

Client *Urgent* Briefing

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HCFA Issues Final Stark Rules

by Amy L. Woodhall

After three years, the Health Care Financing Administration has released the final Stark II Rules on prohibited physician referrals. Phase I of these rules, released on January 4, 2001, significantly changes the ancillary service requirements for physicians and groups and the ability of many entities to compensate physicians, including employees, independent contractors, networks, and academic medical center physicians.

In February, HCFA postponed a provision on physician certifications and treatment plans for home health services until April 6, 2001, which is consistent with a Bush Administration directive requiring review by new HHS appointees. The remainder of the rule is scheduled to go into effect in January 2002.

In the meantime, some practices previously prohibited will now be allowed and other practices previously allowed will now be prohibited. Although the rules are complex, HCFA has provided numerous bright-line tests to clarify how Stark applies and to ease some administrative burdens. Now is a good time to review financial arrangements with all physicians, including any ownership interests or compensation arrangements, to identify the effect of these changes, restructure arrangements as necessary, and ensure that systems are in place to comply with HCFA reporting requirements.

Background

Stark II prohibits a physician referral to an entity for certain "designated health services" covered by Medicare and Medicaid if a financial relationship exists between the referring physician (or an immediate family member) and the entity unless the relationship fits within an exception. Entities cannot bill for services furnished pursuant to a prohibited referral and are subject to civil monetary penalties and exclusion from Medicare.

The devil is in the definitions. HCFA has used its rule-making power to define terms and interpret Congressional intent to allow or prohibit certain arrangements. (For example, a manufacturer generally will not be deemed a furnishing "entity" and a service that a physician personally performs is

no longer considered a "referral"). These definitional changes provide numerous planning opportunities for structuring physician compensation.

Designated Health Services

Key definitions for any Stark analysis are those designated health services for which referrals are prohibited. To help standardize and identify services falling within the statute, HCFA has posted applicable CPT and HCPCS codes for many common ancillaries such as labs, radiology and certain other imaging services, radiation therapy, physical, occupational and speech-language therapy on its web site. For those CPT codes on the list, the professional component is included as a designated health service (e.g., radiology interpretations and certain radiation therapy). HCPCS level 2 codes for all parenteral or enteral nutrients, equipment, and supplies, and for all prosthetics, prosthetic devices and supplies, and orthotics are also designated. HCFA will use Medicare definitions for other designated health services such as DME, home health, Part B prescription drugs, as well as inpatient and outpatient hospital services. DHS does not include services reimbursed by Medicare under a composite rate (ASCs and SNF Part A), unless the service itself is payable through a composite rate (i.e., home health, inpatient and outpatient services.)

Indirect Financial Relationships

Since the statute covers direct and indirect financial relationships (downstream and upstream relationships between referring physicians and a furnishing entity), HCFA has limited the definition to preclude only those relationships where the furnishing entity knows or has reason to know of indirect compensation to a referring physician (or immediate family member) that varies with referrals. Furnishing entities may continue to submit Medicare claims by showing that they neither knew of nor had reason to suspect that an indirect relationship existed. Alternatively, many indirect compensation arrangements can be structured to comply with a new indirect compensation exception.

Big Changes for Group Practices

By far, HCFA received the most critical commentary regarding what constitutes a Group Practice and the exception allowing those Groups to bill for ancillary services in their offices. For traditional Groups, the final rule does a better job of balancing the compliance burden against the types of abuses the statute was intended to prevent. Once within the definition, a Group will have greater freedom to provide designated health services in the office and to refer within the Group.

The Group Practice definition has changed considerably under the idea that bona fide groups should operate with less intrusion into their business and financial operations. Single legal entities organized for the primary purpose of a Group Practice may qualify under a variety of legal forms and ownership models. Loose configurations of physicians, entities owned by Group Practices, and Groups that are owned and controlled through a hospital or physician practice management company but are really separate entities will not qualify as Group Practices under the new definition.

A Group must still operate as a unified business, but may now use profit, location, and cost center accounting to distribute income and expenses. Groups can change their overhead and income distribution methods as frequently as they desire so long as the method is determined prior to receiving the payment giving rise to the overhead or income. Specific methods for distributing profits to owners and bonusing physicians who are employees and certain independent contractors allow Groups to indirectly compensate physicians for DHS referrals. The pooling of Groups of at least five physicians for profit sharing also will be allowed.

Groups must still furnish at least 75% of the total patient care services provided by their physician members (the “physician services test”). Members include owners and employees as well as locum tenens physicians eligible for the Medicare reassignment rule and on-call physicians while on call if billed by the Group. The final rule establishes a bright line test for counting physician time while allowing other measures to qualify based on the facts and circumstances, and eliminates the requirement that Groups provide the carrier with a written attestation that the physician services test has been met. Instead, Groups must maintain records demonstrating that they meet the definition of a Group and the other requirements of the in-office ancillary and physician service exceptions.

Under the in-office ancillary exception, HCFA has greatly simplified the strict supervision requirement it originally proposed. Instead, it will use the existing Medicare supervision rules for payment and coverage for each service. This means that a physician needs to be present in the office suite and immediately available if payment rules so

require (e.g., billing “incident to” services). In a change from the proposed rule, independent contractor physicians can supervise ancillary staff and now can be eligible for productivity bonuses under a contract meeting certain conditions.

In terms of the location requirement for in-office ancillaries, the final rule substantially limits a Group’s ability to use part-time arrangements in buildings where the Group does not routinely provide a wide range of physician services. In addition to meeting the payment supervision rules, the services must be provided either:

- (1) at the same street address (excluding parking lots and mobile vans) where physician members routinely provide substantial physician services unrelated to designated health services; *or*
- (2) in a centralized building used exclusively by the group that the group wholly owns or leases on a full-time basis (i.e., 24/7 for at least six (6) months).

This means that off-site ancillary service facilities cannot be leased on a part-time basis (e.g., one-day rentals) or time-shared among Groups. Groups and physicians may share facilities only when the physicians or Groups also routinely provide their full range of services at the same street address. Mobile units for designated health services may move among group sites, but must be used exclusively by the Group billing for them.

In any event, this exception applies only to those ancillaries that are billed by the physician, the physician’s Group, an entity wholly owned by the physician or Group, or a billing company acting as an agency for the physician, Group, or wholly owned entity (i.e., a shared facility cannot itself bill for the service). Otherwise, a different exception must be met for a prohibited referral.

Physician Compensation

The final rule addresses some common physician compensation problems, although Phase II of the rule will provide further guidance. HCFA maintains that physician compensation for non-DHS services still creates a compensation arrangement requiring an exception. Several new exceptions will be helpful in this regard.

Fair Market Value (FMV) Compensation - Commercially reasonable arrangements with physicians or Groups for leases and services they provide will be allowed if the arrangement is in writing and the compensation does not change over time and is consistent with fair market value without accounting for referrals, among other conditions. If objectively verifiable, compensation may be based on a time basis (e.g., per hour) or unit of service basis, but certain percentage arrangements are expressly prohibited and may need to be restructured. This exception also requires compliance with the Anti-kick-back statute and billing rules.

Networks - Physicians networks should be pleased with several changes. First, IPAs are not considered furnishing

entities unless they directly provide designated health services. For compensation under a risk sharing arrangement (including withholds, bonuses and risk pools), IPAs and MCOs may compensate physicians (directly or indirectly through a subcontractor) for services under employer group health and commercial managed care plans if the arrangement complies with the Anti-kickback statute, Medicare fraud statute, and Medicare billing and claims submission laws or regulations. In addition, physician ownership in, and compensation arrangements with, Medicare prepaid health plans such as Medicare + Choice are exempted. Questions still exist regarding the application of the 75% physician services test for groups that are part of an IPA doing substantial business, and hopefully HCFA will clarify that issue in Phase II.

Faculty Practice Plan - Compensation to employed faculty physicians from various components of an academic medical center (such as the medical school, a facility practice plan, and hospital) can qualify if the total physician compensation from all components does not exceed fair market value, and the payments support the academic medical center mission. This exception generally would not include arrangements with community physicians. Compliance with the exception requires the governing boards of the component entities to adopt a written agreement regarding their relationship.

Conditioned Referrals - A surprising development is that entities may require a physician to refer to a particular provider, practitioner, or supplier under a signed referral agreement if the compensation arrangement meets a Stark exception, is fixed in advance, and represents fair market value, provided that deference is given to patient and insurer choice and the physician's judgement as to the patient's best interest. Note that under current case law, Anti-kickback issues may still remain.

Non-cash Compensation - Non-cash items of up to \$300 per year, hospital-sponsored compliance training for local physicians, and incidental benefits (less than \$25) to hospital medical staff members provided on a hospital campus are exempted under certain conditions.

Transport and Communication Arrangements - Arrangements whereby a physician receive items, devices and supplies used solely to collect, transport, process, or store specimens or solely to order or communicate test results meet a new exception so long as the item is not for surgery and is not used for any other purpose.

Other items - Certain physician ownership interests in, or compensation arrangements involving implants and prosthetics implanted in an ambulatory surgery center, dialysis-related drugs furnished by an ESRD facility, certain preventive screening tests and immunizations, and post-cataract eyewear can qualify for an exception if the arrangement complies with Medicare coverage and billing requirements and the anti-kickback statute.

Relationship with Other Laws

HCFA's approach to set minimum thresholds for acceptable

arrangements and rely on other statutes to address any residual risk. The final rules make clear that definitions and compliance with the Stark rules will not affect compliance with other laws, in particular, the Anti-kickback statute and Medicare and Medicaid billing and coverage rules. For example, consignment closet arrangements whereby a physician or Group leases a closet to a DME supplier can now comply with Stark. HCFA admonishes physicians, however, that compliance with the anti-kickback guidance on leases is required separately and that the supplier may have difficulty meeting the Medicare DMEPOS supplier standards.

Although several new Stark exceptions will require anti-kickback and billing compliance as a condition, providers still must clearly differentiate between the anti-kickback law prohibiting compensation intended to induce referrals and the bright line rules of Stark, which do not require the government to prove intent. HCFA states in the rule that if Stark is intentionally violated, separate civil monetary penalties and false claims liability may be imposed in addition to the Stark penalties of \$15,000 per prohibited referral. Courts are split on whether a Stark violation can form the basis for a false submission to the government, but promulgation of the final rule will increase potential liability for Stark noncompliance under these other theories.

Transition and Enforcement Issues

Transition plans will be difficult to develop. The statute itself and the clinical lab final rules under Stark I are already in effect. This rule, while taking effect next year, is an Interim Final rule and HCFA will accept comments for 90 days. The Bush Administration will undoubtedly review and address these comments further. Phase II, expected later this year, will further address leases, employment and the Medicaid program.

HCFA says that the one year implementation date is designed to allow enough time to restructure arrangements where Phase I proscribes conduct not previously prohibited, but that the statute otherwise remains in full force and effect. When the rules were in proposed form, HCFA stated that any reasonable interpretation of the statute would be sufficient, although the final rule states that certain interpretations are no longer operative.

For areas where the new rule authorizes a practice that was previously prohibited, formal protection is not assured until the rule is final. In many cases, providers may choose to reasonably rely on HCFA's new interpretations as courts generally defer to an agency's interpretation of statutes administered by the agency. Nonetheless, the final rule defines and interprets most of the statutory terms and available exceptions. The improved clarity in many areas of application will now give the statute meaning, compel compliance with its terms, and invigorate the government's enforcement priorities.

Please call Amy Woodhall or Bob Crump at 216-781-1212 with your questions or comments. 

STARK DESIGNATED HEALTH SERVICES:

- Clinical Labs
- Physical Therapy (including Speech-Language Pathology)
- Occupational Therapy
- Radiology and Certain other Imaging Services (excluding Nuclear Medicine, Screening Mammography, and certain procedures integral to, and performed during, nonradiology procedures)
- Radiation Therapy
- Durable Medical Equipment
- Parenteral and Enteral Nutrients, Equipment and Supplies
- Prosthetics, Orthotics, and Prosthetic Devices and Supplies (excluding ASC implants and post-cataract eyewear)
- Home Health Services
- Outpatient Prescription Drugs
- Inpatient and Outpatient Hospital Services (excluding physician services not included in hospital component)

NEED FURTHER INFORMATION?

For more information on this or other health care related issues, please contact one of the following Health Care attorneys:

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