



October 29, 2007

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011, Baltimore, MD 21244-1850

Re: Medicare Program; Physicians; Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)

Dear Mr. Weems:

We would like to bring to your attention an unintended consequence of the Final Rule referenced above, CMS 1810-F, which is of great concern to our members and to most other physicians participating in the Medicare or other Federal health care programs. Specifically, the Final Rule requirement that physicians who pay medical groups for designated health services comply with the Fair Market Value Compensation exception will result in a dramatic interruption in the provision of health care services to an entire class of Medicare beneficiaries who are also physicians.

AMGA's members frequently provide health care services to physicians and their families who are patients, not employees of the groups. Some are undoubtedly Medicare or other Federal health program beneficiaries. Such care was protected by an exception to the Stark regulations that covered payments by physicians, Code of Federal Regulations Sec. 411.357(i), *Payments by a Physician*.

Compliance with this exception caused no undue hardship on physicians, nor did it raise any fraud or abuse issues. However, according to the regulatory exception in the Final Rule (but not the statutory exception in the Social Security Act, section 1877 (e)(8)), this exception is now available *only if no other exception applies*. Therefore, before an entity may provide designated health services (DHS) to physicians and family members who are Medicare beneficiaries, it must now comply with another exception to be in compliance. In many if not most instances, the operative exception would be section 411.357 (l), *Fair Market Value Compensation*.

In order for the exception at Sec. 411.357(l) for fair market value compensation to be effective, AMGA's members would have to meet a number of requirements: Use of a written agreement before services are provided, signed by every physician (and family members) who might obtain who receive services from a participating physician;; and stipulate the payment amount which would have to remain unchanged for 12 months.

Under the Final Rule, physicians and medical groups would have to enter into a written arrangement before the physician or family member was admitted to receive imaging, physical therapy services, or any other DHS. This written agreement would be in addition to the pre-existing agreement between patients and their insurers.

This is clearly impractical, perhaps even impossible for physicians, in particular for those in large practice settings, rendering achievement of compliance virtually unattainable. Further complicating the situation is the reality that provision of medical services and the composition of future patient populations cannot be predicted or anticipated.

We believe this change represents too narrow an interpretation of statutory intent and produces unrealistic burdens to physicians in the care of their patients. There is great potential for broad disruption of patient care if this is not corrected. Provision of services to a physician or family member triggers a relationship that is governed by the Stark regulations. If another exception does not apply, failure to comply with 411.357(l) would mean that billing for DHS provided to any physician or family member who is a Medicare beneficiary or for any subsequent Medicare or Medicaid beneficiary referred by that physician, would be a Stark violation.

While we are certain CMS did not foresee this outcome, the current situation presents a real problem for many AMGA members and countless other physicians treating Medicare patients. We request that CMS clarify its position vis a vis the exceptions to the Stark prohibitions discussed. CMS could issue an advisory opinion clarifying intentions regarding the Fair Market Value exception in the circumstance involved. Another option would involve drafting questions and answers for your website that address the concerns under discussion. Finally, CMS could reply to and assuage our concerns directly by letter, which could also be made broadly available through normal communications channels.

Thank you for considering our request to address what we believe to be an unintended consequence of the Stark III regulations. Feel free to contact George H. Roman of my staff at (703) 838-0033 ext. 342 or by email at groman@amga.org, if you have questions or require additional information.

Sincerely,



Donald Fisher, Ph.D
CEO and President

cc: Donald H. Romano, CMS, Director, Technical Payment Policy