

Health Care Client Bulletin



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Are You Ready to Comply with Stark?

The long awaited Stark regulations (Phase II) were published Friday, March 26, 2004 completing the set of final Stark regulations (“the Final Rule”)¹. Although there is a 90-day comment period, the Final Rule will become effective July 24, 2004. Keep in mind that CMS’ goal in developing the Final Rule is to protect beneficiaries and taxpayers from abusive referral patterns. Therefore, although the CMS press release indicated that the Final Rule provides straightforward rules for physicians and providers to follow, the Stark Statute and its regulations continue to be some of the most complicated rules governing relationships between hospitals and physicians. Furthermore, the commentary to the Final Rule makes clear that even though an arrangement meets an exception under Stark, the arrangement must not violate the Anti-Kickback Statute or any federal or state billing or claims submission requirement².

Although the Final Rule remains complex, CMS has tried to be responsive to comments and to clarify the Final Rule to protect compensation arrangements that are not abusive. It is not our intent with this bulletin to duplicate the Final Rule or even list all the changes from the proposed rule; rather we will comment on some of the most significant changes. The Final Rule is available on our website at <http://www.bricker.com/legalservices/practice/hcare/laws/mmfa.asp>. We will be adding additional

information in the near future including a comparative Stark and Anti-Kickback chart.

Definitions

Designated Health Services (“DHS”). The following changes and clarifications are noteworthy:

- Lithotripsy will not be considered an “inpatient or outpatient service.”
- Commentary in the Final Rule clarifies that audiology services were not intended to be included within the scope of the physical therapy, occupational therapy, and speech-language pathology services. In the Final Rule, numerous audiology CPT codes (92506, 92601, 92602, 92603 and 92604) have been deleted from the CPT list. CMS distinguishes other procedures (specifically, CPT codes 92507 and 92508) as speech/hearing therapy, not audiology, and they remain on the list of DHS.
- The definition of “radiology and other imaging services” has been modified to make clear that radiology services performed immediately after a procedure in order to confirm the placement of an item during the procedure are not DHS. However, CMS specifically declined to exclude similar pre-surgical radiology procedures, such as radiology services to plan the manner in which a needle, catheter, or probe will be guided.

Entities that perform nuclear medicine procedures should be aware that CMS is considering adding nuclear medicine services as DHS.

- Nuclear medicine is not DHS. However, in the commentary to the Final Rule, CMS acknowledges that some nuclear medicine procedures, which are not DHS, are clinical alternatives to radiology procedures, which are DHS. CMS states: “We are making no changes to the treatment of nuclear medicine procedures under the DHS definitions at this time. However, we are mindful of the issue . . . and are continuing to consider the application of [Stark] to nuclear medicine procedures.” **Entities that perform nuclear medicine procedures should be aware that CMS is considering adding nuclear medicine services as DHS.**

Fair Market Value. A “safe harbor” was established to determine fair market value for a compensation exception when a physician is paid an hourly rate. Hourly payment for a physician’s personal services (services performed by the physician personally and not by employees, contractors or others) shall be considered fair market value if the hourly payment is established using one of two specified methodologies.

Indirect Ownership. The Final Rule clarified that common ownership in an entity does not establish an indirect relationship by one common owner in another common owner. An indirect relationship requires an unbroken chain of ownership interests between the referring physician and the entity furnishing the DHS.

Set in Advance. The definition of “set in advance” was expanded to include formula-based compensation as well as time-based amounts or per click compensation amounts.

Existing Exceptions

1. **Whole Hospital Exception.** The whole hospital exception is retained; however, it incorporates the 18-month moratorium on specialty hospitals as enacted by the Medicare Modernization Act.
2. **Personal Services Arrangements.** The clarifications to this exception include:

- The agreement may contain a termination clause (with or without cause); however, if the agreement is terminated within the first year of the original term, the parties are not permitted to enter into another agreement for the same or similar services for the remainder of the first year; and
- The agreement must cover all of the services to be furnished by a physician and the physician’s immediate family members to the hospital by doing one of the following:
 - All separate arrangements between the entity and the physician and the entity and any immediate family member of the physician incorporate each other by reference; or
 - If the arrangements cross-reference a master list of the contracts and the master list is maintained and updated centrally. This master list must be available for review by CMS if requested. The master list should be maintained in a manner that preserves the historical record of contracts.

3. **Physician Recruitment.** The final rule makes significant changes to the physician recruitment exception.

A. Physicians Joining Medical Practices

Hospitals have long struggled with the Stark implications of providing recruitment benefits to a newly recruited physician who is joining an existing medical practice. The Final Rule permits such recruitment benefits under the following conditions:

- The written agreement setting forth the recruitment benefits is signed by the medical practice (as well as the physician) if payments are directly made to the medical practice;
- The benefits must be passed directly through the medical practice to the recruited physician except for actual costs incurred by the medical practice;
- If the recruited physician receives an income guarantee from the hospital, the costs allocated by the medical practice to the

recruited physician may not exceed the actual additional incremental costs attributable to the recruited physician;

- Records of the actual costs and the passed through amounts are maintained for a period of at least five years and made available to the government upon request;
- The recruitment benefits cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or, if the benefits are paid directly to the medical practice, the volume or value of any actual or anticipated referrals by the medical practice;
- The medical practice cannot impose additional practice restrictions (such as a restrictive covenant) on the recruited physician, other than conditions related to quality of care; and
- The arrangement cannot violate the Anti-Kick-back Statute, or any federal or state law or regulation governing billing or claims submission.

The Final Rule makes this regulation generally applicable to any recruited physician who is joining a medical practice, regardless of whether the benefits are paid directly to the recruited physician or to the medical practice – however, two of the requirements (numbers 1 and 5 above), by definition, only apply when the medical practice receives the benefits.

Remember, the Internal Revenue Service (“IRS”) has also expressed concern over recruitment benefits that are paid to a group practice rather than to the recruited physician. It remains to be seen how this Stark Exception and the IRS concerns will be reconciled.

B. Relocation Requirement

The Final Rule clarifies that the relocation requirement applies to the physician’s practice, not his or her residence. Under the Final Rule, a physician will be deemed to have relocated if: (1) The physician has relocated the site of his or her practice a minimum of 25 miles; or (2) at least 75% of the physician’s revenues from services provided to patients (includ-

ing services to hospital inpatients) are derived from services provided to new patients.

For the 75% revenue test, the regulations measure practice revenue annually on a fiscal or calendar year basis (at the physician’s option). In the initial “start up” year of the recruited physician’s relocated practice, the test is whether it is reasonable to expect that the recruited physician will meet the 75% test. New patients are those patients who have not been seen by the physician in his or her previous practice for at least three years.

C. Residents / New Physicians

The Final Rule exempts residents and new physicians from the relocation requirement. New physicians are those who have been in medical practice less than one year. Because residents and new physicians are not considered to have an established practice, they are eligible for the physician recruitment exception regardless of whether or not the physician actually moves his or her practice location.

D. Non-relocating Physicians and Cross-Town Recruitment

It is not uncommon for a hospital to have struggling physicians who are currently working in the community to ask for recruitment type assistance. The hospital may feel that the situation is analogous to a recruitment situation — after all, the community may be just as harmed if this struggling physician moves away as it would be if the community loses out on attracting a new physician. However, the Final Rule makes no changes regarding cross-town recruiting (recruiting of physicians who do not satisfy the relocation requirement and are not residents or new physicians). Because these physicians do not satisfy all of the requirements for the recruitment exception, hospitals must be aware that recruitment-type benefits (i.e., income supplements) paid to these existing physicians are prohibited by Stark, even under a theory that the physician must be retained from leaving the community. In the Final

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Rule, CMS states that if the situation does not qualify as a HPSA retention payment or employment arrangement, retention payments to existing physicians will only be permitted with an Advisory Opinion approval. CMS states that it expects to approve such retention payments only in “unusual and compelling” circumstances. Thus, hospitals cannot rely on the recruitment exception to protect retention payments made to existing physicians or payments for non-relocating physicians (i.e., cross-town recruiting).

4. Non-Monetary Compensation Under \$300 and Incidental Benefits. Several changes and clarifications have been made to the exceptions for non-monetary compensation valued at under \$300 and incidental benefits to medical staff members. The following is a brief summary of the noteworthy changes:

- The \$300 limit on non-monetary compensation and the \$25 limit on incidental medical staff benefits will now be indexed and revised annually. The increases will be adjusted by the Consumer Price Index – Urban All Items. The revisions will be done on or immediately after September 30 each year and will be published by CMS on the web at: <http://cms.hhs.gov/medlearn/refphys.asp>. Hospitals should check these revisions annually to determine the most current limits for these benefits.
- The requirement that incidental medical staff benefits be provided and used “on campus” has been modified to include electronic devices, such as pagers and internet access, used by physicians when away from a hospital campus exclusively for the purpose of accessing hospital information or personnel.
- Commentary clarifies that provision of transcription services by a hospital for hospital records is not a benefit, incidental or otherwise, to the physician. Thus, such services do not constitute remuneration to the physician and do not need to fall into a Stark exception. Transcription services provided by the hospital for

a physician’s private practice would, however, be considered remuneration to the physician.

The Final Rule clarifies that the incidental medical staff benefits exception is not restricted to hospitals. Any entity with a bona fide medical staff (such as a clinic or long term care facility) may provide incidental benefits to its medical staff under this exception.

5. Space and Equipment Lease Exceptions.

These two exceptions were changed in two ways: (i) termination clauses are permitted provided that if the lease is terminated in the first year, the parties are not permitted to enter into a new lease until that year has ended; and (ii) a holdover provision for 6 months is permitted if the lease payment remains the same.

New Exceptions

1. Intra-Family Rural Referral. This new exception, added to the category of ownership/investment interests and compensation exceptions, permits a referring physician to refer to an immediate family member or to an entity with which the immediate family member has a financial relationship if the following conditions are met:

- The patient resides in a rural area; and
- No other person or entity is available to furnish the services in a timely manner in light of the patient’s condition within 25 miles of the patient’s residence.

2. Professional Courtesy. Professional courtesy is defined as the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff. Hospitals and other entities furnishing DHS may offer professional courtesy to physicians and members of their families if all the following conditions are met:

- Professional courtesy is offered to all physicians on the entity’s bona fide medical staff or in the community without regard to volume or value of referrals;
- The health care items and services provided are of a type routinely provided by the entity;

The requirement that incidental medical staff benefits be provided and used “on campus” has been modified...

- The professional courtesy policy is set out in writing and approved in advance by the entity's governing body;
- Professional courtesy is not offered to a physician (or immediate family member) who is a federal health care program beneficiary unless there is a good faith showing of financial need;
- If the professional courtesy involves any whole or partial reduction of any coinsurance obligation, the insurer is informed in writing of the reduction; and
- The arrangement does not violate the Anti-Kickback Statute or any federal or state law governing billing or claims submission.

3. *Retention Payments in Underserved Areas.*

This new exception for compensation arrangements permits hospitals and federally qualified health clinics to make retention payments to physicians who have received a bona fide offer from another hospital or federally qualified health clinic. The exception is only available to hospitals in a HPSA or in an area with demonstrated need for the physician as determined through a CMS Advisory Opinion. The payment may not be more than the difference between the physician's current compensation and the bona fide offer or the reasonable costs of recruiting a replacement physician. The retention payment must be subject to the same obligations and restrictions on repayment or forgiveness of indebtedness as the bona fide recruitment offer.

4. *Community Wide Health Information Systems.*

This new exception permits a hospital to provide items or services of information technology to a physician to allow access to electronic health care records and complementary drug information, general health information, medical alerts, and related information for patients to enhance the community's overall health. To meet this exception, the following restrictions apply:

- Items or services must be principally used by the physician as part of the community-wide health information system;

- The items or services must be provided to the physician in a manner that does not take into account the physician's volume or value of referrals;
- The community-wide health information system is available to all providers, practitioners and residents of the community who desire to participate; and
- The arrangement does not violate the Anti-Kickback Statute or any federal or state law billing or claims submission rules.

5. *Referral Services and Obstetrical Malpractice Insurance Subsidies.* These are two new compensation exceptions that mirror the Anti-Kickback safe harbors.

6. *Charitable Donation Exception.* The Final Rule establishes a new exception for charitable donations from physicians. CMS acknowledged that charitable contributions made by physicians to covered entities, such as the purchase of a hospital charity ball ticket, creates a compensation arrangement between the donor physician and the entity subject to Stark. CMS established a new exception permitting these donations under the following circumstances:

- The donation is made to an organization exempt from taxation under the IRS Code (or to an exempt supporting organization, such as a hospital foundation);
- The donation cannot be solicited or made in any manner that reflects the volume or value of referrals or other business generated from one party for the other; and
- The donation does not otherwise violate the Anti-Kickback Statute or billing or claims filing rules.

CMS notes that broad-based solicitations not targeted specifically at physicians, such as sales of charity ball tickets or general fund-raising campaigns, will qualify under this exception. Hospitals engaged in more selective or targeted fund-raising activities should ensure that those activities are not conducted

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Reporting Obligations

All entities furnishing DHS that are paid for by Medicare must maintain information regarding their financial relationships with referring physicians. The entity must maintain the following information along with documentation sufficient to verify the information and, upon request, make the documentation available to CMS or the Office of the Inspector General (“OIG”):

- Name and UPIN number of each physician who has a financial relationship with the entity;
- Name and UPIN of each physician who has an immediate family member with a financial relationship with the entity;
- DHS provided by the entity; and
- With respect to specified physicians, the nature of the financial relationship including records that the entity is required to retain to comply with IRS, Securities and Exchange Commission (“SEC”) rules, and other Medicare and Medicaid program rules.

The entity will have 30 days from the date of a request by CMS or the OIG to furnish the information. An entity that fails to report is subject to a civil monetary penalty of up to \$10,000 for each day following the deadline of when the report is due to CMS or the OIG.

Hospitals should develop a good tracking system for all of their contracts with referring physicians to assure that each contract fits within a Stark exception as clarified by the Final Rule. The complexity of the Final Rule coupled with the requirements of other state and federal laws governing physician-hospital relations make it imperative for hospitals to work closely with legal counsel to establish physician arrangements. If you have any questions about this Final Rule or any physician arrangement that currently exists or that may exist in the future, please contact any of the following healthcare attorneys.

(Footnotes)

¹ Phase I was published in January 2001.

² These requirements are part of almost every compensation exception. In discussing the exceptions, we will not repeat these requirements every time. Remember that these requirements are an overriding theme to compliance with the Final Rule.

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