

PUBLICATION

CMS Issues Final Stark III Regulations

September 14, 2007

On September 5, 2007, the third phase of final Stark II regulations (Phase III) was published in the Federal Register. These rules become effective on December 4, 2007.

The Stark Law prohibits a physician from making referrals for certain "designated health services" to an entity with which the physician or a member of his or her immediate family has a financial relationship, if Medicare or Medicaid is the payer. There are numerous and exacting exceptions to the Stark Law. Phase III is the Centers for Medicare & Medicaid Services' (CMS) response to public comments on CMS's second phase of final Stark II regulations, published in March 2004 as "interim final regulations" with a comment period.

Although lengthy (the pre-publication posting was 516 pages long), Phase III introduces no new exceptions and makes few major changes to the Stark Law. Instead, Phase III primarily builds on and interprets the exceptions contained in Phases I and II of the final Stark II regulations. CMS states that the three phases of regulations should be read "as a unified whole," and emphasizes this point by republishing the entire regulatory text of the Stark Law except for the unchanged advisory opinion regulations.

The most significant Phase III changes to the Stark Law are the concept of a physician "standing in the shoes" of his or her group practice, and revisions to physician recruitment and retention payments.

"Standing in the Shoes" of a Physician Organization

Under Phase III, a physician is deemed to have a direct compensation arrangement with a DHS entity if the only intervening entity between the physician and the DHS entity is the physician's "physician organization" (meaning the physician, a professional corporation of which the physician is the sole owner, a physician practice or a group practice). In those cases, a physician is considered to "stand in the shoes" of his or her physician organization.

As a result, many compensation arrangements that were considered to be indirect compensation arrangements under Phase II, and that would have been permitted under the exception for indirect compensation arrangements, must now be analyzed as direct compensation arrangements and must now comply with an exception for direct compensation arrangements.

However, if an existing indirect compensation arrangement was entered into prior to September 5, 2007, and met the exception for indirect compensation arrangements on September 5, 2007, then CMS will "grandfather" the arrangement during its original term or current renewal term. Those arrangements may continue to use the exception for indirect compensation arrangements during the original term or current renewal term.

Physician Recruitment (42 C.F.R. § 411.357(e))

Phase III generally relaxes the existing rules on physician recruitment payments, particularly for hospitals and recruits in rural areas.

Service Area. For all hospitals, rural and urban, the definition of "service area" of the hospital is expanded by reference to contiguous zip code areas and certain noncontiguous zip code areas. This service area is the area into which a physician may be recruited. Although this change in definition allows hospitals to recruit physicians to more locations than under Phase II, the change in definition of service area appears to affect only two particular situations: (a) where there is no combination of contiguous zip codes from which a hospital gets at least 75% of its patients (for example, a hospital that gets patients from across the country); and (b) when a zip code from which the hospital gets no patients is surrounded by contiguous zip codes used to reach the required 75% of patient origin for the hospital's service area.

New Flexibility for Rural Hospitals. Under Phase III, a rural hospital (that is, any hospital not located in a Metropolitan Statistical Area, as designated by the federal Office of Management and Budget) may now elect an alternate method to define its service area. Under this method, the hospital's service area is the area composed of the lowest number of contiguous zip codes from which the hospital draws 90% of its patients (as opposed to an urban hospital's smaller service area standard of 75%).

Rural hospitals may now recruit a physician to a location outside of the hospital's service area if the area has demonstrated need for the physician (as determined in an advisory opinion from the Secretary of the Department of Health and Human Services [DHHS]).

In addition, Phase III relaxes restrictions on the amount of income guarantee that a hospital in a rural area or Health Professional Shortage Area (HPSA) may offer when recruiting a physician into an existing practice to replace a physician who retired, relocated, or died within the preceding 12 months. Previously, the income guarantee was limited to include only "additional incremental expenses" of the physician practice attributable to the recruited physician. Under Phase III, a hospital located in a rural area or HPSA may alternatively include in its guarantee the lesser of either (a) the recruited physician's per capita share of total practice expenses, or (b) 20% of the total practice expenses.

Recruitment of Certain Local Physicians. Hospitals, both rural and urban, may recruit local physicians if they were previously employed for at least two years on a full-time basis by a federal or state bureau of prisons or similar correctional agency, the federal Departments of Defense or Veterans Affairs, or the federal Indian Health Service.

Permitted Practice Restrictions. Under Stark II, a physician group into which a physician was recruited was prohibited from imposing "additional practice restrictions" on the recruited physician, other than conditions related to the quality of care. In Phase III commentary, CMS states that it intended to prohibit only restrictions that:

would have a substantial effect on the recruited physician's ability to remain and practice medicine in the hospital's geographic service area after leaving the physician practice or group practice.

CMS states specifically that physician groups or group practices may place the following nonexclusive list of restrictions on recruited physicians:

- Reasonable non-compete provisions (CMS states that provisions which fail to comply with state and local laws "run a significant risk of being considered unreasonable);
- Restrictions on moonlighting;
- Non-solicitation provisions regarding both patients and employees;
- Provisions requiring the physician to treat Medicaid and indigent patients;
- Provisions requiring the physician to not use confidential or proprietary information of the physician practice;

- Provisions requiring the physician to repay losses absorbed by the practice in excess of any hospital recruitment payments; and
- Provisions requiring the physician to pay predetermined and "reasonable" liquidated damages if the physician leaves the practice and remains in the community.

New Restrictions on Physician Recruitment. Although Phase III primarily relaxes rules on physician recruitment, it also contains a few additional limitations. Previously, a physician was considered to have "relocated" his or her medical practice if the physician moved the practice at least 25 miles or derived at least 75% of his or her revenues from professional services provided to new patients.

Under Phase II, "relocation" requires that the physician move his or her practice into the service area of the hospital in addition to meeting either the 25-mile or 75% of revenues test.

Other Recruitment Commentary. In additional Phase III commentary regarding physician recruitment, CMS indicated that a hospital may require a physician practice to guarantee repayment of recruitment loans made to a recruited physician. However, guarantees that are not enforced or are used to shield a recruited physician from any true liability present a "significant risk" of noncompliance with fraud and abuse laws, according to CMS.

CMS declined to expand the physician recruitment exception to permit a hospital to assist a physician group or physician practice to recruit a non-physician practitioner, stating that the risk of abuse inherent in those arrangements is too great.

The physician recruitment exception provides that a hospital may reimburse a group practice or physician group for its actual costs incurred to recruit a new physician. In Phase III commentary, CMS clarified that these actual costs include headhunter fees, tail malpractice insurance from the physician's prior practice, moving expenses, airfare, hotels and other expenses associated with visits by the recruited physician and his or her family.

Retention Payments in Underserved Areas (42 C.F.R. § 411.357(t))

Phase III contains several changes that expand the exception for retention payments made to physicians.

First, hospitals are no longer the only type of DHS entity that may make retention payments to physicians. Under Phase III, Federally Qualified Health Centers (FQHC) and rural health clinics may make retention payments, provided they meet all of the other requirements of the exception.

Second, the hospital, FQHC or rural health clinic no longer needs to be located in a HPSA or area with demonstrated need. Instead, the exception may still be used if the hospital or FQHC is located in a HPSA. However, the exception may also be used if (a) the physician is located in a HPSA, rural area, or area of demonstrated need (as determined in an advisory opinion from the secretary of DHHS); or (b) at least 75% of the physician's patients live in a "medically underserved area" or are part of a "medically underserved population," as determined by the U.S. Health Resources and Services Administration.

Third, Phase III eliminates the requirement that a physician have received a written recruitment offer before retention payments are permitted. Under Phase III, retention payments may be made if the physician has received a recruitment offer or an employment offer. In addition, the offer need not be in writing. In the absence of a written offer, the physician may certify in writing that he or she has a bona fide opportunity for future employment by a hospital, academic medical center or physician organization that would require relocation of

the physician's practice at least 25 miles *and* outside the service area of the hospital, FQHC or rural health clinic making the retention payment.

Fourth, although Phase II required that the recruitment offer come from a hospital, Phase III permits retention payments when the physician receives a recruitment or employment offer from a hospital, academic medical center or physician organization.

Phase III also limits the amount of retention payments to the lower of (a) 25% of the physician's current income (measured over no more than a 24-month period, using "a reasonable and consistent methodology that is calculated uniformly"), or (b) the reasonable costs the hospital, FQHC, or rural health center would otherwise have to expend to recruit a new physician to replace the retained physician.

Rental of Office Space and Rental of Equipment (42 C.F.R. §§ 411.357(a) & (c))

Phase III makes no substantive changes to either the rental of office space or rental of equipment exceptions, although in its Phase III commentary, CMS clarifies several points regarding these leases and their termination or amendment.

CMS states that parties to a lease may amend it multiple times during or after the first year of the lease term. An amended lease must meet all of the requirements of the applicable exception for a space or equipment lease. However, if an amended lease meets all other requirements of the applicable exception, it does not have to continue for an additional one year after amendment if the original lease would have terminated sooner. An amended lease may instead have a shorter term and may terminate as early as the end of one year from original inception of the lease (assuming that was the original lease's term).

CMS also states that parties to a space or equipment lease may not amend the lease to change the rental rate or rental methodology during any term of the lease, even a renewal term. CMS believes a lease with an amended rental rate or rental methodology does not meet the "set in advance" requirement for rental under these two exceptions. Instead, the parties must terminate the existing lease and enter into a new lease that meets the requirements of the applicable exception.

Parties may terminate a lease during the first year of its term. If they do so, however, parties may enter into a new lease only after the first year of the original lease term (regardless of the length of the original term). CMS clarified that the prohibition on entering into a new space lease during this one-year period applies only to leases involving all or part of the same space covered by the original lease. The parties are not prohibited from entering into a new space lease for different space.

CMS also notes that changes that have a material impact on the rental rate (such as the amount of leased space) *may* require termination of the existing lease and entering into a new lease.

CMS rejected a suggestion that the fair market value or payments by a physician exception should appropriately be applied to turn-key "time-share" lease arrangements for the use of office space (and sometimes equipment) during specific intervals on an exclusive basis. Time-share arrangements must meet the applicable rental exception or exceptions.

Personal Services Arrangements (42 C.F.R. § 411.357(d))

Phase III made two substantive changes to this exception. In addition, CMS commentary to Phase III limits the ability of parties to a personal services arrangement to amend the compensation at any time during the term of the arrangement.

The first change allows a holdover for an expired personal services agreement on the same terms as the original agreement, for up to six months after expiration.

The second change eliminates the safe harbor method for calculating fair market value under the exception. Under Phase II, the definition of "fair market value" provided that compensation for a physician's personal services was deemed to be fair market value if: (a) it was less than or equal to the average hourly rate for emergency room physician services in the relevant physician market; or (b) it was determined by averaging the 50th percentile national average compensation level for physicians in the same specialty using at least four of six designated physician compensation surveys.

CMS noted that it may be impractical to obtain the hourly rate for emergency room physician services of competing hospitals, and that some of the designated compensation surveys no longer exist or are not readily available to all DHS providers and physicians. In response, CMS eliminated the safe harbor, stating that compliance with this safe harbor had always been voluntary and that there are many other methods to establish fair market value. In Phase III commentary, CMS offers the following guidance for determining fair market value:

Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value. Ultimately, the appropriate method for determining fair market value for purposes of the physician self-referral law will depend on the nature of the transaction, its location, and other factors. . . . [A]lthough a good faith reliance on an independent valuation (such as an appraisal) may be relevant to a party's intent, it does not establish the ultimate issue of the accuracy of the valuation figure itself.

Phase III commentary also contains an important interpretation by CMS of the "set in advance" standard for compensation under arrangements that meet the personal services arrangements exception. According to CMS, the "set in advance" requirement prohibits amendment of the compensation under a personal services arrangement at any time during its term.

The parties to a personal services arrangement may terminate the arrangement and enter into a new arrangement with different compensation; however, they cannot enter into the new arrangement during the first year of the term of the initial arrangement.

Charitable Contributions by a Physician (42 C.F.R. § 411.357(j))

Phase III clarifies that a recipient's knowledge of a donor's improper intent is an element of the exception for Charitable Contributions by a Physician.

Phase II previously created an exception for charitable contributions made by physicians to a DHS entity if, among other requirements, the donation was neither solicited "nor made, in any manner" that takes into account the volume or value of referrals or other business generated between the physician and the recipient entity.

Phase III revises this exception to provide that the donation may not be solicited "nor offered, in any manner" that takes into account the volume or value of referrals or other business generated between the physician and the recipient entity. This revision clarifies that a charitable donation may still be covered by the exception if the recipient DHS has no knowledge of a donor physician's improper intent in making the contribution.

Nonmonetary Compensation (42 C.F.R. § 411.357(k))

Phase III made two substantive changes to this exception.

The first change is creation of a mechanism to cure violations where the DHS entity inadvertently exceeds the annual limit of \$300 plus CPI (the current adjusted limit is \$329) in nonmonetary compensation per physician. If the payment of excess compensation is inadvertent and exceeds the dollar limit by no more than fifty percent (50%) during a calendar year, then the compensation will still be "deemed" to be within the limit if the recipient physician repays the excess compensation by the earlier of (a) the end of the calendar year in which the excess nonmonetary compensation was received, and (b) one hundred eighty (180) days after the date the excess nonmonetary compensation was received. However, a DHS entity may use this cure mechanism not more than once every three years with respect to the same physician.

CMS states that once a DHS entity learns of a payment of excess nonmonetary compensation "it would be prudent" for the entity not to bill or submit claims for the recipient physician's DHS referrals until the overpayment has been cured.

The second change allows DHS entities with a formal medical staff to host one medical staff appreciation function each year for the entire medical staff. Any gifts or gratuities provided to physicians in connection with the function are still subject to the annual limit of \$300 plus CPI.

Fair Market Value Exception (42 C.F.R. § 411.357(m))

The fair market value exception previously applied only to payments from a DHS entity to a physician (or immediate family member) for the provision of items or services. Phase III expands this exception to include payments by a physician (or immediate family member) to a DHS entity.

However, CMS notes in commentary that this exception does not apply to payments from physician to a DHS entity for space leases in which the physician is the lessee. Instead, these leases must meet the requirements of the exception for space leases.

Compliance Training (42 C.F.R. § 411.357(o))

Phase III expands this exception to allow hospitals to provide compliance training to physicians if the primary purpose of the training program is compliance, even if the physicians receive continuing medical education (CME) credit for the training. Previously under Phase II, this exception did not apply to compliance training if the training included CME credits.

In related Phase III commentary, CMS states that parties may use the fair market value exception to protect an equipment lease with a term of less than one year, even though the specific exception for equipment leases requires a term of one year or more.

Professional Courtesy (42 C.F.R. § 411.357(s))

Under Phase III, this exception now applies only to professional courtesy provided by DHS entities who are hospitals or providers with formal medical staffs. Suppliers such as DME companies or laboratories cannot use the exception.

In addition, CMS deleted the previous requirement that the DHS entity providing the professional courtesy notify an insurer when the professional courtesy involves the whole or partial reduction of a coinsurance obligation.

In-Office Ancillary Services (42 C.F.R. § 411.355(b))

Phase III did not make any substantive changes to this exception. However, CMS indicated its concern with arrangements not having a sufficient nexus between the physician group's practice and the ancillary services.

For example, CMS declined to provide a quantitative measure for requirement that at least "some" DHS physician services unrelated to the furnishing of DHS be provided in the same building as the in-office ancillary service. In applying this standard, CMS stated that it would take into account the nature of the group's overall practice (such as the specialties of the group's physicians) and the referring physician's full range of practice.

CMS also raised the possibility of "sham" arrangements that do not meet the requirements of this exception:

Creating a satellite office that appears to satisfy the "same building" requirements, but in fact is merely a sham arrangement, will result in claims denial. For example, renting office space part-time in a freestanding imaging facility purportedly to provide physician services unrelated to DHS at the facility location would be considered a sham if few or no such services were actually contemplated or provided. . . . [T]he operation of an arrangement, not its form on paper, is determinative.

Phase III commentary states that, for purposes of the in-office ancillary services exception, all Medicare program conditions related to supervision, location, and billing must be strictly satisfied for each DHS claim submitted to Medicare.

CMS also indicated that it was considering whether "sophisticated imaging equipment" and in-office pathology laboratories should continue to be subject to this exception.

Academic Medical Centers (42 C.F.R. § 411.355(e))

Phase III revises this exception to clarify that the total compensation from each academic medical center (AMC) *component* (and not merely the AMC as a whole) to a faculty physician must be set in advance and not be determined in a manner that takes into account the volume or value of referrals by the physician.

Phase III also revises the definition of an AMC to require that an AMC-affiliated hospital must either include or exclude all physicians holding the same class or privileges when determining whether the majority of physicians on the medical staff of the hospital consists of faculty members.

Definition: "Physician In The Group Practice"

Phase III modifies the definition of "physician in the group practice," a phrase whose relevance under the Stark Law includes determining which physicians may supervise the performance of in-office ancillary services for a group practice. The revised definition requires that, in order to be considered a "physician in the group practice," an independent contractor physician must furnish patient care services for the group under a contract *directly* with the group. Leased employees are not considered "physicians in the group practice" under the revised definition.

This requirement that a contract be "directly" with a physician is contrary to the common practice of a physician group contracting with another physician group to provide professional services (such as a contract with a radiology group to provide professional radiology reading services). The group practice requiring professional services of an independent contractor physician must now contract directly with each physician who will provide services, or else the physician will not be considered a "physician in the group practice."

Other Changes

Phase III made numerous minor additional changes to definitions and exceptions contained in the Stark Law regulations that must be considered when applying the Stark Law to an existing or proposed arrangement. In addition, CMS's commentary provides insight into its interpretation of existing law and the Phase III revisions.

Conclusion: Likely Effect on Existing Business Arrangements

Although the revisions to the physician recruitment and retention exceptions and the new "standing in the shoes" doctrine for physicians in a group practice are significant, Phase III is not likely to affect existing business arrangements to the same degree as the revisions to the Stark Law and Medicare's anti-markup provisions contained in CMS's proposed updates to the Medicare Physician Fee Schedule (MPFS) for fiscal year 2008. The proposed MPFS updates were the topic of a July 2007 Baker Donelson Health Stat, *Proposed Stark Law Revisions Could Affect Many Existing Business Arrangements Between Physicians And Hospitals And Other Providers*.

Phase III is unlikely to be the last word on the Stark Law.

In its commentary, CMS indicates several areas with respect to which it is considering changes to the regulations. As an example, although CMS declines to make any substantive changes to the definition of "entity," it indicates a willingness to consider adoption of the Medicare Payment Advisory Commission's March 2005 recommendation that a Stark Law "entity" include any entity that derives a substantial portion of its revenues from a provider of designated health services. CMS expresses its intent to study this issue to determine the best approach to protect against program and patient abuse. CMS also indicates that any change made to address this issue, whether through the definition of "entity" or otherwise, will be made in a separate rulemaking, subject to public comment.

The MPFS proposes amendments to the Stark Law (and to related laws that affect physician-DHS provider relationships) that would prohibit certain "per-click" leases and percentage compensation arrangements, eliminate "under arrangements" physician joint ventures and limit use of the in-office ancillary services exception. The MPFS also identifies other areas where it may propose additional revisions CMS has begun a survey process that will require 500 hospitals to provide detailed information about their financial relationships with physicians, including copies of documents defining these relationships. There is also legislation pending in Congress which would narrow the Stark Law exception for physician ownership of hospitals.