

Stark Phase III regulations take effect December 4, 2007

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The Stark Law (often referred to as the Physician Self-Referral Law) prohibits physicians from referring Medicare patients for certain designated health services (DHS) to an entity with which the physician or a member of the physician's immediate family has a financial relationship (ownership or compensation)—unless an exception applies and prohibits an entity from filing claims with Medicare for those referred services. Penalties for violating the Stark Law include denial of payment for the service, civil monetary penalties, or even the possibility of being excluded from the Medicare or Medicaid programs.

Proposed regulations were first published in 1998, followed by Phase I of final rule making in 2001 and Phase II interim final rules in 2004. Phase III, published on September 5, 2007, responds to public comments on the Phase II interim final rule. The effective date of Phase III is December 4, 2007. Phases I, II, and III of the regulations are intended to be read together as a unified whole.

On November 15, 2007, Centers for Medicare and Medicaid Services (CMS) published a final rule

delaying the effective date of certain provisions of Phase III. The final rule delays for 1 year the “stand in the shoes” provision in Phase III, but only as applied to academic medical centers and not-for-profit integrated health systems. All other aspects of the Phase III regulations go into effect on December 4, 2007.

A brief summary of the more notable changes in Phase III is set forth below.

- **Personal Service Arrangements.** Phase III allows a “holdover” of a physician service agreement (PSA) for up to 6 months following the expiration of a PSA. The PSA must be on the same terms as the original agreement.
- **Physician Recruitment.** Phase III expands physician recruitment and physician retention exceptions. This expansion means that more physicians than ever before should qualify for hospital recruitment and retention assistance. In addition, Phase III considerably loosens the rule against groups imposing practice restrictions (ie non-compete agreements, requirements to treat Medicaid and indigent patients, restrictions on moonlighting, prohibiting the solicitation of patients or employees) on new physicians who receive hospital recruitment assistance. Phase III now prohibits only “unreasonable” practice restrictions. Furthermore, Phase III provides rural hospitals with

more flexibility in determining the “geographic area served by the hospital” for purposes of recruitment and allows for the payment of more expenses associated with the practice of a recruited physician who joins an existing group to replace a member of the group who left the area or died within the previous 12 months.

- **Recruitment Assistance Agreements.** Phase III makes clear that a recruited physician is required to be a signatory to the recruitment agreement between the hospital and physician practice.
- **Physician Retention.** Currently the physician retention exception requires a bona fide firm written recruitment offer to relocate the physician outside the area currently served. Phase III allows this exception to be used when the physician has a “bona fide opportunity for future employment” with an academic medical center or physician organization that would require a move of his or her medical practice at least 25 miles and outside of the service area of the current hospital. Phase III further expands the retention exception for a physician whose current medical practice is in a rural area or Health Professional Shortage Area (HPSA) by the addition of “or where at least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically

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underserved population.”

- **Fair Market Value (FMV) “Safe Harbor.”** Phase III eliminates the “safe harbor” provision created in Phase II for hourly payments for a physician’s personal services. The safe harbor was eliminated based on the large number of comments concerning the FMV safe harbor in general, the lack of availability of the surveys identified in the safe harbor (2 of the 6 specified salary surveys are no longer published) and complaints from industry that the surveys identified underestimated physician worth.
- **FMV Exception.** The FMV exception is expanded to include payments from and to physicians. The effect of this expansion is to eliminate the availability of the “payments by a physician” exception for such payment arrangements.
- **“Stand in the Shoes” Doctrine.** Phase III introduces a new doctrine, under which referring physicians will be treated as “standing in the shoes” of their group practice (or other physician organization) for the purposes of applying rules that describe direct and indirect compensation arrangements. According to CMS, the “effect of this new provision is that many arrangements that would have constituted indirect compensation if analyzed under Phases I and II are now deemed to be direct compensation arrangements and the indirect compensation exception cannot be used.” Current arrangements that comply with the old indirect compensation rules will be grandfathered for their current and renewal term. As noted earlier, the final rule delays for 1 year the “stand in the shoes” provision in Phase III, but only as it applies to academic medical centers and not-for-profit integrated health systems.
- **Physician in the Group Practice.** Phase III modifies the definition of “physician in the group practice” to require that a physician who is an independent contractor to contract directly with the group practice, not through his or her employer or a staffing company. A large number of contracts may need to be restructured as a result of this change.
- **Productivity Bonuses.** The rule allowing group practices to pay productivity bonuses for services personally performed by their physicians is revised to make clear that “incident to” services do not need to be personally performed by a physician to be included in bonus calculations, provided that the services are directly supervised by the physician. Overall profit sharing must be allocated in a manner that does not relate directly to DHS referrals, including any DHS that is billed as an “incident to” service.
- **Academic Medical Center (AMC) Exception.** Phase III clarifies this exception with respect to designation of “faculty” physicians on medical staff and computation of permissible compensation for each AMC component and in the aggregate.
- **Physician Sale of Equipment to Hospitals.** Under Phase II, if a physician sold a piece of equipment to a hospital on an installment basis and retained a security interest in the equipment to secure the hospital’s payment, he or she would have been deemed to have “ownership” interest in the hospital. Phase III addresses this issue by expressly stating that the security interest creates only a “compensation relationship” between the physician and the hospital, not an “ownership relationship.”
- **Compliance Training.** The compliance training exception now allows inclusion of compliance training programs that offer continuing medical education (CME) credit, if compliance training is the primary purpose of the program. CMS cautions that programs offering CME credit are of substantial value to physicians, as physicians are required to obtain CME credit for state licensure purposes, and that CME programs do not meet the exception merely because they contain a compliance training component.
- **Non-monetary Compensation.** Phase III adds a deeming provision to the non-monetary exception. In the event that a DHS entity inadvertently provides a physician with non-monetary compensation in excess of the limit (currently \$329), the parties can cure the non-compliance if the excess value is repaid by the physician within 180 days of receipt or by the end of the calendar year, whichever is earlier. This new provision can only be relied on once every 3 years with respect to the same referring physician.
- **Staff Appreciation Events.** Phase III permits a DHS entity that has a formal medical staff to hold 1 annual “staff appreciation event” without counting the cost of the party as non-monetary compensation to physicians. However, invitations must be extended to all medical staff members and any gifts or giveaways at the party are still subject to Stark and must fit within the annual per physician “non-monetary compensation” limit.
- **Professional Courtesy.** The professional courtesy exception no longer requires that an en-

tity notify the applicable insurer when it involves the reduction of any coinsurance obligation. CMS clarified that this only applies to entities with medical staffs (ie hospitals, not labs or DME companies) and urged entities to continue to provide such notification even though it is no longer required.

- **Charitable Donation Exception.** This exception was expanded to permit such donations, as long as the donation is made to a tax exempt entity, is neither solicited nor offered in any manner that takes into account the volume or value of referrals or other business generated between parties and does not violate the anti-kickback statute or any other federal or state law governing billing and claims submission.
- **Rental of Office Space and Equipment.** Phase III notes that a physician sharing a DHS facility in the same building as other providers must control the facility and the staffing at the time the DHS is furnished to the patient. Specifically, it states that this “likely necessitates a block lease agreement” and that per-use agreements are “unlikely to satisfy the supervision requirements of the in-office ancillary exception and may implicate the anti-kickback statute.” Phase III clarifies that space and equipment lease agreements may be amended multiple times after the first year of the agreement provided that the rental charges and terms that are material to the rental charges (ie amount of space, type of equipment) are not amended.
- **Required Referrals.** Required referrals only to approved providers are a permissible condition for physician payment

under an employment, managed care or personal services contract. Such required referrals do not violate the Medicare requirement to provide discharged hospital patients with a choice of home health agencies because 1 condition is that the referral requirement does not apply if the patient expresses a different preference.

- **Intra-Family Rural Referrals.** The exception for intra-family rural referrals was amended to include an alternative test to determine whether a physician may refer a patient to an immediate family member for DHS. Under the new test, if no other person or entity is available to furnish the DHS in a timely manner (within 45 minutes transportation time from the patient’s home), a physician may make a referral for the DHS to an immediate family member or entity with which the immediate family member has a financial relationship, provided that all other conditions of the exception are met.

While Phase III makes a number of changes, it primarily clarifies previously published regulations. In July 2007, CMS proposed additional significant changes to the Stark

Law as part of the 2008 Physician Fee Schedule Proposed Rule. These proposed changes were discussed in the August 2007 edition of the *Wisconsin Medical Journal* (Volume 106, Issue 5)⁴.

The content of this article is intended to provide a general guide to the subject matter. You should contact your personal attorney for advice on your specific circumstances.

Endnotes

1. The full text of Phase III can be viewed at: http://www.cms.hhs.gov/PhysicianSelfReferral/04a_regphase3.asp#TopOfPage. Accessed December 17, 2007.
2. The final rule published in the Federal Register on November 15, 2007 can be viewed at: <http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-5655.pdf>. Accessed December 17, 2007.
3. CMS Press Release “CMS Issues Final Rule Prohibiting Physician Self-Referral”, August 27, 2007.
4. Per click, under arrangement, mark-up, and other dirty words. Lyons L, Katayama A. *WMJ* 2007; 106(5); 280-284

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