The Stark II regulations: an analysis

On January 4, 2001, the Health Care Financing Administration (HCFA) issued Phase I of the long-awaited final regulations implementing the Stark II self-referral statute.[1,2] Stark II prohibits a physician or immediate family member who has a direct or indirect financial relationship with an entity from making referrals to that entity to provide designated health services (DHS) payable by Medicare or Medicaid, unless an exception applies.

To meet an exception, an arrangement must meet all its requirements. Any DHS performed as a result of a prohibited referral cannot be billed to any payer, including the patient. Any physician or entity that violates the Stark II statute may be subject to significant civil penalties and exclusion from participation in all federal health care programs. Stark II violations may also form the basis of a False Claims Act violation (see box for a summary of the Phase I regulations).

PRACTICE SCENARIOS

The purpose of the Phase I regulations is to guide physicians regarding the financial arrangements the federal government will permit with a person or other entity to whom a referral has been made. The Stark II regulations address what is permissible under various arrangements, some of which are straightforward whereas others are highly complex. The following practice scenarios and discussion highlight some of the more common Stark II issues that can arise in the physician office practice setting.

Scenario A: Four primary care physicians are members of a group practice and would like to offer their patients radiologic services in the medical office complex next to their office. The physicians want to be equitable and base compensation on productivity, but each physician's practice pattern is different. One physician does all his own radiologic procedures, and another uses a technician working under the physician's supervision. The other 2 physi-

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Stark Phase I regulation summary

- Clarifies DHS definitions

  Clarifies concept of "indirect financial relationships" and creates a new exception for indirect compensation arrangements
- Substantially broadens the in-office ancillary services exception by easing criteria for qualifying as a group practice and conforming supervision requirements to HCFA coverage and payment policies for specific services
- Expands the in-office ancillary services exception to cover certain durable medical equipment provided to patients in physicians' offices
- Allows shared DHS facilities in the same building where physicians routinely provide services that are in addition to federal and private pay DHS
- Excludes from the "referral" definition those services personally performed by referring physicians
- Creates a new exception for faculty compensation in academic medical centers
- Adds a "risk-sharing" exception for commercial and employer-sponsored managed care plans
- Broadens interpretation of the "volume or value" standard to permit unit of service or unit of time-based payments, so long as the unit of service or unit of time-based payment is fair market value and does not vary over time
- Creates an exception where DHS are furnished by entities that did not know of or have reason to suspect the identity of the referring physician

cians frequently request radiologic examinations for their patients to be performed by others within the practice. The group will see both Medicare and non-Medicare patients. Everyone wants to structure the compensation so it is equitable.

Scenario B: A primary care physician in solo practice would like to offer her Medicare and commercial patients the convenience of obtaining limited clinical laboratory tests at her office. She does not have sufficient patient volume, however, to make the overhead costs affordable. Another sole practitioner in her building would like to offer similar laboratory testing to her patients. Can they share the laboratory expenses, including the equipment and technician, without integrating their practices? What if a physician down the street also wants to share these services?

DISCUSSION

Stark II applies if there is a "financial relationship" and a "referral" to an "entity" for a DHS. Scenario A could involve 2 types of financial relationships: the ownership interest in the group as well as any compensation the physicians receive as employees of the group. In scenario B, each sole practitioner's share of expenses is a financial relationship. Although the physicians in scenario B will be making referrals for DHS because clinical laboratory tests are DHS and will be performed by an employee or independent contractor, not all the physicians in scenario A are making referrals. Radiographic studies are DHS; however, only 3 of the physicians are making referrals because they are not personally performing the radiologic studies (see next box for definitions of key terms).

Physicians in situations similar to those in scenarios A and B generally rely on the in-office ancillary services exception to permit their DHS referrals to their practices. This exception applies to both sole practitioners and group practices, but group practices must also meet the regulatory definition of a group practice. In complying with the group practice definition, the physicians in scenario A must recognize the definition's prohibition against using a compensation methodology that *directly* compensates physicians for referrals of DHS performed by someone else within the group. A compensation mechanism does not directly consider the volume or value of DHS referrals if no direct correlation exists between the physician's total compensation and the volume or value of the physician's DHS referrals. Examples of permitted compensation are per capita distribution of overall profits, distribution of overall profits and productivity bonuses based on the distribution methodology for non-DHS or on relative value units or total patient encounters (see box for criteria to define group practice).

The in-office ancillary services exception allows DHS to be furnished in clinic settings provided the provision,

Key definitions

- *Financial relationship* includes direct or indirect ownership or investment interests held through debt, equity, or other means and any compensation arrangement involving any remuneration, whether direct, indirect, overt, covert, in cash, or in kind
- *Entity* includes the physician's solo practice or group practice or any other person or entity organized to provide DHS. An entity does not include the referring physicians individually.
- *Referral* includes DHS performed by the referring physician's employee or independent contractor or other physician owner, but does not include DHS personally performed by referring physicians
- *DHS* include clinical laboratory studies; physical therapy; occupational therapy; radiology; radiation therapy and supplies; durable medical equipment; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health; outpatient prescription drugs; and inpatient and outpatient hospital services. Certain DHS are classified by specific Current Procedural Terminology (CPT) and HCFA Common Procedural Coding System (HCPCS) codes; others are defined by HCFA regulation.

Group practice definition

- Must consist of 2 or more physicians organized as a single legal entity for the primary purpose of being a group practice
- Each physician member (owners and employees) furnishes, through joint use of shared office space, facilities, equipment, and personnel, a substantial portion of the full range of services routinely offered by the physician
- At least 75% of the physician member's total patient care services are furnished through the group and billed under the group billing number, and amounts received are treated as group receipts
- The overhead expenses and income of the practice are distributed by predetermined methods
- The group must be a unified business with centralized decision-making and utilization review and with consolidated financial systems.
- No member directly or indirectly receives compensation based on the volume or value of referrals by the physician, except as permitted for distribution of overall profits and productivity bonuses
- Members must personally conduct at least 75% of the physician-patient encounters

In-office ancillary services exception

- DHS are furnished personally by the referring physician, another physician in the same group practice, or an individual supervised by the referring or other physician, provided the supervision complies with all other applicable Medicare payment and coverage rules
- DHS are furnished in either a centralized building that is used by the group practice for the provision of some or all of the group practice's DHS or in the same building, but not necessarily the same space or part of the building, in which (a) the referring physician (or another physician in the same group practice) furnishes at least 75% of his or her total patient care services and provides, substantially, the full range of physician services unrelated to the furnishing of DHS payable by Medicare, any other federal health care payer, or private payer, even though the unrelated services may lead to the ordering of DHS, and (b) the receipt of DHS (whether payable by a federal health care program or private payer) is not the primary reason the patient comes in contact with the referring physician or group practice
- DHS are billed by the physician performing or supervising the DHS, the group practice of the performing or supervising physician using the group practice's billing number, or an entity—wholly owned by the performing or supervising physician or by his or her group practice—under the entity's, the physician's, or the group practice's billing number

location, and billing requirements are satisfied. In scenario A, the provision requirement can be met if the referring physician, another physician in the group, or an individual (such as a technician) directly supervised by the referring or other physician furnishes the DHS. In scenario B, only the referring physician or the technician can furnish the DHS (see box). Medicare's payment and coverage rules for the DHS determine the level of supervision required.

All DHS must be furnished either in the "same building" as the physician's office practice or in a "centralized location." "Same building" means the same street address as the physician's office practice. Mobile vans and trailers located in a parking lot will not qualify. A "centralized" location may be all or part of a building, or a mobile vehicle, van, or trailer if owned or leased on a full-time exclusive basis by the group for at least 6 months. Independent physicians can share DHS facilities located in the same building, but cannot share centralized facilities. The physicians in scenario A will have to meet the centralized location requirement. The physicians in scenario B will have to meet the same building requirement, and the physician with the office down the street will not be able to participate.

Finally, the performing or supervising physician, the group practice, or a wholly owned DHS entity must bill the DHS. The physicians in scenario B will be required to bill separately, whereas those in scenario A likely will bill under their group practice's number. Medicare's payment, coverage, and billing rules will ultimately control which options may be used, and physicians should consult their local carrier to confirm which rules will apply.

EFFECTIVE DATE

Physicians have until January 4, 2002 to change any arrangements that no longer comply with the Stark II referral prohibitions because of the Phase I regulations. HCFA cautions, however, that the Stark II statutory prohibitions remain in full force and effect in the interim; anyone not complying with the law may be subject to penalties and sanctions now. Because penalties may be imposed, physicians should consult with an attorney with expertise in these issues before entering into any arrangements covered by Stark II.

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References

1 Phase I, 66 *Federal Register* 855-965 (January 4, 2001).
2 Stark II, 42 USC §1395nn (1999).