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FAST FACTS 28

STARK II: HCFA PUBLISHES PROPOSED REGULATIONS

On January 9, 1998, the Health Care Financing Administration (HCFA) published proposed regulations implementing Stark II (Vol. 63, No. 6, pp. 1659-1728). The Stark II legislation expands federal self-referral legislation to cover additional ancillary services, including:

- physical and occupational therapy services;
- radiology services, including magnetic resonance imaging, computerized axial topography scans, and ultrasound services;
- radiation therapy services and supplies;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices;
- home health services;
- outpatient prescription drugs; and,
- inpatient and outpatient hospital services.

Throughout the remainder of this Fast Facts these services are referred to as "designated health services."

The law and proposed regulations prohibit physicians (or an immediate family member) who have a financial relationship with an entity from referring a patient to that entity for the ancillary services covered by Stark II. In addition, if the entity receives a prohibited referral it cannot submit the claim for Medicare payment. Both the referring physician and the entity can be prosecuted if the Stark II law is violated. Physicians are most familiar with these requirements as they pertain to clinical laboratory tests.

The Stark II rules are vast and cover a wide variety of ownership and compensation arrangements. They incorporate, clarify, and revise the requirements of the original Stark I rules and expand the requirements to the additional designated health services.

Physicians should consult with their attorneys when entering or evaluating existing ownership and compensation arrangements with any entity providing the health care services now covered by the Stark II regulations.

In-Office Ancillary Services

Like the original Stark law and regulations, the Stark II law and regulations do include exceptions to the ban on referrals for designated health care services when provided by a physician or group practice as an integral part of their practice of medicine.

According to proposed regulations, solo physician offices and group practices must meet certain supervision, location, and billing tests to be exempt from the ban on referrals.

1. To qualify as in-office ancillary services, the services must be furnished personally by a referring physician or another physician in the same group practice, or be furnished by individuals who are "directly supervised" by one of these physicians.

   Direct supervision means supervision by a physician who is present in the office suite in which the services are being furnished, throughout the time they are being furnished, and immediately available to provide assistance and direction.

   "Present in the office suite" means that the physician is actually physically present. However, the physician is still considered "present" during brief

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unexpected absences as well as during routine absences of a short duration (such as during a lunch break), provided the absences occur during time periods in which the physician is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirements in the Medicare program for a particular level of physician supervision.

HCFA recognizes that Stark supervision requirements deviate from those used for Medicare coverage purposes. HCFA indicates that many issues related to physician proximity for direct supervision (e.g., can a physician supervise services performed on another floor) will be left to local Medicare carriers.

2. Also, the services must be furnished in either of the following:
   a. A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services.
   b. In the case of a referring physician who is a member of a group practice in another building that is used by the group practice for either of the following:
      i. Furnishing some or all of the group's clinical laboratory services.
      ii. The centralized provision of the group's designated health services (other than clinical laboratory services).
3. The ancillary services must be billed by one of the following:
   a. The physician performing or supervising the services.
   b. A group practice of which the physician is a member under a billing number assigned to the group practice.
   c. An entity that is wholly owned by the physician or group practice.

Group Practice Exceptions

Stark explicitly defines "group practice" as a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association that satisfies certain standards discussed next.

The following are some of the key provisions regarding group practices in the proposed rule:

- In the proposed rule, HCFA defines "members of the group" as physician partners and other physician owners (including physicians whose interest is held by an individual professional corporation) and full-time and part-time physician employees. These physicians are "members" during the time they furnish "patient care services" to the group.
- HCFA has excluded independent contractors from its definition of "member." This change will preclude independent contractors from supervising designated health services if the group intends to utilize the in-office ancillary services exception.
- 75 percent of the patient care services of the group practice members are billed under a billing number assigned to the group. HCFA proposes to interpret "under a billing number assigned to the group" to permit a group or a wholly-owned subsidiary of the group to have more than one billing number.

Reporting Requirements

Stark provides that each entity providing Medicare-covered services must provide the Secretary of the Department of Health and Human Services with information concerning all of its financial relationships (ownership, investment, and compensation arrangements) with physicians (including the names and unique physician identification numbers (UPINs)) or immediate relatives of physicians. The entity must provide the information in such form, manner, and at such times as the Secretary specifies.

The Proposed Regulations would require an entity to report on virtually all arrangements that fall within the scope of the statute, regardless of whether they meet an exception. HCFA is developing a procedure for implementing the reporting requirements and, therefore, until affected parties are notified about the procedure, they are not required to report.

Medicaid

The Proposed Regulations delegate to the states the responsibility of precluding providers from billing Medicaid for designated health services that would be precluded under Stark if covered by Medicare. While HCFA is not directly applying Stark regulations to the Medicaid program, you can expect that the states will likely begin applying the Stark rules to Medicaid covered services.

COLA will continue to monitor the development of the final regulations as well as state legislative and regulatory activity of referrals which may affect Medicaid and other third-party payers.

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