

Part 1

# Key changes to the Stark II final rule

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On Sept. 5, the Centers for Medicare & Medicaid Services published the long-awaited third phase of the Stark II final rule that covers physician referral practices. The rule finalizes, and responds to, public comments regarding the Phase II interim final rule published March 26, 2004, which addressed applicable definitions and interpreted various statutory exceptions to the Stark II prohibitions. The final rule tends to tighten up restrictions rather than add additional regulations. In a two-part article, we will summarize some of the more salient aspects of the Phase III rule.

## Definitions

► The final rule eliminates the Phase II safe harbor for determining the fair market value of physician compensation, increasing the importance of independent fair market value analyses. This provision was part of the Phase II interim rule and of particular interest to the dialysis community. CMS created the safe harbor in the definition of fair market value based upon hourly payments to physicians for their personal services. This safe harbor caused great concern in the physician and nephrology community and resulted

in litigation filed by the Renal Physicians Association seeking to undo the regulatory proposed change. Although the lawsuit was dismissed in the courts, CMS agreed to reverse its position and determined that many of the compensation surveys for physician pay were outdated or no longer available and that it might not be feasible to obtain information on hourly rates from emergency room physicians at competitor hospitals. Thus, in the con-

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text of medical director agreements and other arrangements where fair market value of personal services arrangements is required, the general definition of fair market value provided in the regulations must be relied upon.

CMS went on to explain, “Nothing precludes parties from calculating fair market value using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits the definition of the Act.”

► CMS modified the definition of physician in the group practice setting to clarify that an independent contracting physician must furnish patient care services for the group under a contractual arrangement directly with the group practice and on the premises of the group practice.

## Financial Relationships

► A physician is deemed to have a direct compensation arrangement (rather than indirect) with an entity furnishing Stark

designated health services if the only intervening entity between the physician and the entity is his or her physician organization.

► A physician “stands in the shoes” of his or her physician organization and is deemed to have the same compensation arrangements as the physician organization. Under the original Stark regulations, there was an argument that certain indirect compensation arrangements would not violate the Stark Act. For example, a hospital might own a clinic or foundation, and that clinic or foundation would employ physicians. The relationship between the hospital and the employed physicians, in this example, was indirect so as not to implicate the Stark Act. CMS determined that some of these relations may

be abusive and stated:

“We believe that it is necessary to collapse the type of relationship discussed above to safeguard against program abuse by parties who endeavor to avoid the application of the physician self-referral requirements, by simply inserting an entity or contract into a chain of financial relationships linking the designated health service entity and a referring physician.”

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## Exceptions to the referral prohibition related to compensation arrangements

The final rule now states that a “holdover” personal services arrangement for up to six months following the expiration of an agreement of at least one year that met the personal services



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arrangement exception will also meet this exception, provided that the hold-over arrangement is on the same terms and conditions as the immediately preceding arrangement.

► **Physician recruitment**

The final rule now stipulates that the geographic area served by a hospital may include one or more zip codes in the geographic area from which the hospital draws at least 75% of its inpatients.

The final rule clarifies that a physician must relocate his or her practice from outside the hospital's geographic service area to a location inside the hospital's geographic service area and either 1) move his or her medical practice at least 25 miles; or 2) satisfy the 75% inpatient test.

CMS added additional avenues for a recruited physician to avoid the relocation requirement—specifically, the requirement may be avoided if the Secretary deems in an advisory opin-

ion that the physician does not have an established medical practice comprised of a significant number of patients who are or could become patients of the recruiting hospital.

CMS added language permitting a more generous income guarantee under certain circumstances where a physician is recruited to replace a deceased, retiring, or relocated physician in a rural area or health practitioner shortage area.

► **Nonmonetary compensation**

► Where an entity has inadvertently provided nonmonetary compensation in excess of the annual aggregate limit, such compensation is deemed to be within the limit if the value of the excess compensation is no more than 50% of the limit and the physician returns the excess by the end of the calendar year or within 180 consecutive days of the physician's receipt of the compensation.


► An entity with a formal medical staff may now provide one local medical staff appreciation event per year for the entire medical staff; and any gifts or gratuities provided in connection with the event are subject to the nonmonetary limit.

► **Fair market value compensation.** CMS has clarified that compensation resulting from an arrangement between an entity and a physician or group of physicians for the rental of office space cannot qualify for this exception.

► **Compliance training.** This now includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

► **Professional Courtesy.** This rule adds language that an entity must have a "formal medical staff" to qualify for this exception. This exception applies to such items as meals, health care, and other similar items.

In Part 2 of this article, to appear in the January 2008 issue of *NN&I*, we will look more in depth at the commentary from the Phase III Final Rule and additional implications for the dialysis industry. **N**



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