of these hospital services may make it more difficult to rely on this

exception for physicians with a significant hospital practice.

Prepaid Health Plans. This exception applies to services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following types of prepaid health plans: (1) An HMO or a CMP in accordance with a risk-sharing or cost-based contract with HCFA; (2) a health care prepayment plan in accordance with an agreement with HCFA; (3) an organization that is receiving payments on a prepaid basis for Medicare enrollees through certain demonstration projects; (4) a federally qualified HMO; and (5) a coordinated care plan (as defined in the Social Security Act) offered by an organization in accordance with a Medicare + Choice contract with HCFA.

Globally Billed Lab Services. The exception is the same as in the proposed rule. It applies to clinical laboratory services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice, if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively. Any such services will not be deemed to be DHS for purposes of the Stark Law.

Academic Medical Centers. This new exception is essentially a group practice exception for tax-exempt academic medical centers (comprised of a medical school, teaching hospital and faculty practice plans) where teaching is the primary mission. Faculty physicians typically receive compensation from and refer to multiple entities within the medical center, creating a variety of direct or indirect compensation arrangements and referral patterns that often do not fit well within the in-office ancillary services exception. This exception, however, will only apply to faculty practice plans that are tax-exempt under Section 501(c)(3) or (4) of the Internal Revenue Code and related hospitals where faculty physicians constitute a majority of the medical staff and account for a majority of all admissions and where the components of the academic medical center have outlined their relationship in a written agreement. The exemption and admissions requirements in particular will limit the utility of this new exception, though in the comment process HCFA may be persuaded to loosen the standards if there is a sufficient response from teaching hospitals and faculty physicians explaining the difficulty in meeting these standards.

In addition, to qualify for the exception, an arrangement must meet four requirements: (1) the referring physician is a bona fide full-time or substantial part-time employee of a component of an academic medical center (and not principally a community physician), licensed to practice medicine in the state, holds a bona fide faculty appointment at the affiliated medical school and provides substantial academic or clinical teaching services in his/her employee capacity; (2) total compensation paid for the prior annual period from all components of the academic medical center to the referring physician must be set in advance and, in the aggregate, can not exceed the fair market value of the services provided (as compared to similar academic settings located in similar environments) and it can not be determined in a manner that takes into account the volume or value of any referrals or other business generated by that physician within the academic medical center (though it may include a productivity bonus for personally performed services and pay based on quality measures that are unrelated to the volume or value of DHS referrals or other business generated); (3) all transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research or community service and all money paid to a referring physician for research is used solely for the support of bona fide research; and (4) the referring physician's compensation arrangement must not violate the Antifraud Statute. In terms of similarity of compensation for faculty physicians, HCFA also noted that "[r]elevant factors include geographic location, size of the academic institutions, scope of clinical and academic programs offered, and the nature of the local health care marketplace."

Implants in an ASC. HCFA has created a new exception for implants, including cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices and implanted DME furnished in a Medicare-certified ASC under the following conditions: (1) the implant is furnished by the referring physician or a member of the same group practice in an ASC with which the referring physician has a financial relationship; (2) the implant is implanted in the patient during a surgical procedure performed in the same ASC where the implant is furnished; (3) the arrangement for the furnishing of the implant does not violate the Antifraud Statute; and (4) all billing and claims submission for the implants complies with all Federal and state laws and regulations.

Dialysis-related Outpatient Prescription Drugs. In recognition that Congress did not intend the Stark Law to preclude physician ownership of ESRD facilities, HCFA has created a new exception for EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD

facility owned by physicians. The exception is applicable under the following conditions: (1) the dialysis-related drugs are furnished in or by an ESRD facility; (2) the arrangement for the furnishing of the dialysis-related drugs does not violate the Antifraud Statute; and (3) the billing and claims submission complies with all Federal and state laws and regulations.

Preventive Care. HCFA has created a new exception for certain preventive screening tests, immunizations, and vaccines that meet the following conditions: (1) subject to HCFA-mandated frequency limits; (2) reimbursed by Medicare based on a fee schedule; (3) the arrangement does not violate the Antifraud Statute; and (4) the billing and claims submission complies with all Federal and state laws and regulations.

Eyeglasses and Contact Lenses. In recognition that Medicare reimbursement for eyeglasses and contact lenses is limited and presents little opportunity or incentive for overutilization, HCFA has excluded referrals for eyeglasses and contact lenses from the reach of the Stark Law. The exception applies to eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery under the following conditions: (1) the eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in Medicare regulations; (2) the arrangement does not violate the Antifraud Statute; and (3) the billing and claims submission complies with all Federal and state laws and regulations.

Compensation Exceptions. Other exceptions in the Stark Law and regulations apply only to compensation arrangements (as opposed to ownership or investment interests). If a compensation arrangement fits one of these exception, referrals may be made by and accepted from the interested physician. The Phase I regulations add six new compensation exceptions.

De minimis Non-monetary Compensation. The exception applies to compensation from an entity in the form of items or services (excluding cash or cash equivalents) that does not exceed an aggregate of $300 per year, if the following conditions are satisfied: (1) the compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician; (2) the compensation may not be solicited by the physician or the physician's practice; and (3) the arrangement does not violate the Antifraud Statute.

Fair Market Value Compensation. The fair market value compensation exception applies to compensation arrangements between an entity and either a physician (or immediate family member) or any group of physicians (whether or not a "group practice") for the provision of items or services by the physician (or an immediate family member) or group to the entity, if the arrangement is set forth in an agreement that meets the following conditions: (1) is in writing and signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement; (2) specifies the time frame for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement covering the same items or services during the course of a year (however an arrangement made for less than one year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change); (3) specifies the compensation that will be provided under the arrangement; (4) the compensation is set in advance, is consistent with fair market value and is not determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician; (5) involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties; (6) the arrangement complies with an Antifraud Statute safe harbor, has been approved by the OIG in a favorable advisory opinion, or does not violate the Antifraud Statute; and (7) the services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a state or Federal law.

Medical Staff Incidental Benefits. The exception protects items and services (excluding cash or cash equivalents) that are: (1) offered by a hospital to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties; (2) offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital and its patients; (3) provided by the hospital and used by the medical staff only on the hospital's campus; (4) reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital; (5) consistent with the types of benefits offered to medical staff members by other hospitals in the same local region or, if no such hospitals exist, by comparable hospitals located in comparable regions; (6) of low value (i.e., less than $25) with respect to each occurrence of the benefit; (7) not determined in any manner

that takes into account the volume or value of referrals or other business generated between the parties; and (8) not illegal under the Antifraud Statute.

Risk-sharing Arrangements. In recognition that a typical risk-sharing arrangement between a physician and a managed care plan (e.g., capitation or withhold arrangement) would not be eligible for the statutory exceptions for bona fide employment relationships or personal service arrangements, the regulations include a new exception for certain bona fide risk-sharing arrangements. This exception applies to compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the Antifraud Statute or any law or regulation governing billing or claims submission.

Compliance Training. This exception protects compliance training provided by a hospital to a physician (or the physician's immediate family member) who practices in the hospital's local community or service area, provided the training is held in the local community or service area.

Indirect Compensation Arrangements. The exception for indirect compensation arrangements is intended, in practice, to equalize direct and indirect arrangements. In fact, without the exception, certain arrangements that would be protected if entered into directly between the referring physician and the DHS entity (e.g., a physician leasing an MRI machine to a hospital with fixed, fair market value per-click payments, including for imaging services rendered to patients referred by the physician) could not be accomplished indirectly (e.g., a physician referring to a hospital which contracted for MRI services with a company owned by physician, with fixed, fair market value per-click payments). In the former case, there is a direct compensation arrangement to which the "does not take into account" standard applies; as discussed above, per-click payments do not implicate the "takes into account volume or value" standard where the payments are fair market value and fixed throughout the term. Conversely, in the latter case, assuming requisite knowledge by the hospital of the financial relationships, the referring physician will be deemed to have an indirect compensation arrangement with the hospital. Since the MRI company will generate more revenue each time the referring physician refers a patient to the hospital requiring MRI imaging services, the contract between the hospital and the MRI company will "reflect" the volume or value of the referring physician's referrals.

To fit within the indirect compensation exception, the arrangement must comply with three requirements: (1) the compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is fair market value for the items or services provided under the arrangement and does not take into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS; (2) the compensation arrangement between the referring physician (or immediate family member) and the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship is set out in writing, signed by the parties, and specifies the services covered by the arrangement (in the case of a bona fide employment relationship, the arrangement need not be in writing, but it must be for identifiable services and be commercially reasonable even if no referrals are made to the employer); and (3) the compensation arrangement does not violate the Antifraud Statute or any laws or regulations governing billing or claims submission.

Home Health Plan of Care. HCFA liberalized the rules regarding financial relationships between physicians and home health agencies and reconciled the Stark Law with the physician certification requirements for home health services. Home health services provided by a home health agency ("HHA") are not payable by the Medicare program unless a plan of care for such services has been certified (or recertified) by a physician. Under the prior rules, the required certification could not be provided by a physician who had either (1) a 5% or greater ownership interest in the HHA (i.e., a significant ownership interest) or (2) a financial or contractual relationship with the HHA with a value equal to or in excess of $25,000 (i.e., a significant financial relationship). The 5% ownership limit and the $25,000 financial or contractual limitation have been removed and the regulation now permits a physician to certify or recertify the need for home health services to be provided by an HHA, or establish or review a plan of treatment for an HHA, as long as the financial relationship between the physician and the HHA meets one of the relevant ownership or compensation exceptions under the Stark Law. Although this portion of the regulations was to be effective February 5, 2001, as a result of an Executive Order it was delayed until April 6, 2001.

COMING ATTRACTIONS

HMS&C Attorneys frequently are asked to speak at conferences and seminars. A calendar of upcoming speaking engagements is provided below. For additional information on any of these speaking engagements, please call the speaker(s) at the phone number listed below.

Topic	***Date(s)***	***Location***	***Speaker(s)***
7th Annual Michigan Health Law Institute:	March 9	Troy, MI	
Physician Recruitment			Gerald M. Griffith
eHealth: A Helping of HIPAA			Linda S. Ross
Michigan Recruitment and Retention Network	March 15	Lansing, MI	Carey Kalmowitz, Patrick LePine
It's the Law: A Legal Briefing on Stark II, TBOR2 and Gainsharing	March 20-21	Lansing, MI and Novi, MI	Gerald M. Griffith, Patrick LePine
AHLA Institute on Medicare & Medicaid Payment Issues: Special Cost Reporting Issues for Cost-based Providers (with HCFA)	March 28-30	Baltimore, MD	Chris Rossman
Health Law Update	March 29	Novi, MI	Gerald M. Griffith, Linda S. Ross, Carey Kalmowitz, Patrick LePine
AHLA In-house Counsel Program: Hiring Consultants	June 17	Orlando, FL	Gerald M. Griffith
AHLA Annual Meeting: TBOR2 (with IRS)	June 18-20	Orlando, FL	Gerald M. Griffith

Honigman Miller Schwartz and Cohn is a general practice law firm headquartered in Detroit, with an additional offices in Bingham Farms and Lansing, Michigan. Honigman Miller's staff of more than 175 attorneys and more than 300 support personnel serves thousands of clients regionally, nationally and internationally. Our health care department includes the fourteen attorneys listed below who practice health care law on a full-time or substantially full-time basis, and a number of other attorneys who practice health care law part-time. Except as denoted below, attorneys in the health care department are licensed to practice law in the State of Michigan only.

William M. Cassetta
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William O. Hochkammer
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Julie E. Robertson**
Linda S. Ross
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For further information regarding any of the matters discussed in this newsletter, or a brochure that more specifically describes our practice in health care law, please feel free to contact any of the attorneys listed above at our Detroit office by calling (313) 465-7000, our Lansing office at (517) 484-8282 or our Bingham Farms office at (248) 566-8300.

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