

## **Changes to Stark Regulations: A Refresher**

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As many providers already know, the so-called "Stark law" prohibits physicians from making referrals to providers who render "designated health services" (DHS) if referring physicians or their immediate family members have an ownership or investment interest in, or compensation arrangement with the provider. Designated health services generally include home health, home medical equipment (HME), infusion services, and outpatient hospital services, among others. DHS does not, however, include hospice services. Likewise, providers of DHS generally cannot bill for services provided to patients referred by physicians who have ownership or investment interests in, or compensation arrangements with them that violate the Stark law.

Exceptions to these general rules were published in the form of final regulations on January 4, 2001, the so-called "Phase I" Stark rules. On March 26, 2004, "Phase II" Stark regulations were published as interim final rules in the Federal Register. These Phase II regulations further clarified exceptions to the statute described above.

Changes to the regulations went into effect on December 4, 2007. Revisions to the regulations related to payments to consulting physicians from whom providers receive referrals, training and education, and non-monetary compensation are relevant for home health agencies.

### **Use of Physicians to Provide Consulting Services**

The Phase II regulations provided specific guidance regarding the use of physicians to provide consulting services to physicians. Many providers utilize the services of referring physicians as consulting physicians to their organizations. These consulting physicians provide a variety of appropriate services to providers.

According to the Phase II regulations, there is an exception for personal service arrangements that may include payments to referring physicians for consulting services. In order to meet the requirements of this exception, providers must ensure that:

- They enter into a written agreement with physicians that is signed by providers and physicians, which specifies the services covered by the arrangement.
- The arrangement must cover all of the services to be furnished by referring physicians to providers.
- Aggregate services provided by consulting physicians do not exceed those that are reasonable and necessary for the legitimate business purposes of providers.

- The term of each arrangement is for at least one year. To meet this requirement, if an arrangement is terminated during the initial term of the agreement, with or without cause, the parties may not enter into the same or substantially the same arrangement during the remainder of the first year of the original term of the agreement.
- Compensation paid over the term of the agreement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement, or other activity that violates any State or Federal law.

As described above, providers must pay for services from consulting physicians at fair market value. Many providers have asked how they should determine fair market value.

Previously, the Stark II rules made it clear that fees paid to referring physicians for their services were considered to be at fair market value only if hourly payments were calculated using either of the following two methodologies:

- The hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market.
- If there are fewer than three hospitals that provide emergency room services in the geographic area where the provider operates, or if providers choose to do so, they may pay physicians at an hourly rate that is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty or, if the specialty is not identified in the survey, for general practice in at least four of the following surveys divided by 2,000 hours. The surveys are:
  - Sullivan, Cotter and Associates, Inc. - Physician Compensation and Productivity Survey
  - Hay Group - Physicians Compensation Survey
  - Hospital and Healthcare Compensation Services - Physician Salary Survey Report
  - Medical Group Management Association - Physician Compensation and Productivity Survey
  - ECS Watson Wyatt - Hospital and Health Care Management Compensation Report
  - William M. Mercer - Integrated Health Networks Compensation Survey

*As of December 4, 2007*, the above formulas no longer apply. Nonetheless, providers must be able to demonstrate, using some reasonable basis, that compensation paid to consulting physicians who also make referrals is at fair market value.

Providers could, for example, conduct what amounts to a “salary survey” of providers that operate in the same geographic area regarding the amount per hour that other providers pay consulting physicians. Such a survey is likely to produce a range of hourly rates. Providers should document the results of these surveys and pay physicians at rates that do not exceed the highest end of the range.

The above described change with regard to the use of formulas to calculate compensation at fair market value is an appropriate and welcome change. The formulas proved difficult, if not impossible, for home care providers to use. Providers can now avoid the frustration of trying to comply and breathe a sigh of relief.

### Training and Education

The Phase II Stark rules also include an exception for "compliance training," which appears to allow organizations to provide a variety of types of training and education to physicians from whom they receive referrals.

*Previously*, according to this exception, providers could provide such training to physicians, their immediate family members, and office staff who practice in the provider's local community or service area so long as the training is held in the local community or service area. "Compliance training" means:

- Training regarding the basic elements of a compliance program, such as establishing policies and procedures, training of staff, internal monitoring, or reporting;
- Specific training regarding the requirements of Federal and State health care programs, such as billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements; or
- Training regarding other Federal, State or local laws, regulations, or rules governing the conduct of the party for whom the training is provided.

This exception did not, however, include medical education.

*As of December 4, 2007*, compliance training may include programs that offer continuing medical education credits, provided that compliance training is the primary purpose of the program.

## Non-monetary Compensation

According to another exception under the Stark laws, providers may give physicians and/or their immediate family members non-cash items that have a relatively low value and are not part of a formal, written agreement. Staff may, for example, provide lunch or snacks, such as cookies, to physicians and their personnel at their offices. Providers have also routinely left items of limited value, such as coffee mugs, pens, and notepads at physicians' offices.

*Previously*, the regulations indicated that non-monetary compensation did not violate the Stark laws as long as all of the following criteria are met:

- The annual aggregate value of non-monetary gifts to a physician does not exceed \$300.00. (This amount increases each year if the consumer price index rises.)
- Providers that give non-monetary compensation to physicians make it available to all similarly situated physicians, regardless of whether physicians refer patients to the company for services.
- The compensation is not determined in any way that takes into account the volume or value of a physician's referrals to the supplier.

Thus, it is clear that agencies that meet these criteria for non-monetary compensation can avoid violation of the Stark laws.

Providers should, however, also be aware of the following limitations:

- Protection from violations of the Stark laws is not available for gifts that are solicited by physicians or group practices. The reason for this limitation is to prevent physicians from making such gifts a condition or expectation of doing business.

The "classic" example of solicitation of gifts is insistence by physicians that they will only meet with staff to discuss patients receiving services if the staff supplies lunch. Such requirements may amount to solicitation that will preclude protection for companies that supply lunch under these circumstances.

- The exception for non-monetary compensation up to \$300.00 only protects gifts to individual physicians. Thus, gifts given to a group practice will not qualify for this exception. Non-cash gifts, however, could be given to one member, several individual members, or each member of a group practice if each such gift meets all of the conditions of the exception for non-monetary compensation up to \$300.00. The exception does not apply to gifts, such as holiday parties, office equipment, or supplies that are valued at not more than \$300.00 per physician in the group, but are, in effect, given or used as a group gift.

As of December 4, 2007, Stark provides for a limited exception when providers inadvertently provide nonmonetary compensation to physicians who make referrals to them in excess of the above limit. Such compensation is deemed to be within the limit if:

- The value of the excess non-monetary compensation is no more than 50% of the limit; and
- Physicians return to providers who receive referrals the excess non-monetary compensation or an amount equal to the value of the excess non-monetary compensation by the end of the calendar year in which the excess non-monetary compensation was received, or within 180 consecutive calendar days following the date the excess non-monetary compensation was received by physicians, whichever is earlier.

The above changes should generally be welcomed. At the same time, it is important to master them in order to achieve and maintain compliance.