Almost 20 years after the Stark Law’s effective date (1995), in August 2014, the Office of the Inspector General and the Department of Justice entered into the very first settlement with a physician group based on internal compensation practices that did not meet the definition of a group practice. Paying more than $1.3 million for compensation practices in 2007 and 2008, the partners in New York Heart Center allegedly compensated themselves based on the volume of their internal referrals for designated health services (DHS), primarily CT scans and nuclear diagnostic studies. They were not obligated to enter into a Corporate Integrity Agreement.

Although no whistleblower is mentioned in the settlement, and it has gotten relatively little press, it is extraordinarily important for several reasons: (1) When the law was enacted, it was almost impossible to imagine how the government would ever be in a position to look at internal private practice operations unless they were investigating a group for something else; and (2) To take such a long time to enforce with regard to a basic and fundamental definition in the statute and regulations means that now every aspect of the law is fair game for the enforcers, even if they have never taken action before.

This is a warning shot over the bow. Every group practice should not only reexamine their compensation formulas involving DHS, but look very closely at whether they are meeting the other indicia of a physician group set forth in regulation.

This article looks at each of the elements of the definition of a group practice and elucidates the complexities lurking there. The drafters of the legislation were protecting against ills they little understood themselves. Their language is replete with misused terms that have long had meaning in Medicare, such as “personal supervision,” “direct supervision,” and “incident-to.” Fortunately, many of these confusions were fixed by regulation. In the only attempt to repeal parts of the statute in the Balanced Budget Act of 1995 (which President Clinton vetoed, thus shutting down the government), one of the major elements was removing the implications of the law for the internal operations of a group practice. Nothing like that has happened since.

**Why the definition matters**

Many people still think that there is a group practice exception in the Stark Law. There is
no such thing. In order to avail oneself of some of the exceptions, you must be a group practice. The principal exceptions that require this precondition are: (1) the referral to a physician in the group practice; (2) in office ancillary services; and (3) certain group practice arrangements with hospitals, which no longer has much relevance since the arrangements had to have been in place before December 19, 1989. The safe harbor regulations under the Anti-Kickback Statute (AKS) have added a couple of protections that turn on meeting the group practice definition. These include investments in group practices as well as referral agreements among specialists within group practices.

The fundamental prohibitions under the Stark Law are against an improper referral by a physician where the referral does not meet an exception under the law, and then the real impact is the prohibition on submitting claims which include violating transactions. From the original statutory provisions, the paid claim is an overpayment, which is also subject to a civil money penalty of $15,000 and potential exclusion from Medicare. The same provision of the statute requires repayment to be made to the patient for any amounts paid in association with the overpayment. There had long been a debate as to whether Stark violations could be false claims. There is no longer any question about this. The Affordable Care Act provided that any claims submitted pursuant to a Stark or AKS violative transaction must be repaid within 60 days or they convert to false claims. This is now whistleblower country.

**Single legal entity**

In order to qualify as a group practice, the group must consist of a single legal entity operating primarily for the purpose of being a physician group. The regulations are widely liberal with respect to what kind of legal structure may be used, permitting partnerships, professional corporations, limited liability companies, foundations, non-profit corporations, faculty practice plans, or virtually anything else. There are no specifications with regard to who must or may own or organize the entity, which can include physicians as well as healthcare facilities or any other persons or entities.

To qualify as a single legal entity, the group practice may be owned by another group, but it may not be owned by a group that continues to practice as a group. As rigid as that qualification appears to be, it is somewhat undermined by a sentence further on in the same paragraph which says, “A group practice that is otherwise a single legal entity may itself own subsidiary entities.” One could well imagine a primary care physician group that continues to operate as a group practice owning and operating a separate professional corporation or limited liability company which consisted solely of specialists. Going all the way back to the first final regulations in 2001, the regulators rejected the concept of allowing separate entities under common control to qualify as a group practice. In response to fairly extensive comments on the proposed regulations, the regulators agreed that many group practices are formed out of merging prior practices. It was in that context that they took the position that the practice should consist of a single legal entity.

Even today, I am asked by attorneys whether a group of physicians employed by a hospital can constitute a group practice. While the old line fully integrated medical groups such as the Cleveland Clinic, the Billings Clinic, and Park Nicollet, these are in fact
physician practices which own the hospitals and do meet the definition of a group practice. The traditional community hospital that now employs physicians likely cannot claim that they are a group. When they set up a separate entity that employs the physicians, then that entity may well constitute a group practice, even though the sole member is the hospital with which it is affiliated.

Physicians
The group practice must have at least two physicians who are members of the group. Members are defined as those physicians who are a direct or indirect physician-owner of a group practice, a physician employee of the group practice, a locum tenens physician, or an on-call physician covering for a member of the group practice. A physician is a member of the group practice during the time he/she furnishes “patient care services” to the group as defined in the regulatory definition. An independent contractor is not a member of the group. This was a major controversy when proposed regulations were published. An independent contractor can be a physician “in the group” for purposes of supervising personnel and receiving referrals from other physicians in the group. Independent contractor physicians are only physicians “in the group” when they are using the group’s offices. The regulation actually says the group’s “facilities,” which is nowhere defined.

Range of care
Each physician who is a member of the group must furnish substantially the full range of patient care services that he/she routinely furnishes, including medical care, consultation, diagnosis, and treatment through the joint use of shared office space, facilities, equipment, and personnel. This means that if a physician really only does one service, such as Mohs surgery, and if that is all he does with the group practice, there is no problem. However, this provision was intended to prevent groups consisting of members who served in that status only to deliver a limited range of services, such as cardiac catheterizations from which the referring physicians in the group would profit. But because the provision only refers to the members of the practice, there can be independent contractor arrangements for limited services provided by other physicians, billed by the group practice.

Services furnished by group practice members
At least 75% of the total patient care services of the group practice members must be furnished through the group and billed under a billing number assigned to the group. Revenues received from that billing must be treated as receipts of the group. In calculating whether the members of the group meet the 75% standard, the regulations look at the total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). The regulations offer the example of a physician who practices 40 hours a week and spends 30 hours on patient care services for the group practice as meeting the 75% rule. If, however, a physician is only engaged in clinical practice 10 hours a week, but spends all of those 10 hours with the group practice, he would meet the standard at 100%. The calculation has to take into account all of the members of the group practice so that the average is 75% among them. This provision is intended to limit loosely knit organizations of clinicians who do not practice together most of the time.

Any other alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented is also permitted. These rules do not pertain to a group practice that is located solely in a
health-professional shortage area. The regulations offer a grace period of 12 months for a new physician who joins a practice.

**Distribution of expenses and income**

The regulations say relatively little about how expenses must be allocated, but require that the expenses and income must be distributed according to methods that are determined before the receipt of payment for the services that give rise to the overhead expense of producing the income. In the preface to the regulations, there is little discussion of this provision. The regulators did state explicitly that many types of cost center and location or specialty-specific allocations are permitted, as long as they are prospectively determined.5

**Unified business**

The regulations require that the group practice must be a unified business. The government has taken the position that this would be manifested by having at least the following features: (1) centralized decision-making by a body representative of the group practice that maintains effective control of the group’s assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and (2) consolidated billing, accounting, and financial reporting. This is typically referred to as “one tax ID number, one checkbook.” However, the extent of the required consolidation is not described.

**Volume or value of referrals**

As the touchstone for safety, the regulations set forth that no physician who is a member of the group practice may directly or indirectly receive compensation based on the volume or value of his/her referrals, except in compliance with the regulations pertaining to productivity bonuses and profit shares. However, the regulators have also made clear that as incident-to services often are reflective of a referral for a DHS, they are an exception to the rule, because they are part of the definition of a group practice.

**Physician patient encounters**

In yet a second 75% rule applied to group practices, the regulations require that members of the group must personally conduct no less than 75% of the physician-patient encounters of the group practice. Again, there is almost no explanation of what this provision means, other than it is based on a per capita calculation rather than a time-based calculation. The term “encounters” is unclear. Generally speaking, under Part B, one would talk about visits rather than encounters. Is the interpretation of a diagnostic test an encounter? What happens if in an oncology practice, for example, there are infusions that are conducted with virtually no physician involvement on multiple patients during the day? Are those encounters? In the absence of any real guidance, it would be hard to imagine a whistleblower making much of this, unless a group used mostly independent contractors to conduct the practice.

**Productivity bonuses**

Here, the regulators address the issue of allocating to physicians revenues associated with services that they have personally performed. In addition, the revenues from services incident-to the physician’s services to the patient may also be allocated to that physician, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

Many lawyers have continued to be confused about this. The regulation goes on directly to say “except that the bonus may directly relate to the volume or value of DHS referrals by the physician if their referrals are for services ‘incident to’ the physician’s personally performed services.” The regulators
made this point clearly in the discussion of incident-to services in the preface to the 2001 regulations. Although commenters were apparently still confused, in 2004 the regulators noted that “a number of commenters asked that we clarify that physicians in the group practice can be paid a productivity bonus or profit share based directly on services that are ‘incident to’ services personally performed by the physician,” and they did so again. For example, independent contractors may be paid 60% of the revenues they generate through personally performed and incident-to services. Finally, in 2007, after some debate as to whether handing a continuous positive airway pressure (CPAP) machine to a patient would qualify as a personally performed service, the regulators made it clear that such a transaction would not qualify as an incident-to or personally performed service. They did clarify, again, that revenues from services and supplies such as drugs were allocable under the incident-to provision, which by that time, they had said three times—in 2001, 2004, and 2007.

What qualifies as incident-to under Medicare’s general reimbursement rules applies to what is permissible under Stark. In 2007, turning their back on the entire 40-year history of the Medicare program, the regulators announced that diagnostic testing could no longer be considered incident-to a physician’s services. This may well be where the New York Heart Group went wrong. Note that the dates at issue in the “allocation formulas” were 2007-2008, when rules which had been in place for years were trashed in these little-known regulatory publications. Revenues from diagnostic tests that are DHS must be allocated in a profit-sharing formula. The regulators took this position because, they say, diagnostic testing has its own benefit category in the Medicare statute; but so do physical therapists, occupational therapists, nurse practitioners, physician assistants, and others, and their services all can be billed incident-to a physician.

The basic requirements for incident-to Medicare services must be met. There has to be a physician service to which the ancillary services are incidental in a course of treatment established by the treating physician. A physician in the group—meaning a member or an independent contractor who re-assigns payment to the group—must be on the premises, in the office suite, and immediately available to assist the ancillary personnel. The supervising physician need not be the treating physician. Incident-to services can be billed on a day when no physician sees the patient at all. Incident-to services are paid at 100% of the Medicare physician fee schedule and they are billed as if the physician performed them himself. The Stark regulators have repeatedly stated that the level of supervision that is required (despite the statute’s misguided reference to “direct supervision” in some instances and “personal supervision” in others) is the level of supervision that otherwise pertains under Medicare policy: (1) general—no physician on premises required; (2) direct—a physician in the office suite required; or (3) personal—physician and patient in the same room while the service is rendered.

A related concept for the allocation of productivity bonuses is the shared visit, which
pertains only to hospital services—inpatient, outpatient, and in the Emergency Department. Here, a non-physician practitioner in the same group as the treating physician can perform and document most of an evaluation and management (E&M) service. The physician can later perform any portion of the visit in a face-to-face encounter with the patient, and both of their services can be “grossed up” and billed in the physician’s name. These count as personally performed services for Stark, but they are actually not DHS at all, so Stark has little to say about them. The same is true of visits billed by nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) on their own provider numbers and paid at 85% of the physician fee schedule. Unless they are performing Stark diagnostic tests, most of their interactions with patients are not DHS and their revenues can be directly attributed to the treating physician. That is not the case for physical therapists or occupational therapists billing on their own provider numbers and paid at 100% of the physician fee schedule, because physical therapy and occupational therapy are DHS. This brings us to profit sharing, which is often not well understood. There is much more liberality to be found there than many practices and even attorneys realize.

Profit sharing
Although the statute says that a physician in a group practice may be paid a share of overall profits of the group, in fact, Stark has little to say about profits from services that are not DHS. Profit sharing is sharing in the revenues from the fruits of others’ labors from DHS, such as sharing diagnostic testing revenues or physical therapy revenues from services that were not provided incident-to.

The rules allow subgroups within a group as long as each pod consists of at least five physicians. A single group of fewer than five means that all must be paid in accordance with the same formula, which need not produce the same amount of compensation to each. Profit sharing cannot include current DHS ordering patterns, but there is nothing to prohibit a historical look at ordering projected forward for the coming year. This does not directly reward current referrals.

Some groups allocate on the basis of the volume of E&M services or the work relative value units (RVUs) associated with non-designated health services. Some use number of patients. Some share equally. Nothing is mandated nor, in a larger group, is there a requirement that everybody participate in profit sharing. In very large groups, we have seen profits shared by historical referral patterns by differing ancillary services (e.g., the physical therapy pod, the infusion pod, the CT and MRI pod, the imaging pod, etc.). As long as each subgroup is at least five physicians and the formula does not directly reflect the volume of referrals, it will be compliant with the statute and regulations.

Conclusion
The definition of a group practice is a fundamental predicate to being able to refer in accordance with any of the exceptions under the Stark Law that make reference to group practices. With the New York Heart Center settlement, it is abundantly clear that this will be fertile ground for enforcers and whistleblowers. All group practices should review each of the relevant criteria to make sure it complies.