What surgeons should know about...

The new Stark Phase II rules

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The Centers for Medicare & Medicaid Services (CMS) released a regulation on March 26 implementing additional provisions of the physician self-referral law and making some changes in the existing rules. The self-referral legislation is better known as the "Stark" law, in reference to its principal congressional sponsor, Rep. Fortney "Pete" Stark (D-CA). The new rule, known as the Stark Phase II regulation, becomes effective July 26. The purpose of this article is to notify surgeons about the scope of the changes, but it is not a substitute for legal advice.

What were the purposes of the Stark law?

The self-referral law is intended to protect the public from referral patterns for certain services in which the physician or a member of the physician's family has a financial interest. The scope of the law is very broad, defining what are acceptable physician compensation arrangements and other financial arrangements between physicians and certain other health providers.

Congress passed the Stark law after a number of studies showed that physicians who had an ownership interest in entities to which they referred ordered some services in excess. The original law, passed in 1989, was limited to clinical laboratory services, but the expanded bill now in effect was passed in 1993. The amended bill extended coverage of the Stark rule to nine additional services and extended portions of the restrictions on referral to the Medicaid program.

This law is closely linked to the federal Anti-Kickback Statute, which prohibits offering or taking a kickback to induce a referral. The two laws cover much of the same turf , but the federal Anti-Kickback Statute requires "wrongful intent" for violation of its law and a violation is a criminal matter. On the other hand, the Stark law does not require wrongful intent and a violation is considered a civil matter rather than a criminal one.

Why is the government issuing these new regulations?

The first of the regulations implementing the expanded 1993 statute were not issued in final form until 2001. It took slightly more than three additional years for CMS to develop the Stark II regulation, which refines existing exceptions, adds new ones, and sets the reporting requirements and sanctions. In the new regulation, CMS has continued the practice started in Stark Phase I of interpreting the prohibitions on referral narrowly and the exceptions, where a referral is permitted, broadly.

The regulation continues to have a very broad definition of the physician's immediate family and no exceptions are provided. (See Table 1, page 9, for a list of immediate family members.) For example, the regulation does not create an exception for a relative on the list who does not live in the same household as the physician. The law says no referral may be made for any of 10 designated heath services (DHS) unless an exception exists in the regulation. (See Table 2, page 9, for a listing of DHS.) Needless to say, exceptions are at the heart of Stark Phase II, as they were with Stark Phase I. There are three categories of exceptions: those related to the prohibition on referrals, those related to ownership or investment, and those related to compensation arrangements. (See Table 3, page 10, for a complete listing of the exceptions.)

What are some of the new exceptions offered in Stark Phase II?

A new exception was created for physicians to participate in communitywide health information systems. Health information systems must be available to everyone in their communities who wants to use them, and they must allow electronic records to be exchanged among providers and practitioners in those communities.

Some observers have noted that "community" is undefined, so controversy may ensue regarding how wide a community must be. Not only does this provision apply to electronic medical records, but it also may include complementary drug information systems, general health information, medical alerts, and related information for patients. The physician may use both hardware and software under this exception.

To better meet the needs of rural residents, an additional exception has been created for intrafamily rural referrals. This exception has been created for cases where no other entity furnishes the DHS within 25 miles of the patient's home. If the patient is getting in-home care, the exception applies if no DHS entity is available "in a timely manner in light of the patient's condition." There are also newly created exceptions for physician retention payments from hospitals, from federally qualified health centers, and from practices in health professional shortage areas (HPSA).

What other changes are made in the Stark Phase II regulations?

A grace period of up to 90 days has been established for arrangements that have fallen out of compliance for reasons beyond the control of the DHS entity. This will be particularly useful in situations such as loss of rural or HPSA designations or delays in obtaining signed copies of renewal agreements.

Table 1.
Definition of immediate family member

- Physician's husband or wife
- Birth or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law
- Grandparent or grandchild
- Spouse of a grandparent or grandchild

Table 2.
Designated health services (DHS)

- 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
- Inpatient and outpatient hospital services

Note: The CPT codes included in each category of services appears on the ACS web site at: *http://www.facs.org/ahp/cptcodes.pdf.*

The Stark law says financial arrangements between a physician (or a family member) and an entity may be direct or indirect and includes both ownership and investment interests as well as compensation arrangements. Direct financial relationships occur when there is no person or entity imposed between the entity furnishing DHS and the physician (or family member); indirect financial relationships occur when at least one person or entity separates the physician or a family member from the entity furnishing DHS. The Stark II

Table 3.

Exceptions to the Stark Phase II regulation

Prohibition on referrals does not apply to:
• Services that are provided by or under the supervision of the physician or by or under the supervision of another physician in the same group
• In-office ancillary services, including canes, crutches, walkers and folding manual wheelchairs, blood glucose monitors, and infusion pumps (including external ambulatory infusion pumps)
• Services furnished by a prepaid health plan, including a Medicaid HMO
• Services performed by an academic medical center
• Implants furnished by an ambulatory surgical center during surgery, including, but not limited to, cochlear implants, intraocular lenses, other implanted prosthetics and prosthetic devices, and implanted durable medical equipment
• Dialysis-related drugs furnished in or by an end-stage renal disease facility
• Preventive screening tests, immunizations, and vaccines
• Eyeglasses and contact lenses following cataract surgery
• Intrafamily rural referrals
Ownership or investment interests that do not constitute a financial relationship:
• Publicly traded securities
• Mutual funds
• Physician ownership or investment in rural providers and hospitals
Compensation arrangements that do not constitute a financial relationship under certain circumstances:
• Payments for the rental of equipment or office space
• Bona fide employment relationships
• Personal services arrangements
• Physician incentive plans
• Retention payments made to a physician by any hospital or a federally qualified health center in underserved areas
• Isolated transactions (such as one-time sale of property)
• Remuneration provided by a hospital to a physician as long as it is divorced from furnishing DHS
• DHS furnished by a group practice but billed by a hospital
• Payments by a physician to an entity furnishing DHS for items priced at fair market value
• Charitable donation by a physician to an entity furnishing DHS
• Nonmonetary compensation up to $300 per year (to be adjusted by CPI-U each year)
• Fair market value compensation by the entity furnishing DHS to the physician
• Medical staff incidental benefits from a hospital (such as free parking)
• Risk-sharing arrangements between health plan and physician (such as withholds, bonuses)
• Compliance training for a physician conducted in the local community by an entity furnishing DHS
• Indirect compensation arrangements between the receiving physician and the paying entity that furnishes DHS
• Referral services (such as a physician referral service operated by a hospital)
• Obstetrical malpractice insurance subsidies
• Professional courtesy offered by an entity furnishing DHS
• Communitywide health information systems

Note: Remember the word “physician” means physician and family members shown in Table 1.

regulation makes exceptions for physician investment in publicly traded securities and mutual funds and physician ownership of rural hospitals and other facilities.

The fundamental themes of the compensation rules remain the same: most physician compensation must be of fair market value and compensation cannot be related to the value or volume of referrals. The revised regulation clarifies that physician employees may be paid personal productivity bonuses, but not bonuses based on ancillary referrals. The regulations also deem certain hourly compensation arrangements to be at fair market value. Certain fluctuating compensation arrangements are permitted if the compensation methodology is set in advance. Finally, group practice and employed physicians may be paid under risk-sharing arrangements.

The exception for services provided to members of a prepaid health plan had Medicaid health maintenance organizations added to it.

The Office of the Inspector General (OIG) of the Department of Health and Human Services is responsible for protecting the integrity of the Medicare program and, therefore, shares responsibility for enforcement of the Stark law with CMS. In the event information is needed regarding the financial relationships an entity furnishing DHS has with a physician, either CMS or the OIG may request the information. The request is made to the entity, not the physician, and sanctions for violating the law are applied to both. The regulations call for nonpayment for any Medicare claims for DHS and the imposition of civil monetary penalties on physicians and entities that furnish DHS.

Is this the end of the Stark regulations, or will more follow?

A Phase III is to come. CMS has announced that the Stark III regulation will contain most of the Medicaid restrictions on referrals. CMS also will have to respond to comments made on parts of the Stark II regulation.

Where can I learn more about the Stark law and its related regulations?

Material on the Stark law, including the Stark II regulation, is available at *http://www.cms.hhs.gov/physicians,* in the "Physician Highlights" box at the top of the page. CMS will accept comments on certain parts of the Stark II regulation until June 24. The College, of course, will be preparing comments.

The Stark Phase I regulation has had a major impact on the way physicians structure their business arrangements. Now that the Stark Phase II regulation has been published, many physicians will want to, or, more importantly, have to, change the way their practice is structured or their financial affairs. The regulation is welcome because it will generally permit more flexibility in relationships between physicians and other entities and provide many more "bright line" rules than the existing regulation. Any physician who may be affected by the regulation should seek the advice of an attorney, preferably one who specializes in health affairs. Ω