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INTRODUCTION
On January 4, 2001, three years after publishing the proposed rule, HCFA has begun to issue a final rule implementing the federal statute prohibiting certain physician referrals. Familiarly called the "Stark law" after it's chief Congressional sponsor, Representative Fortney "Pete" Stark (D-Calif.), the law prohibits physicians from referring Medicare and Medicaid patients to entities for the provision of certain designated health services (DHS) if the physician or an immediate family member has a financial relationship in that entity. The entity cannot bill Medicare, Medicaid, the patient or any other third party payer for those services if a financial relationship exists.

The Stark law was originally enacted in two parts. Stark I prohibited physician referrals for clinical laboratory services in which the physician or an immediate family member had a financial interest. A final rule implementing this part of the law was published in August 1995. Stark II, enacted as part of the 1993 Omnibus Budget Reconciliation Act, expanded upon the original statute by adding other DHS. While the law became effective in January 1995, providers' only legal guidance until now has been the Stark I final rule.

HCFA states that this interim final rule is "Phase I," since it does not fully implement all of the law. Only sections (a) Prohibition Of Certain Referrals, and (b) *General Exceptions To Both Ownership And Compensation Arrangement Prohibitions*, "and related definitions, as applied to the Medicare program" are implemented through this phase of the final rule. The remaining sections—basically pertaining to ownership and investment interests and other compensation arrangements and the Medicaid program—will be finalized in "Phase II" of the rulemaking process.

While the basic premise of the Stark law was clear, the statute contained numerous exceptions to the prohibition. These exceptions have been the subject of many diverse interpretations over the years. To some extent, the confusion was not alleviated by HCFA's publication of the proposed rule. In response to the massive public comments outlining the confusion and limitations of the proposal, HCFA revised and simplified many of the provisions of that proposed rule, thereby giving providers more flexibility in some situations.

Notwithstanding HCFA's attempt to simplify the regulation, HCFA also acknowledged that providers might need time to "restructure" their business arrangements to comply with the regulation. Therefore, with the exception of the prohibition of referrals for home health services (which

becomes effective February 5, 2001), the rule does not become effective for one year.

HOME HEALTH SERVICES
There is no change in the interim final rule from the proposed rule prohibiting physicians from certifying or recertifying the need for home health services "if the services will be furnished by a home health agency in which the physician has a significant ownership interest or with which the physician has a significant financial contractual relationship." Of particular note, HFCA reiterated that the "five percent ownership limit and the $25,000 limit on financial or contractual relationships" were removed from the regulation. Again, this section of the interim final rule is effective February 5, 2001.

THE DESIGNATED HEALTH SERVICES
There are 10 specific DHS for which referrals by physicians who have financial relationships with the entity providing the DHS are prohibited: clinical laboratory services; physical and occupational therapy and speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

One of the largest areas of confusion was what constituted a specific DHS. To alleviate the confusion and provide some closure, HCFA included an addendum to the rule listing the specific procedural codes that constitute prohibited services for clinical laboratory services; physical and occupational therapy and speech-language pathology services; physical and occupational therapy and speech-language pathology services; radiology and certain other imaging services; and radiation therapy services and supplies. This addendum will not be included in the *Code of Federal Regulations*. Rather, the list will be updated annually as part of the physician fee schedule rule.

Recognizing additional ambiguities as to what constitutes radiology services, the rule states that the following services are not considered DHS:

> (1) X-ray, fluoroscopy or ultrasonic procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;
>
> (2) Radiology procedures that are integral to the performance of, and performed during, nonradiological medical procedures; and
>
> (3) Nuclear medicine procedures.

HCFA originally proposed that the designated health services could not be bundled with other services to circumvent the referral prohibition. Pulling back somewhat from this blanket prohibition, the interim final rule now

states that "DHS do not include services that are reimbursed by Medicare as part of a composite rate." However, skilled nursing facility (SNF) consolidated billing requirements result in the SNFs generally being considered DHS providers. "Accordingly, a physician will not be able to refer Medicare patients who will require DHS to a SNF in which he or she has an ownership or investment," unless another exception to the law applies.

GROUP PRACTICES

The discussion of "Group Practices" is now in a separate section in the rule. HCFA stated its belief that overall "Phase I of this rulemaking is more expansive than our January 1998 proposed rule and affords physicians substantial flexibility in designing and managing their medical practices." Thus, many of the provisions considered by commenters to be too limiting have been revised. Most notably, there is no longer an attestation requirement. The purpose of the attestation was to "warrant" that the group practice met the exception as outlined in the regulation. HCFA determined that this would "impose unwarranted burden on group practices." Instead, groups should document that they are a group practice "in the same manner as any information a furnishing entity must provide" to HCFA pursuant to other regulatory reporting requirements. HCFA also intends "to develop a streamlined 'reporting' system that does not require entities to retain and submit large quantities of data."

HCFA continues to define a group practice as a single legal entity, adding that the

> *single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization.*

The interim final rule expanded the definition of "unified business." According to the Preamble, while there are requisite features—consolidated billing, accounting, and financial reporting—the interim final rule "permits many forms of cost center and location-based accounting, provided that compensation formulae with respect to DHS revenues otherwise meet the requirements of the law."

The interim final rule does not make any changes to the "substantially all" test. In other words, at least "75 percent of the total patient care services provided by group practice members must be furnished through the group." The services must be billed under the group's billing number. Reimbursement must be considered "receipts of the group." The interim final rule continues to except those group plans in designated rural areas from this test. While the proposed rule included only one method by which to measure "patient care services," the interim final rule gives groups alternative methods for that measurement.

Productivity bonuses are acceptable as long as the bonus is not related to the volume or value of referrals of DHS.

DEFINITIONS
In addition to tying the definition of some of the DHS to procedural codes, HCFA made other changes to existing definitions and added new terms.

Centralized building
This is a new term created by HCFA to provide increased flexibility for the in-office ancillary and group practice exceptions. HCFA originally proposed to limit the exception for group practices to the "building that is used by the group practice for the centralized provision of the group's designated health services (other than clinical laboratory services)." In the interim final rule, HCFA defines the new term as a "mobile vehicle, van, or trailer that is owned or lease on a full-time basis … by a group practice and that is used exclusively by the group practice." Moreover, the "group practice may have more than one centralized building."

Consultation
HCFA added this definition in response to public comment expressing concern over HCFA's original interpretation of the term in the Stark I final rule. The new definition is not intended for payment purposes, but "for the very limited purpose of determining when a pathologist's, diagnostic radiologist's, or radiation oncologist's ordering of DHS from a facility with which he or she has an otherwise prohibited financial relationship will not prohibit submission of a claim to Medicare."

Entity
HCFA clarified that the definition of entity "does not include the referring physician himself or herself, but does include his or her medical practice."

Fair Market Value
HCFA clarified this term to state that the bargaining buyers and sellers "are not otherwise in a position to generate business for the other party." The "fair market value" for leases may not take into account the proximity of a referral source, but it may factor in "costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements."

"Incident to"
There are many instances in which "incident to" services are exempt from the referral prohibition. HCFA added this term in its definition section to clarify that it has the same meaning as can be found in the Carriers Manual.

Inpatient and Outpatient Hospital Services
HCFA clarified both definitions to state that "professional services" performed by physicians and other providers are not included in the inpatient or outpatient hospital service "if Medicare reimburses the services independently and not as part of the inpatient or outpatient hospital service." It does not matter that the hospital bills for the service under an assignment or reassignment.

Member of the group
HCFA agreed with comments requesting a more flexible definition of this term as it applies to group practices. To be a "member of the group," the

physician can have direct or indirect ownership in that group. This means that the physician's interest in the group can be held by a professional corporation. The physician can also be a "member of the group" if he or she "substitutes … in exigent circumstances" for a physician who is a member of the group. This is called a *locum tenens* physician. Finally a physician who is an employee of the group is considered a "member of the group." An independent contractor or leased physician is not a "member of the group;" however, an independent contractor physician may be considered a "physician in the group practice" while he or she "is furnishing patient care services … to the group practice under a contractual arrangement with the group practice."

Outpatient prescription drugs
In the proposed rule, HCFA excluded "erythropoietin and other drugs furnished as part of a dialysis treatment." The definition in the interim final rule does not include this exclusion; however, these drugs remain excluded. The provision is incorporated into a broader section outlining other exceptions.

Referral
Just as HCFA excluded the physician him or herself from the definition of "entity," HCFA also excluded from the definition of "referral" any DHS that are performed personally by the physician. A referral occurs, however, if a member of the physician's staff performs the service.

Remuneration – minor billing errors
While there were no substantive changes to this definition in the interim final rule, there is a discussion in the Preamble regarding "minor billing errors" that should be noted. HCFA agreed with the comment that "minor" billing errors "could have large dollar consequences, particularly in situations in which bills are computer generated." Furthermore, the term "should refer to the kind of billing error rather than the sum of money involved." HCFA concluded that it would interpret "'minor billing errors' to cover isolated or infrequent instances in which an administrative error, such as a typographic, keying, or other transcribing error, results in an incorrect charge or bill. Conversely, any patterns of "similar or consistent billing error 'corrections' may suggest improper remuneration and subject the business arrangement to scrutiny."

DIRECT VS. INDIRECT FINANCIAL RELATIONSHIPS
In the interim final rule, HCFA distinguishes between direct and indirect financial relationships. An indirect relationship occurs when there is a chain of at least one entity connecting the referring physician (or immediate family member) to the entity providing the DHS. Notably, the entity providing the DHS may receive payment if it "did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of the indirect relationship.

EXCEPTIONS FOR CERTAIN COMPENSATION ARRANGEMENTS
While most of the exceptions relating to compensation arrangements will be addressed in "Phase II" of this final rule, some changes and additions were included in "Phase I." For example, in the provision allowing cash equivalents totaling no more than $300 per year, HCFA deleted the

requirement that the compensation be no more than $50 at a time. HCFA cautions that the agency will be "watching" how providers use this provision. Furthermore, the gifts are still subject to the provisions in the federal Antikickback Statute.

HCFA also noted several comments regarding how this exception could apply to professional courtesy discounts. HCFA stated that the exception could apply depending upon the cash amount involved in the discount. HCFA is considering adding another exception to the rule to specifically address this issue along with a definition of "professional discounts."

Of particular note, HCFA created a separate provision specifically allowing compliance training provided by a hospital to a physician (or the physician's immediate family) as long as the training is held in the local community or service area. HCFA reasoned that "such programs are beneficial and do not pose a risk of fraud or abuse." The training can cover issues such as billing, coding, reasonable and necessary services, documentation and unlawful billing arrangements.

HCFA also included a new exception for compensation through risk sharing arrangements. HCFA defines these arrangements to include withholds, bonuses, and risk pools. The arrangement must still meet the limitations of the federal Antikickback Statute "or any law or regulation governing billing or claims submission."

OTHER EXCEPTIONS

In-office ancillary services
"In the interests of patient convenience," the interim final rule allows physicians to provide crutches, canes and other ambulating devices needed "to depart the physician's office" as well as blood glucose monitors. The physician or group practice must meet the DME supplier standards.

Academic medical centers
Services provided by an academic medical center are now excluded from the referral prohibition. The referring physician must be a full- or "substantial" part-time employee of the medical center with a faculty appointment at the affiliated medical school.

SUMMARY – NEXT STEPS
In several sections of the publication, HCFA stressed its desire to make these rules as flexible as possible. HCFA acknowledged that Congressional intent was to prohibit those financial relationships that could result in overutilization, and, therefore, changed the focus of the final rule toward that goal. The agency further acknowledged that some of the "provisions of the January 1998 proposed rule did not appear to address overutilization so much as other potential abuses, such as unfair competition." This interim final rule redirects the focus back to overutilization.

Representative Stark has been mindful of the pitfalls of his legislation and has been critical of HCFA over its implementation. In a January 4, 2001,

press release, Rep. Stark stated his belief that

> *The new regulations are a major improvement over earlier proposals. They protect patients and taxpayers while greatly reducing the hassle to providers. As the Justice Department and HHS Inspector General have said, this law has saved the public hundreds of millions of dollars – I would say billions – and prevented patient abuse. Ethical providers will have no trouble complying with these new regulations.*

The January publication is an interim final rule. Public comments will be accepted until April 4, 2001. In addition, HCFA states that this interim final rule is only "Phase I," since it does not fully implement all of the law. HCFA plans to issue a final rule implementing the rest of the law in the near future. Since the preamble states that "Phase II" will include responses to any public comments about "Phase I," it is likely that "Phase II" will be published well after April.

Notwithstanding the regulatory exception for compliance training offered to physicians by a hospital, providers should be cautious when conducting training sessions for physicians. To avoid any possible violation of the Antikickback Statute—a federal criminal statute—the training should be closely connected to the hospital's policies. For example, a hospital that provides coding training to nonemployee physicians should directly connect that training to the hospital's coding policies. The training session should not be a general session about CPT codes and HCPCs. To do so could lead the government to conclude that physicians are gaining an economic benefit—free coding information that would be useful to the physician in other settings—thereby inducing referrals to the hospital, which would violate the Antikickback Statute.

While most of this interim final rule is not effective until next year, providers should begin to take a close look at their arrangements to ensure that they are, at a minimum, on the road toward compliance. Entities currently relying on, or considering relying on the group practice exceptions should have their structures, compensation formulas and compliance plans reviewed by legal counsel to ensure compliance with these rules and to consider the options and advantages remaining to them under the "single legal entity" provision of the Rules. Other issues to consider, for example, is whether, in a group practice setting, there is a centralized billing function. In addition, do entities providing DHS have sufficient knowledge of their referring providers to ensure against indirect financial relationships? These and other questions should be incorporated into each provider's compliance program.

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