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STARK III: Refinement NOT REVOLUTION (PART 1)

Find out how the latest round of self-referral regulations affects your practice.

The final Stark III regulations, which went into effect on Dec. 4, hardly justify the panic that preceded their release. On the other hand, they do raise significant issues for physicians in group practices and for relationships between physicians and hospitals by clarifying and refining matters that were addressed in the interim final regulations published in 2004, known as "Stark II, Phase II." This article is the first in a two-part series on Stark III. This first article addresses the significant issues for physicians in group practices. The second article, to be published in a future edition of *FPM,* will address the issues that arise from relationships between hospitals and physicians.

History

The original Stark statute, then known as the "Ethics in Patient Referral Act," took effect in 1992 and became known as "Stark I" (for its author, Rep. Pete Stark, D-Calif.) only after Congress made substantial additions to the range of services covered by the statute. The expanded statute, known as Stark II, took effect in 1995. The Stark II, Phase I regulations were published in 2001 but failed to take into account all of the exceptions under the law. We had to wait another three years for the Stark II, Phase II regulations to provide clarification and an additional three years for the now final regulations in Stark III.

The "Stark II" statute prohibits a physician or his or her immediate family members from referring a Medicare patient to any entity with which the physician or family member has a financial relationship when the referral is for a hit list of "designated health services" (DHS), unless the transaction meets an exception. (For a list, see "Designated health services" on page 27.) The definition of a "referral" is very broad. It includes any request for a service, item or good paid for under Part B and any services that flow from such a request and fall within the category of DHS, including the development of a treatment plan. As a result, the Stark statute reaches directly into the operation of physician practices, primarily in terms of compensation and the use of in-office ancillary services.

"Incident to" and diagnostic testing

The Stark statute sets seven criteria that must be met for a group of physicians to qualify as a "group practice" in order to use any exceptions relevant to a group. (For more on these criteria, see "The Stark Truth About the Stark Law: Part I," *FPM*, November/December 2003.) For referrals within a group for DHS services, whether to another physician or for in-office ancillary services, the group's compensation formula must comply with the law, as follows. ➤

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The big change in Stark III is that revenues from diagnostic testing technical components may not be considered "incident to" the physician service.

This article covers Stark III as it pertains to physicians in group practice; a second article covering physicians and hospitals will appear in a later issue of *FPM*.

The final Stark III regulations include few significant changes to the rules.

As the result of one change, clinical lab and imaging tests may not be credited to the ordering/treating physician; instead they must float up into a profit pool for the group.

Physicians may be compensated and given direct credit for services they personally perform, and they may receive a productivity bonus that can include "incident-to" services (that is, services that are incidental but integral to the physician's services to the patient). For a physician to get credit for those services, they must be billed in accordance with Medicare's incident-to standards: There must be a physician service to which the ancillary services are incidental; the services must be provided during a course of treatment in which the physician remains involved periodically; and there must be a physician of the group in the office suite when the services are performed. The supervising physician need not be the ordering or treating physician. The ancillary personnel are invisible on the claim form. The claim looks as though the physician rendered the entire service.

"Incident to" services include the services of all ancillary personnel as well as supplies such as drugs, vaccines, immunizations or allergy antigens. Stark III has clarified that revenues from both the nonphysician services and the drugs themselves can be allocated directly to the treating physician. Similarly, when services provided by nurse practitioners, physician assistants and physical therapists (who may bill for services under their own numbers) are billed using incident-to rules, those revenues may also be allocated directly to the treating physician.

The big change in Stark III is that revenues from diagnostic testing technical components may not be considered "incident to" the physician service. As a result, clinical laboratory and imaging tests (including MRIs, CTs, nuclear imaging tests, PETs and ultrasounds) may not be credited to the ordering/treating physician but must float up into a profit distribution pool for the group.

Evaluation and management (E/M) services performed by nurse practitioners, physician assistants and clinical nurse specialists, however, are not DHS. Even when these services are billed by the physician group using the midlevel providers' own numbers at 85 percent of the Medicare Fee Schedule, and not incident to another physician's services, those revenues may be allocated to the treating physician because they are not DHS. Physical therapy, however, is a DHS, so services provided by a physical therapist not incident to a physician's services may not be allocated to the doctor.

Hospital visits shared between physicians and midlevel providers allow the midlevel to round on the patient and even perform the bulk of a visit. If the physician goes to the hospital later and performs some aspect of the E/M service face-to-face with the patient, everything the midlevel did can be merged with what the physician did and billed under the physician's number. Even though the physician and the midlevel provider may not share a consult, this sounds very much like "incident to" billing. Medicare insists that it is not. As a result, the services that are included under the physician's number for this billing count as services personally performed by him or her and can be directly allocated to the physician.

The profits from DHS that cannot be allocated directly to a physician must be allocated in a way that does not reward the volume or value of DHS referrals. In a larger group, pods of a minimum of five physicians can be established to share profits. The overall profits of the group may be shared among everyone, or any component of the DHS profits may be shared among any group of at least five physicians. For example, a group could decide that

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DESIGNATED HEALTH SERVICES

There are 11 categories of DHS that are subject to the Stark law's referral restrictions. For the complete and updated list, sorted by CPT code, go to http://www.cms.hhs.gov/physicianselfreferral/11_list_of_codes.asp.

1. Clinical laboratory services;
2. Physical therapy services;
3. Occupational therapy services;
4. Radiology services including MRI, CT, ultrasound, nuclear imaging and PET;
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 hospital services.

not everyone will share in the diagnostic testing profits or the physical therapy profits, as long as the pool of physicians that does share those revenues has at least five members.

Formulas to make those allocations cannot reward any physician directly for the volume or value of his or her DHS referrals. So looking to non-DHS productivity can be useful. Measures such as the proportion of practice E/M services that the physician provides or the proportion of practice RVUs (excluding RVUs of DHS) or even the proportion of total non-DHS revenues may be the basis for profit allocations. As long as DHS is excluded from the basis for the allocation and no physician is rewarded for the volume or value of DHS referrals unless they are incident to his or her services, the compensation complies. For a group of less than five physicians, though, the profits must be allocated the same way among all physicians and may not directly reward volume or value of DHS referrals.

Other in-office ancillary services

The Stark III regulations did not really change the in-office ancillary services rules. But the regulators did express concern that independent contractor physicians, who can order, perform and supervise DHS and be paid on a productivity basis for any of the DHS services they provide, must now have a direct contractual relationship with the group that bills for them. The government feels that this will help groups control the physician more directly than they could if their contract was with a staffing company.

Stark III also clarified again that the independent contractor is only "in the group" when he or she uses the group's premises. Therefore, using telemedicine to transmit images to an off-site independent contractor physician will not comply with the in-office ancillary services rule. For example, if a family practice uses the services of an outside radiologist to read imaging studies taken at the family practice, the independent contractor radiologist must come to the family practice's office to do the readings if the family practice wants to bill for the interpretations. By contrast, if a group practice has multiple offices and uses telemedicine within the group to transmit images, the interpretation of an image that is transmitted by telemedicine for reading within the group's own premises will comply with the law.

Intra-family referrals

In today's world, it is not unusual for physicians' family members – including spouses, children, parents and siblings – to all be professionals or involved in health care in some way. Because Stark prohibits a physician or a family member from referring a patient for DHS to an entity with which another immediate family member has a financial relationship, referrals can be difficult in some communities. For example, if a family physician is married to a radiologist with an imaging center, or if a family physician's son owns a home health agency, the family physician may not refer patients to either entity unless the arrangement meets Stark's intra-family referral exception. In Stark II, Phase II, the regulators allowed the referral if there is no alternative

Stark III did not change the in-office ancillary services rules, but it did provide more details on them.

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Stark III includes an intra-family referral exception if there is no alternative resource within 45 minutes of the patient's residence.

The Centers for Medicare & Medicaid Services has begun to enforce the statute but has not yet reached into physician groups.

provider within 25 miles of the patient. Stark III offers an additional option: The physician may make the referral if there is no alternative resource within 45 minutes of the patient's residence. Astonishingly, the regulators recognize that the 45-minute test will have seasonal applicability in places with snow or hurricanes. For example, a physician wants to refer to her husband's imaging center, which is 15 miles from the patient. In the winter, when icy roads can cause the trip to take longer than 45 minutes, and there is no other alternative, the referral is fine. In the summer, it would not be.

The Stark statute has a very liberal definition of what constitutes a "rural" provider.

Referrals and claims that violate the Stark statute are subject to harsh penalties, including a $15,000 civil penalty.

Rural physicians

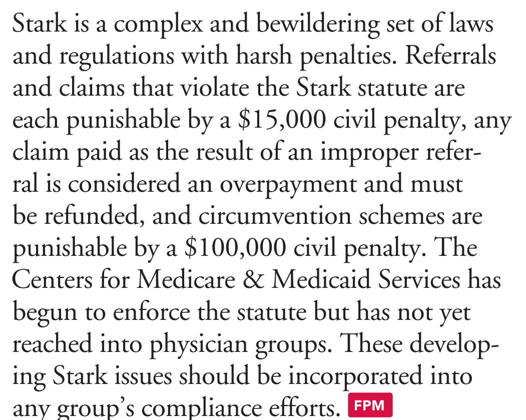
The Stark statute allows a physician to refer a patient for DHS to an entity that the physician or a family member has invested in as long as the entity qualifies as a "rural" provider and 75 percent of its patients come from rural areas. The standard here is very liberal: Stark III has restated that a rural area is any place outside of a metropolitan statistical area as determined by the U.S. Census Bureau. For example, Hilton Head, S.C., is classified as a "micropolitan" area, which is smaller than a metropolitan area, and therefore open for physicians to have invested in DHS entities to which they refer. The Census Bureau posts its most current list of metropolitan areas online at http://www.census.gov/population/www/estimates/metrodef.html.

Keep in mind, however, that this provision pertains exclusively to the referral based on the investment interest and does not change any of the other applicable rules associated with the operation of the entity.

Permissible conditions on referrals

Many groups have been under the impression that Stark precludes them from requiring their physicians and employees to refer patients in accordance with their established referral patterns to their preferred physicians and other providers. On the other side of the table, many physicians complain when larger entities, such as big hospital systems that now employ physicians, require that their physicians refer within their system. The Stark III regulations specifically acknowledge the legitimacy of restricting referrals in these ways, but only under the employment, managed care and personal services exceptions.

Conclusion



Stark is a complex and bewildering set of laws and regulations with harsh penalties. Referrals and claims that violate the Stark statute are each punishable by a $15,000 civil penalty, any claim paid as the result of an improper referral is considered an overpayment and must be refunded, and circumvention schemes are punishable by a $100,000 civil penalty. The Centers for Medicare & Medicaid Services has begun to enforce the statute but has not yet reached into physician groups. These developing Stark issues should be incorporated into any group's compliance efforts. FPM

Send comments to **fpmedit@aafp.org.**

SUGGESTED READING

"Ten Myths About the Stark Statute Debunked." Gosfield AG. *Journal of Medical Practice Management*. January/February 2004:200-203.

"The Stark Truth About the Stark Law: Part II." Gosfield AG. *FPM*. February 2004:41-45.

"The Stark Truth About the Stark Law: Part I." Gosfield AG. *FPM*. November/December 2003:27-33.

"AGG Notes" on the Stark regulations available online from Alice G. Gosfield and Associates at http://www.gosfield.com/notes.