



## WHAT ASNC MEMBERS NEED TO KNOW ABOUT

# Stark

## CMS Issues New Stark Rules with Some Surprising Changes

The Centers for Medicare & Medicaid Services (CMS) issued new Stark regulations on September 5, 2007. These Stark changes, called the “Phase III” regulations, are final rules, and become effective on December 4, 2007. These new Stark rules, together with the Stark changes proposed in July as part of the 2008 Medicare physician fee schedule rule, create a dizzying set of new rules governing health care relationships. This summary focuses on the just-released final Stark rules. Please see the September 2007 issue of “What ASNC Members Need to Know” for a report on the proposed physician fee schedule rule changes.

### Indirect Compensation

The Phase III regulations revise the definition of an indirect compensation relationship such that each physician in a physician practice “stands in the shoes” of his or her “physician organization” and is deemed to have the same compensation arrangements (with the same entities providing Stark designated health services [DHS] and on the same terms) as the physician organization does.

This is a fundamental and important change in Stark regulation. It means that many arrangements that previously met the indirect compensation exception must now satisfy a Stark exception applicable to direct compensation to a physician (e.g., personal services, equipment lease).

For instance, under the current rules, a hospital having a professional services arrangement with a physician group could consider the resulting Stark relationship with each individual physician in that group to be indirect, so the hospital could avoid many of the technical contracting requirements of the personal services exception (e.g., one-year term, cross-referencing a master contract list or every other arrangement with that group).

These arrangements no longer apply. Hospitals relying on the indirect compensation exception must revisit their contracting practices to avoid potentially huge overpayment, and even false claims liability.

CMS did, however, provide some relief. If a signed arrangement satisfied the indirect compensation exception as of September 5, 2007, then you need not comply with an applicable direct compensation exception until the original term or the current renewal term of the arrangement expires. But no similar relief was provided for entities that have used the indirect compensation rules to conclude that an arrangement creates no Stark compensation at all: those arrangements must fit into an applicable direct compensation exception by December 4. Interestingly, an arrangement with several links not involving a physician organization (e.g., DHS entity/leasing company/physician) should still be analyzed as an indirect compensation arrangement subject to the indirect compensation exception. As under current rules, to satisfy the requirements of the indirect compensation exception, each link of the chain of financial relationships need not satisfy the requirements of a separate exception.

### Recruitment

The Phase III rules make a number of changes that relax the existing Stark rules on hospital payments for physician recruitment.

Most importantly, CMS recognizes that prohibiting physician practices from imposing non-compete provisions may make it difficult for hospitals to recruit physicians. Phase III permits group practices to impose practice restrictions on a recruited physician so long as they do not unreasonably restrict the recruited physician’s ability to practice medicine in the hospital’s service area. Although CMS says they are not necessarily conditioning payment for DHS on compliance with state and local laws regarding non-compete agreements, any practice restrictions or conditions that do not comply with applicable state and local law run a significant risk of being considered unreasonable under Stark.

The Stark exception on hospital recruitment support mandates that the physician relocate his or her practice to the geographic area that the hospital serves, which was defined as the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients. Phase III ex-

pands the definition of “geographic area served by the hospital.” First, if a hospital draws fewer than 75% of its inpatients from contiguous zip codes, the hospital’s service area can be the area represented by *all* contiguous zip codes from which the hospital’s inpatients are drawn.

Second, it permits rural hospitals to determine their “geographic service area” using an alternative test that encompasses the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients.

Other recruitment changes will benefit rural areas. Phase III permits rural health clinics to utilize the recruitment exception. The new rules also permit a more generous option for allocating costs to a recruited physician joining an existing practice when replacing a deceased, retiring, or relocating physician in a rural area or health professional shortage area. A physician practice may allocate to the recruited physician, for purposes of an income guarantee, a per capita allocation of the practice’s aggregate overhead and other expenses, not to exceed 20% of the practice’s aggregate costs.

Also relating to the physician relocation standard, Phase III exempts from the relocation requirement physicians employed full time by a federal or state bureau of prisons, the U.S. Departments of Defense or Veterans Affairs, or facilities of the Indian Health Service, provided that the physician did not maintain a separate private practice in addition to such full-time employment. In addition, physicians whom the secretary deems in an advisory opinion not to have an established medical practice comprised of a significant number of patients who are or who could become patients of the recruiting hospital are also exempt from the relocation requirement.

Finally, Phase III permits rural hospitals to recruit physicians into an area outside of the hospital’s geographic service area if CMS determines through an advisory opinion that the area has a demonstrated need for the recruited physician.

### **In-office Ancillary Services Exception**

While CMS made no substantive changes to the oft-used in-office ancillary services exception, it did provide additional guidance on the exception’s interpretation relating to physician groups that share ancillary services facilities in the same building.

The Stark rules permit multiple physician groups who co-locate in the same building to share an imaging center, clinical laboratory, or other facility providing DHS. A commenter asked for guidance on the provision of DHS in a shared space in the same building where physicians simultaneously use the facilities and

simply share the costs of the administration of DHS without separate lease arrangements. In a response that will likely affect a number of arrangements, CMS declared that to satisfy the in-office ancillary services exception “this likely necessitates a block lease arrangement for the space and equipment used to provide the [DHS]” and that “per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the anti-kickback statute.” In justifying its statement, CMS noted “A physician sharing a DHS facility in the same building *must* control the facility and the staffing (for example, the supervision of the services) at the time the [DHS] is furnished to the patient” (emphasis added).

The agency provides no further explanation as to why they believe that block leasing furnishes each of the leasing groups with greater control over the facility and staffing during the leased periods. As a practical matter, each physician group’s control over a shared ancillary services center is a function of each group’s active participation in staffing, clinical protocol, and operational decision-making rather than block leasing. Nonetheless, the response apparently articulates CMS’s interpretation of the regulatory provision and may force the restructuring of a number of per-click or other shared-use arrangements.

For rural providers, CMS commented on the interplay between telemedicine and the “same building” requirement. A commenter desired to know how the same building requirement applied to a physician providing telemedicine in a location physically separate from the patient. CMS responded that it does not consider the physician providing telemedicine to be in the same location as the patient in the rural office for purposes of satisfying the “same building” requirements.

### **Group Practice Definition**

The “group practice” definition is important for a number of Stark exceptions, in particular the in-office ancillary services exception. One aspect of the group practice definition is the flexibility it affords groups in compensating their physicians. In particular, prior to Phase III, the Stark regulations permitted groups to pay physicians productivity bonuses and profit shares. However, the regulations required such profit sharing or productivity bonuses to be “based on services that [the physician] personally performed (including those services “incident to” those personally performed services), *provided* that the share or bonus *is not* determined in any manner that is directly related to the volume or value of referrals of DHS by the physician” (emphasis added). The regulation was not clear as to whether a productivity bonus could take into account the volume and value of items and services provided “incident to” the physicians’ professional services.

CMS revised the group practice definition on this point. The change clarifies that productivity bonuses can directly relate to the volume or value of DHS referrals by the physician if the referrals are for services “incident to” the physician’s personally performed services. For example, a productivity bonus can consider referrals by the physician for physical therapy or outpatient drugs performed “incident to” his or her services. However, a productivity bonus cannot consider any other DHS referrals (e.g., referrals for diagnostic tests). In addition, CMS noted that profit sharing cannot consider “incident to” services — profits must be allocated in a manner that does not relate directly to DHS referrals, including DHS billed as “incident to” services.

### **Fair Market Value Exception**

A Phase III modification that may have important benefits is the broadening of the Fair Market Value exception. Previously this exception only applied to compensation provided from a physician to a DHS entity. The new rules apply both to compensation from a DHS entity (such as a hospital) to a physician or physician group as well as to compensation from a physician to a DHS entity.

It may not be applied, however, to leases for office space. Nonetheless, this exception may now be used more broadly when many arrangements do not meet other direct compensation exceptions, such as the personal services exception.

### **Definitions**

**Fair Market Value.** CMS previously created a safe harbor provision in the definition of “fair market value” for hourly payment to physicians for their personal services. The safe harbor consisted of two alternatives for calculating hourly rates that would be deemed “fair market value” under the physician self-referral regulations: (1) the average hourly rate for emergency room physician services in the relevant physician market, or (2) averaging the 50th percentile salary for the physician’s specialty of four national salary surveys specified by CMS and dividing the resulting figure by 2,000 hours. CMS has eliminated this safe harbor in the Phase III final rule. CMS states, however, that “[r]eference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value.”

**“Incident to” Services.** CMS changed the definition of “incident to” services to state that the term refers to both applicable services and supplies. The intention is to conform the Stark definitions as much as possible to existing Medicare coverage and payment rules.

**Physician in the Group Practice.** CMS modified the definition of “physician in the group practice” to clarify that an independent contractor physician must furnish patient care services for the group under a contractual arrangement directly with the group

practice in order to be considered a “physician in the group practice.” CMS’s interpretation is that “a contractual relationship with a group practice” means a direct contractual relationship and not a contract between the group practice and another entity (such as a staffing company).

### **Other Stark Exceptions**

**Personal Service Arrangements.** The Phase III rules allow a holdover period of up to 6 months following the expiration of an agreement that was in effect for at least one year and that met the other conditions of the personal service exception. The holdover provision is similar to that allowed under the exception for the rental of office space.

**Charitable Donations by a Physician.** The new rules clarify that a donation may not be solicited or offered in any manner that reflects the volume or value of referrals.

**Nonmonetary Compensation.** CMS added a provision allowing physicians to repay certain excess nonmonetary compensation within the same calendar year. Specifically, nonmonetary compensation is within the exception if the entity inadvertently exceeded the limit by no more than 50% during a calendar year, and the physician repays the excess compensation within the earlier of: (1) the end of the calendar year in which the excess nonmonetary compensation was received, or (2) 180 days from the date the excess nonmonetary compensation was received. The payback provision may only be used once every three years with respect to the same physician.

The agency advised that once a DHS entity becomes aware that it has inadvertently provided nonmonetary compensation in excess of the limit, it is prudent for the DHS entity to delay all billing and claims submission for the physician’s DHS referrals until the physician has refunded the money in compliance with the above payback provision.

Hospitals and other DHS entities may provide one medical staff appreciation function, such as a holiday party, for the entire medical staff each calendar year. However, any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit set by the nonmonetary compensation exception.

The agency also clarified that the annual nonmonetary compensation limit applies to each DHS entity and not to a parent health system.

**Compliance Training.** This exception was amended to permit training programs that involve CME credit, provided that compliance training predominates.

**Professional Courtesy.** This exception now requires the entity offering the courtesy to have a formal medical staff and requires that the offer be made to all physicians on the entity's bona fide medical staff. It deletes the requirements that if the professional courtesy involves the whole or partial reduction of a coinsurance obligation, the insurer is informed in writing.

**Retention Payments in Underserved Areas.** This exception was reworked significantly. It now allows retention payments based on offers of employment that are not in writing and expands the exception to offers from academic medical centers and physician organizations. Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness as the written recruitment offer or offer of employment. Added flexibility is provided for retention payments to physicians who serve underserved areas and populations. The new exception allows Federally Qualified Health Centers and rural health clinics to make retention payments as well.

### Conclusion

Although there are not many fundamental changes in the new Stark regulations, the changes in the definition of indirect compensation should make clear that hospitals and other entities that bill Medicare for Stark designated health services can no longer avoid a centralized listing, legal review, and management of contracts with referring physicians and groups. In addition, all compensation relationships with physicians need to be re-evaluated to determine whether the inapplicability of the indirect

compensation exception requires the creation of a new contract or contract modifications. CMS's recent efforts to implement a Stark disclosure program make such an effort even more critical.

Another problematic area is the impact of CMS commentary on same building arrangements. Although the substance of the comments are highly questionable, they exist nonetheless and may limit the willingness of some groups located in the same building to use shared ancillary facilities.

Some of the new Stark changes are helpful. Eliminating the prohibition of practice restrictions for hospital recruitment support is a significant step. And opening up the fair market value exception has some interesting possibilities.

In many ways, the proposed changes to Stark from the 2008 physician fee schedule rule could have a greater number of negative repercussions and ambiguity than these final Stark rules. It is apparent that CMS reserved the final Phase III promulgation for their set of Stark changes that are, for the most part, clear in their application, while the agency's more vague, bold, and sometimes puzzling Stark ideas were placed into a proposed rule to allow for public comment.

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