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A physician's guide to Stark rules

We'll give you the ABCs, plus a look at what's changed. Reviews of the new version have been good, but don't lower your guard yet.

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On March 26, the government released the latest version of that hydra-headed monster known as Stark II, named for California Rep. Pete Stark, the author of the 1993 legislation upon which the current Medicare and Medicaid regulations are based.

Like the earlier iteration, Phase II is long, complex, and draconian in its basic prohibition against physician self-referrals. But the latest version is also a lot more reasonable, say experts.

"They've taken the worst piece of healthcare legislation I've seen in my 30 years in the business, and done what they could to make it rational," says Philadelphia attorney Alice G. Gosfield, a former president of the American Health Lawyers Association. Patrick A. Hope, legislative counsel at the American College of Physicians, agrees: "They've been very responsive to comments, ours included, and have made a difficult rule easier. There's much more black and white—and not as much gray."

Greater specificity has its downside, of course.

On the one hand, vaguely worded language has now been clarified, which is good if the less explicit language of earlier versions made you nervous. After all, how do you keep from crossing the line when you aren't sure where that line is? But the new, more precisely worded language is less good if you now find it harder to meet the tougher updated standards. (Most states also have laws prohibiting self-referral. Typically, they apply to Medicaid, state health and workers' compensation plans, and to private health plans.)

And there's other potentially bad news for doctors. "Stark has always been a sleeping giant—but the sleeping giant is now crawling out of bed," says Boston healthcare attorney Lawrence W. Vernaglia, who predicts an uptick in government enforcement activity.

Not coincidentally, just two days before the Centers for Medicare & Medicaid Services published the latest update, the Department of Justice announced a \$22.5 million settlement with Tenet Healthcare for improper Medicare claims stemming from alleged violations of the Stark statute.

With the government's sights trained on big players like Tenet, it would be a mistake for individual doctors to relax, says Vernaglia.

"If you're a doctor in a small practice that has a financial relationship with a larger entity, you can easily get ensnared when the larger entity does," he says. How? Through the whistleblower (or qui tam) provisions of the False Claims Act.

In this physician guide to Stark, we outline the law's ABCs, take a look at the new rules and how they're likely to affect your practice, and give you a list of additional resources.

A kinder, gentler, and clearer Stark II?

For something as complex and sprawling as Stark, its basic message is fairly simple: You can't refer Medicare or Medicaid patients for certain services that you—or an immediate family member—have a financial relationship to—unless an exception applies.

Leaving aside the final phrase for a moment, let's examine each of the key elements in this basic prohibition against physician self-referral.

What constitutes a referral? Under Stark, it's when you request or order certain tests or services, or when you certify the medical necessity for these tests or services. You're also said to make a referral whenever someone you "direct" or "control"—a nurse practitioner or physician assistant, for example—does so. "Incident to" services—that is, services performed by ancillary employees or other group practice doctors under the supervision of a qualified Medicare provider—also constitute a referral. The same is true for services ordered by a consultant, with exceptions under certain conditions for referrals made by pathologists, diagnostic radiologists, and radiation oncologists.

Which health services fall under Stark? There are 11 categories of covered services that are subject to referral restrictions:

- Clinical lab services. Includes the 80000-series CPT codes (except certain blood collection codes) and some Healthcare Common Procedure Coding System (HCPCS) level 2 codes.
- Physical therapy, occupational therapy, and speech-language pathology services. Includes the 97000 series and certain other CPT codes. This category also includes some HCPCS level 2 codes, such as those for evaluation in physical therapy.
- Radiology and other imaging services. Includes X-rays, ultrasound, CT scans, and MRIs, but not nuclear medicine.
- Radiation therapy. Includes some 70000-series CPT codes and other radiation services, but, once again, not nuclear medicine.

- Durable medical equipment and supplies. Includes items identified in the Durable Medical Equipment, Prosthetic/Orthotics, and Supplies (DMEPOS) fee schedule. Also includes HCPCS code E1399, a catchall for DME items not on the fee schedule.
- Prosthetics, orthotics, and prosthetic devices and supplies. Includes items enumerated in the DMEPOS fee schedule, and all HCPCS level 2 codes for these items covered by Medicare.
- Home health services. Generally, these are services provided by a home health agency certified by Medicare.
- Outpatient prescription drugs. Currently, this category includes all drugs covered by Medicare Part B. But observers believe this category will be expanded in the near future, because the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 expands coverage of prescription drugs, creating a new definition for "covered Part D drug."
- Inpatient hospital services. Includes those covered by Medicare (listed in the Medicare payment and coverage rules).
- Outpatient hospital services. Again, those covered by Medicare.
- Parenteral and enteral nutrients and PEN-associated equipment and supplies. Those defined by HCPCS level 2 codes.

What constitutes a financial relationship with an organization providing designated health services? One test looks at whether you have an ownership interest—either directly or indirectly—in the organization that provides the designated health services. Another looks at whether you have an investment interest. A third considers whether you're being compensated either directly or indirectly by the organization. Indirect relationships are especially tricky, since they can trigger Stark in surprising ways.

For instance, some doctors may be tempted to refer patients to an organization that they don't own directly but still have a financial relationship with through one or more intermediate organizations (referred to in Starkspeak as "an unbroken chain of financial relationships"). An example is an imaging facility owned by an IPA that you belong to. If you refer to the imaging facility Stark is in play. Under the old rules, Stark would have applied only if the imaging facility knew about your relationship to the IPA, or had reason to know about it. The latest version of the rule goes a step further, noting that the organization providing designated health services needn't know precisely about each link in the chain or about the specific terms of the investments.

Who's an "immediate family member"? The latest version of Stark left the earlier list unchanged. Beyond the obvious (husband or wife, birth or adoptive parent, child or sibling), it includes stepparent, stepchild, stepbrother, stepsister, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, grandparent, grandchild, and spouse of grandparent or grandchild.

If you ignore the basic Stark prohibition, and then bill CMS for those designated health services, you may be subject to civil monetary penalties of up to \$15,000 for each service, plus twice the reimbursement claimed, and may be excluded from participating in Medicare and Medicaid.

No, you can't—unless the Feds say otherwise

Given the penalties for flouting the law, understanding which exceptions apply—and which should but don't—is crucial.

But that hasn't been easy to do, even for the smarty-pants experts, who've faulted earlier versions of the rules for being at once vague and internally inconsistent. This time around, however, rule makers have taken pains to get things right: They've cleared up ambiguities, softened overly restrictive language, and added to the list of exceptions.

The new material in this latest version of Stark II covers a range of topics. Among those especially relevant to doctors in smaller and moderate-size practices are:

In-office ancillary services. The Stark law permits doctors to offer ancillary services—that is, designated health services that supplement routine patient care. If you did so in the past, you had to meet certain requirements, including "the same-building test," which required that services be offered in the same building where you normally worked (or in a central building, if you were a member of a group practice).

The new Stark II rules expand the definition of "same building." As the referring physician, you can now meet the requirements, as long as you or your group practice has an office in the building that satisfies one of three tests:

The first is fairly straightforward. The office is normally open to patients at least 35 hours per week, and either you or one or more members of your group provides physician and other services to patients in this office at least 30 hours per week.

The second test cuts the minimum number of hours the office must be opened to patients to eight, but requires that you yourself provide physician services in this office at least six hours per week. Among the patients you must see are those receiving ancillary services. (Members of your group practice may also see these ancillary service patients, but that doesn't lessen your obligation to see regular patients in the office at least six hours per week.)

Like the second test, the third also cuts the minimum number of office hours to eight. But it allows that either you or a member of your group practice may offer regular physician services in that office at least six hours per week. In return for this option, you or a member of your group must be present while the ancillary services are being administered.

Many observers say that the new three-part test offers practices with a second location more flexibility. "Rulemakers seem to be acknowledging that doctors in the real world often have more than one office—and that shouldn't preclude them from offering certain

services," says Aaron Krupp, senior counsel at the Medical Group Management Association.

But some interpret the new language differently, arguing that it could end up hurting some practices. "Under the old rules, multiple groups could share a common MRI machine, as long as each group also provided unrelated physician services in this same location on a regular basis," says William H. Maruca, a Pittsburgh attorney and chair of the American Health Lawyers Association Practice Group on Fraud and Abuse, Self-Referrals, and False Claims. "The old rules didn't say how often, but the new ones do, which means some cost-effective arrangements will now have to be restructured."

Physician compensation. When it came to dividing practice revenues, the earlier version of Stark drew a clear distinction between group members, on the one hand, and employed physicians and independent contractors, on the other. The new Stark II rules relax these distinctions, giving nongroup members added privileges in two key areas:

1. Percentage compensation arrangements. Under the earlier version of Stark, independent contractors couldn't be reimbursed based on a percentage of fees from referrals. Now, independent contractors can participate in percentage arrangements on a limited basis, if the methodology for calculating the compensation is set in advance, and if this methodology remains the same regardless of the number of referrals or their value.
2. Productivity bonuses. All doctors—whether group practice members, employees, independent contractors, or academic doctors—are now eligible for productivity bonuses, based on services they perform themselves. Group practices may also pay all doctors other forms of compensation based on productivity, including bonuses for "incident to" services, as long as certain distribution conditions are met.

Nonmonetary compensation. Among the changes in this area, the government has created a new exception for information technology, including hardware and software. For example, if a hospital providing certain designated health services offers you technology to participate in its electronic information system, you can accept it if the system is community wide and open to all (doctors and residents), and if it permits healthcare records to be shared among providers. In addition, the technology can't exceed what's minimally necessary to participate in the system (which may be nothing more than the right computer and software), and it can't be tied in any way to the volume or value of your referrals. Finally, the arrangement can't violate the federal antikickback law. (We'll cover that law in an upcoming installment of this series on Physician's Guides.)

Other compensation arrangements. If a hospital recruits you, the money it pays you to relocate isn't considered a Stark violation, provided that the money isn't tied to the number and value of your referrals, you aren't required to refer patients to the hospital, and you aren't barred from establishing staff privileges at another hospital.

The updated rules clarify several of these points. For example, the definition of "relocate" has been made substantially more flexible, so that you're no longer required to move your actual residence from outside the hospital's geographical area to within it. Instead, you can now meet the relocation standard by either moving your practice at least 25 miles or by recruiting enough new patients so that they constitute 75 percent of your income.

Residents and doctors who have been in medical practice for less than a year are exempt from even these requirements.

If you work in a Health Professional Shortage Area and have your own practice or have been recruited by another facility, your hospital or federally qualified health center may pay to retain you, under certain conditions. First, the offer from the other facility must be in writing and require that you move at least 25 miles, putting you outside of your current facility's geographical area. Second, the payment can't exceed a certain limit (either the difference between your current income and that of the offer, or the "reasonable" costs to recruit someone to replace you, whichever is less).

Rural providers. You can refer a patient to a facility owned by an immediate family member if there's no other facility offering the designated health service within 25 miles of the patient's home. (Stark defines a "rural provider" as someone who furnishes at least 75 percent of designated health services to patients living in a nonurban area, as defined by the US Census Bureau.) Experts say that this new "intra-family" exception demonstrates that rulemakers acknowledge that a different set of standards must apply to the nation's underserved areas.

Temporary noncompliance. If you suddenly and unavoidably fall out of Stark compliance (for instance, unknown to you, your rural area has been reclassified as urban, and yet you've been referring patients to your brother-in-law's imaging facility), the updated rules give you some breathing space. Assuming you've been in compliance for the prior 180 days, the new rules give you up to 90 days to get your act together. One caution: You can take advantage of this grace period only once every three years.

Fair-market value. This exception says that individual doctors or group members who have an "arrangement" with an organization providing designated health services may be compensated, if certain requirements are met. For instance, the arrangement must be in writing and for a specified time period. Similarly, compensation must be set in advance, must be consistent with fair-market value, and must not take into account the value or volume of referrals generated by the referring physician.

While the latest version of Stark leaves the basic exception largely intact, it does revise the meaning of "fair-market value" as it relates to leases and to hourly payments for physicians' personal services. In the area of rentals and leases, for example, the amount a doctor pays for the use of a device or piece of equipment must be consistent with what he would pay in the general commercial market. The organization providing the equipment can't charge a lower rate because it anticipates a potential referral source. In the case of equipment leases only, however, the organization can make adjustments for high-volume users. (A busy practice leasing a chemistry analyzer, for instance, could get a discounted lease without triggering Stark.)

Bona fide employment relationship. Even before the latest revision, Stark permitted doctors to refer to organizations that employed them, if certain conditions are met. (A department chairperson in a university hospital or the medical director of a nursing home facility could fall into this category.)

But since 1998, when the government published the first version of Stark II, these employed doctors weren't permitted to receive productivity bonuses based on their referrals, even for designated health services they performed themselves. The latest version drops that exclusion, permitting doctors in legitimate employment relationships to receive productivity bonuses for services performed by the doctors.

Ownership/investment in publicly traded securities and mutual funds. As noted above, if you refer a patient for designated health services to an organization that you own or have an investment interest in, you risk violating Stark. But what if your financial relationship to the organization is through a publicly traded stock, bond, or mutual fund? In such cases, according to the latest clarification, an exception applies if the securities or mutual funds "may be purchased on terms generally available to the public" at the time of the referral, are listed on recognized exchanges, and involve a corporation in which shareholder equity exceeds \$75 million for the most recent fiscal year or averages that amount for the past three fiscal years.

Physician charitable donations. Stark permits doctors (or immediate family members) to donate to a tax-exempt charitable organization if the donation isn't tied in any way to the volume or value of referrals, and doesn't violate the federal antikickback statute. Broad-based solicitations—such as fundraising campaigns or charity-ball ticket sales that don't target physicians specifically—are included in this exception.

This should be comforting to charity-minded doctors, but the mere inclusion of the charity exception among the others is troubling to some health attorneys. "It lends credence to the idea that any financial relationship can trigger a Stark violation, even if the doctor is paying out money, not receiving it," says health attorney Larry Vernaglia.

A few words of caution

Despite their generally favorable reviews, most experts think it's too soon to give the new rules a final grade. "It will take time to see how all this plays out in the real world," says the MGMA's Aaron Krupp. He's particularly interested in gauging the "true impact" of the updated building test, which he predicts "will probably be for the good."

Whichever way things turn out, it's clear that more than a few existing Stark arrangements will need to be rethought, says Vernaglia.

And experts like Vernaglia caution that doctors should be wary of Stark-related deals that look too good to be true: "A lot of dealmakers are pedaling products to doctors—like X-ray machines, cardiac monitors, lithotripsy machines—and about 50 percent of these deals are bad, from a Stark point of view," he says. "These guys set up some crazy arrangement, and give doctors a ton of money to participate. The government may be after the vendors, but the doctors are breaking the law, too, and they can also get scooped up."

The release of the new Stark rules, says Vernaglia, provides doctors with a golden opportunity: "Re-examine your deals—because, if they violate Stark, you've got a possible out."

Where to get more information

Here are some resources you may find helpful:

- The **American College of Physicians** has **Stark** information on its Web site, www.acponline.org. Click on "Advocacy," scroll down to "Latest News," and then click on "HHS releases Long-Awaited **Stark II**, Phase **II** Final Rule."
- The **Centers for Medicare & Medicaid Services** has established a "Quick Reference Guide," which includes links to the latest rule, a summary of the **Stark** law, a list of current designated health services codes, and other physician resources (www.cms.hhs.gov/medlearn/refphys.asp).
- The **Medical Group Management Association** offers both members and nonmembers a subscription site dealing with **Stark**, www.starkcompliance.com. MGMA members pay \$150 for a 12-month subscription; nonmember cost is \$495. To subscribe, call toll-free at 877-275-6462, ext. 888.
- The **American Health Lawyers Association** (www.healthlawyers.org) makes a wealth of **Stark** materials available. Go to the AHLA Web site, click on "Publications," then on "Browse by Topic," and then on "**Stark**." Also be alert for AHLA-sponsored **Stark** teleconferences, announced under "Features" on the home page.

When in doubt, consult a health attorney specializing in **Stark** and other regulatory issues affecting physicians. The AMA has urged state and local medical societies to make such lists available to members.