More than six years after the statute’s effective date, bearing the weight of over 10,000 comments, the regulations implementing the so-called Stark II law are, more or less, nearly in final form. After years of minimal enforcement, the Justice Department and private plaintiffs are seeking tens of millions of dollars for alleged violations of the Stark law. Put these two facts together, and it becomes clear: The reach of the federal ban on physician self-referrals has grown.

The physician self-referral statute—known as the Stark law after its sponsor, Rep. Fortney “Pete” Stark—prohibits certain referrals by a doctor to an entity in which the doctor has a financial interest. It also precludes Medicaid and Medicare reimbursement for services that result from such prohibited referrals.

The original ban, enacted in 1989, was limited to referrals for clinical laboratory services. The Health Care Financing Administration (HCFA) did not propose implementing regulations until 1992, and these regulations did not take effect until September 1995. Indeed, the Stark I regulations did not take effect until after the enactment of Stark II in 1993.

Stark II dramatically expanded the law, extending the ban to 10 designated health services, including physical/occupational therapy, home health services, and hospital services. Under Stark II, unless one of several defined exceptions applies, a doctor cannot refer a patient to an entity for a designated service if the doctor, or an immediate family member, has an ownership, investment, or compensation relationship with the entity. The entity, in turn, may not make a claim for Medicaid or Medicare reimbursement for a service furnished pursuant to a prohibited referral.

Although Stark II went into effect in January 1995, HCFA did not release proposed regulations for comment until January 1998. These proposals generated nearly 13,000 (mainly critical) comments. Three years and many meetings later, HCFA released a substantially revised proposed Stark II final regulation on Jan. 4, 2001. Even this doesn’t cover all of Stark II (additional regulations will be published later). But it provides guidance on the most contentious issues raised by the public commenters—the basic self-referral prohibition and the main exceptions, particularly the in-office ancillary services exception.

The proposed regulations, with one exception (home health services), will not become effective until early 2002 in order to give providers time to adjust their relationships. And there is still a distinct possibility that this “final” regulation will be modified yet again, as many more comments have been received since January.

On the whole, the 2001 proposal represents an improvement over the 1998 proposal. HCFA stated in its 100 pages of accompanying comments that it sought to “interpret the [Stark] prohibitions narrowly and the exceptions broadly,” and to a large extent it has done so. The 2001 proposal gives providers somewhat greater flexibility in managing their relationships and provides several bright-line tests that should reduce some of the uncertainty that now plagues Stark compliance. Changes in two areas are key.

- **Indirect financial arrangements.** The existence of a financial relationship between the physician (or immediate family member) and the entity furnishing the service is, of course, a linchpin for liability under Stark II. The statute defines financial relationship to include an “ownership or investment” interest in the entity or a “compensation arrangement” between the physician (or her immediate family member) and the entity.

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  Under Stark II, the ownership interest or compensation arrangement may also be indirect—which caused many complaints during the public comment process. As HCFA itself noted, “many commenters expressed concern that by extending liability for indirect financial relationships,” the proposed regulation “imposed an unfair burden on entities furnishing [services] affirmatively to ferret out and discover potential indirect financial relationships or else risk submitting improper claims because of relationships they knew nothing about.”

  In response to that quite reasonable concern, the proposed final regulation has three relatively helpful provisions. First, it adds a knowledge requirement in cases of indirect financial relationships. Under the new rule, a claim will be impermissible only if the service provider had actual knowledge of a prohibited relationship involving the referring doctor or “acted in reckless disregard” or “deliberate ignorance” that such a relationship existed.
Second, the regulation defines “indirect compensation” using a bright-line, three-part test. And third, it creates a new exception for indirect compensation arrangements where the referring physician’s compensation is “fair market value” and not based on the volume or value of referrals.

HCFA (which last week was renamed the Centers for Medicare and Medicaid Services) hopes these modifications will silence the main criticism of the 1998 proposal—that it “inappropriately micro-managed physician practices.”

- In-office ancillary services and group practices. In a significant change from 1998, the 2001 regulation excludes from the definition of “referral” those services “personally performed” by the referring physician. The rationale, of course, is that a doctor cannot refer services to himself. HCFA cautions that services performed by another group-practice member or group-practice employee might be considered a “referral,” although the commentary notes that, in “most cases,” such services will be permitted under the in-office ancillary services exception.

In-office ancillary services constitute one of the most important exceptions to Stark’s general prohibition. Under this exception, a doctor may refer patients for designated services within her own group practice provided that certain location, supervision, and billing requirements are met. The new proposal broadens this exception by expanding the range of services that may be provided in-office (for example, outpatient prescription drugs and items such as walkers and canes) and by permitting group members to provide ancillary services outside the main office so long as the doctor’s arrangement with the practice is not “part-time” or “intermittent.” The expansion better reflects the realities of many medical groups.

The in-office ancillary services exception is further expanded by a wider definition of “group practice.” The new proposal relaxes the degree of business integration required to constitute a group practice. It also permits group practices to pay physician productivity bonuses so long as they are not based on the volume or value of referrals. The goal, according to HCFA, is to benefit “bona fide group practices” and not “loose confederation[s] of individual physicians bound together primarily to profit from referrals.”

**History of Restraint**

Even with broader Stark exceptions, what happens to a health care provider that violates the Stark law? That too is changing.

Stark does not provide for criminal penalties. Nor is there a private civil enforcement or damages provision. Instead, violators are subject to sanctions—such as disgorgement of Medicare reimbursement and civil monetary penalties—imposed by the Office of Inspector General (OIG) in the Department of Health and Human Services. The Justice Department can also bring civil actions under the False Claims Act for violations of Stark. Stark does not provide for criminal penalties. Nor is there a private civil enforcement or damages provision. Instead, violators are subject to sanctions—such as disgorgement of Medicare reimbursement and civil monetary penalties—imposed by the Office of Inspector General (OIG) in the Department of Health and Human Services. The Justice Department can also bring civil actions under the False Claims Act for violations of Stark.

Since 1995, the OIG has brought few, if any, public administrative Stark penalty actions. And until recently the Justice Department brought few Stark penalties under the False Claims Act.

Of course, over the past few years, HCFA and the OIG have been busy developing and revising Stark’s interpretive regulations, and the provider community has been attempting to digest these very complex rules and restructure physician-hospital relationships accordingly. In this climate, active enforcement would have been unwise and unwarranted.

Private plaintiffs have not shown the same restraint. In the past three years, private plaintiffs have increasingly attempted to bootstrap alleged Stark violations into qui tam cases under the False Claims Act. Their theory is that providers submit false claims if they certify compliance with anti-fraud laws on their Medicare cost reports and then submit claims based on improper referrals. The courts have permitted several of these cases to proceed, although many of the basic liability issues remain undecided.

**Joined by Justice**

A far more significant and troubling development is that after years of relatively quiet enforcement, the Justice Department has joined several of these False Claims Act cases alleging Stark violations. Just in the past six months, the department has signed on to three high-profile suits.

First, late last year, the department joined an existing False Claims Act suit alleging that the McLaren Regional Medical Center unlawfully submitted Medicare claims for services referred by a physician group to whom McLaren indirectly paid rent for office space. According to the government’s complaint, McLaren made lease payments at above-market value to the physician group’s real estate entity to induce the doctors to refer patients to the McLaren facilities. The resulting claims to Medicare and Medicaid were improper, the government asserts, regardless of whether the services provided were medically necessary.

Second, in February 2001, the Justice Department intervened in a pending False Claims Act case against the Tenet Healthcare Corp. The suit alleges that Tenet acted unlawfully by submitting cost reports to Medicare certifying compliance with Stark while paying certain physicians above-market value compensation to induce referrals to one of Tenet’s Florida hospitals.

Finally, in March 2001, the Justice Department intervened in eight False Claims Act suits pending against HCA-The Healthcare Company, several of which alleged Stark violations. Notably, many of the Stark allegations are based on physician compensation and lease arrangements dating back to the late 1980s and early 1990s, before Stark II was even effective—and well before the first draft of the Stark II implementing regulations were distributed to a mystified provider community in 1998.

These recent lawsuits represent a significant escalation in Stark and health care fraud enforcement. HCA, Tenet, and other providers not only confront the possibility of disgorging reimbursement obtained from physician referrals, but may also face treble damages and per-claim penalties under the False Claims Act. Even if one agrees with the notion of enforcing Stark (which has no private enforcement provision) through the False Claims Act, it is certainly troubling to see multimillion-dollar lawsuits predicated on financial arrangements that the government now believes may not represent fair market value, but that were developed well before even the 1998 proposed regulations. Nevertheless, this is likely to be the trend in Stark enforcement, not the exception.

Health care providers should brace themselves for more False Claims Act cases based on these complex new Stark regulations. They should anticipate more enforcement from the OIG and state Medicaid enforcers once the implementing regulations become truly final late next year. So now would be the time to review those existing physician relationships very carefully.

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