Final Stark I Regulations are Here – Finally!

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On August 14, 1995, the Health Care Financing Administration (HCFA) published the much-promised final regulations implementing the original physician self-referral law, which was also known as “Stark I.” Even though the final Stark I regulations (“the Regulations”) had an effective date of September 13, 1995, HCFA allowed a sixty-day comment period that ended October 13, 1995. The effective date of the Regulations came three years after the effective date of Stark I, and nine months after the effective date of the amendments to Stark I, which have been dubbed “Stark II.”

The Regulations reflect significant changes from the proposed Stark I regulations of March 11, 1992. Many questions that have been raised regarding the interpretation of the statute are now answered, but the Regulations have also raised a number of other issues that require further clarification. The Regulations will have a substantial impact on the structuring of arrangements between health care entities and physicians, as well as the interrelationships of physicians in group practices.

Brief Statutory History

In an effort to reduce overutilization of laboratory services by physicians with financial interests in clinical laboratories, Congress passed the Ethics in Patient Referrals Act, which became commonly known as the “Stark” law after its sponsor, Representative Fortney “Pete” Stark of California. Stark I, which acquired its numeral after an expanded version of the statute was passed in 1993, prohibited physicians that have a financial relationship with an entity from referring any Medicare patients to that entity for clinical laboratory services absent a specific exception. Stark I took effect on January 1, 1992, and the proposed Stark I regulations followed on March 11, 1992.

In August 1993, Congress significantly amended Stark I, thus creating “Stark II,” which expanded the Stark I ban on self-referral for clinical laboratory services to include referrals of Medicare and Medicaid patients for eleven “designated health services.” The designated health services of Stark II are:

1. Clinical laboratory services
2. Physical therapy services
3. Occupational therapy services
4. Radiology services, including MRIs, CAT scans, and ultrasound services
5. Radiation therapy services and supplies
6. Durable medical equipment and supplies
7. Parenteral and enteral nutrients, equipment and supplies
8. Prosthetics, orthotics and prosthetic devices and supplies
9. Home health services
10. Outpatient prescription drugs

11. Inpatient and outpatient hospitalization services

The effective date for most of Stark II was January 1, 1995.

The Regulations

Although the Regulations specifically address only clinical laboratory services and not the designated health services of Stark II, HCFA has taken the position that the Regulations would establish the parameters of its reviews of referrals involving any of the designated health services. In appropriate cases, HCFA intends to rely on the language and interpretations in the Regulations when reviewing referrals for designated health services. “Appropriate cases” are those in which interpretations of the statute apply equally to situations involving referrals for clinical laboratory services and any other designated health services.

Group Practice

There is a significant exception to the Stark statute for referrals between physicians if the physicians are in a "group practice" that meets the statutory definition. The Regulations contain several changes in the group practice definition from the proposed Stark I regulations. One of the requirements for a group practice is that "substantially all" of the patient care services of the physicians who are members of the group be furnished through the group and billed in the name of the group. The proposed Stark I regulations had set the "substantially all" threshold at 85% of the total patient care services of the group members. The Regulations lowered this threshold to 75%. In the comments, HCFA provided a precise formula for determining whether the 75% threshold is met. The measure for this percentage test is the time spent by the group practice physicians addressing the medical needs of specific patients, whether or not they involve direct patient encounters. Consequently, to meet the requirements of the "substantially all" threshold, physicians that spend less than 100% of their patient care time in a group practice will have significant timekeeping responsibilities.

The Regulations clarify that a "member" of a group practice includes physician partners and full-time and part-time physician contractors and employees during the time those contractors and employees furnished services to patients of the group practice. With the expansive definition of the term "member," even a contracting physician may supervise services provided in an in-office clinical laboratory. However, the services of such contracting physician must be counted in determining whether the group practice meets the 75% threshold of the "substantially all" rule. Therefore, a contracting physician who devotes only 10% of documented time to the group practice could significantly decrease the group’s chances of meeting the 75% threshold. Group practices will also be required to submit an annual attestation that the 75% threshold is met for the total patient care services of the group practice members and that such services were billed under the group provider number and, finally, that the amounts received were treated as receipts of the group. New practices must also attest that they will meet such standard.

HCFA’s comments on the qualification of legal entities under the group practice definition are controversial and will affect the organization of a number of group practices if applied without modification. In the comments to the Regulations, HCFA suggests that it does not view "interrelated organizations" as a single group practice because Stark I’s definition of group practice "clearly contemplates only single legal entities." HCFA did not reference to any corporate statutes or state medical practice acts when coming to this conclusion. Therefore, according to such an interpretation, the group practice definition would not encompass a partnership if the partners are separate legal entities (e.g., a partnership of professional associations), even if the partnership met all the other requirements for a group practice. When questioned about this issue, a HCFA representative indicated that there is some possibility that HCFA might further clarify its position on this issue. Importantly, HCFA stated that if a regulation or the statute was not clear on its face, it would not be enforced.
Isolated Financial Transactions

The exception for isolated transactions, such as a one-time sale of a practice to a hospital, was clarified by the Regulations. The Regulations add a requirement that there can be no additional transactions between the parties for six months after the isolated transaction, except for transactions that specifically meet other Stark exceptions. Unfortunately, HCFA has also taken the position that an isolated transaction must involve only a single payment between the parties. Therefore, according to HCFA, a transaction that involves installment payments is not considered an isolated transaction, because it results in an ongoing financial relationship between the parties. This interpretation will have a significant impact on many existing financial relationships, including health care entities' purchases of physician practices with installment payments.

Services Furnished in Certain Settings

HCFA has added new Stark exceptions for services furnished in an ambulatory surgical center, end-stage renal disease facility, or a hospice, provided that such services are reimbursed by Medicare through the ASC rate, the ESRD composite rate, or as part of the per-diem hospice charge. According to HCFA, these inclusive rates are a sufficient deterrent to abuse, because the Medicare program pays only a set amount to the facilities regardless of the number and frequency of laboratory tests that are ordered.

Shared Laboratories

Unfortunately, HCFA did not create an additional exception for physicians who practice in the same building (but not the same group practice) and who operate a "shared laboratory."

Physicians will only be permitted to refer patients to a laboratory as long as the referrals otherwise fall within the in-office ancillary services exception, which requires, among other things, each physician's direct personal supervision of the laboratory tests or the technician performing the test.

Reporting Requirements

The Regulations also establish the reporting requirements under the Stark statute. Entities furnishing items or services for which payment may be made under Medicare must submit information to HCFA regarding their financial relationships with physicians. Failure of an entity to submit this information can result in a civil monetary penalty of up to $10,000 for each day that the information is not submitted. However, until HCFA issues the relevant reporting forms, these reporting requirements will not be effective.

Conclusion

The Regulations add as many questions as they answer. Despite the promise of further rulemaking and possible clarifications, HCFA has not indicated when these questions will be addressed. HCFA is currently preparing proposed regulations for Stark II, but the expanded list of designated health services has made this task difficult and time-consuming. In addition, the House is considering a bill that would drastically reduce the list of designated health services covered under the Stark law and eliminate the restrictions on compensation arrangements. Consequently, further change is inevitable. Nonetheless, for now, the Regulations, which obscured almost as many issues as they clarified, will be the health industry's only guide through the Stark maze.

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