June 12, 2008

Mr. Kerry Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC  20201

RE: CMS-1390-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) and Fiscal Year 2009 Rates; Proposed Rule (Vol. 73, No. 84), April 30, 2008

Dear Mr. Weems:

The Medical Group Management Association (“MGMA”) appreciates the opportunity to submit these comments on the proposed changes to the Stark physician self referral and hospital acquired conditions regulations noticed as part of the proposed IPPS rule for FY 2009. MGMA serves 21,500 members who lead and manage more than 13,500 organizations in which almost 270,000 physicians practice.

**Physician Self Referral Law**

As MGMA has commented to CMS on various Stark rule-makings over many years, our members support reasonable restrictions on physician self-referral as long as they are practical, understandable and implementable, and do not unduly interfere with the ability of group practices to provide a full range of physician and ancillary services to their patients. Unfortunately, as the Stark regulations have evolved over time, they have become ever more complex to the point where they are now virtually incomprehensible to the average physician or group practice administrator. Even routine business and clinical arrangements now require development and review by high priced lawyers and consultants, adding to the cost of practice, but frequently leaving groups uncertain as to their compliance status.
The complexity of the regulatory structure is compounded by the constant changing of the rules and the seemingly endless list of issues under consideration for possible future changes. With the use of both Medicare Physician Fee Schedule and Hospital IPPS rulemakings to supplement those devoted exclusively to Stark, there is now virtually never a time when some aspect of the Stark law is not in a state of flux. The current rulemaking illustrates the point.

Less than five (5) months from the effective date (eight (8) months from promulgation) of the long-awaited Phase III Stark rules, groups are now confronted with another set of complex proposals—some with specific regulatory language proposed for amendment and some simply preamble musings on what options for change may be under consideration—dealing with just a few aspects of this hydra-headed monster. The possible “tweaking” of the rules in just this one regulatory round takes many times more words in the Federal Register to explain than the entire statutory scheme occupies in the U. S. Code.

MGMA submits that it is time for the government and the regulated to take a TIME OUT! Further, MGMA thinks it is time for all concerned to step back and re-examine some structural aspects of the rules that add complexity for group practices. While group practice has gradually become the prevailing mode of delivering physician services in this country, the Stark rules (like many in Medicare) read as if solo practice is the rule, and group practice the exception, requiring modifications to “standard” rules in the case of groups.

For example, the current rules include a chain of provisions that starts by distinguishing between “direct” and “indirect” compensation relationships, and leads to a special definition, exception, policies (“stand in the shoes” and other “deeming” clauses), grandfathering, delays to policies, exceptions to policies, and “conventions” for the application of policies. The end result is an analytical nightmare that may not be necessary to achieve the desired result, at least as to the vast majority of “plain vanilla” relationships between medical groups and DHS entities to which group physicians refer.

A more straightforward approach might be to apply the threshold prohibitions on self-referral in 411.353 to situations where a physician’s group has a financial relationship with a DHS entity, just as the law already does when the financial relationship is between a DHS entity and an immediate family member rather than the physician. If this were the case, then the exceptions could be made directly applicable to these financial relationships between the group and the DHS entity without the need for complicated “deeming” provisions of the type buried in 411.354 (c)(3)(i), where only the proverbial “Philadelphia lawyer” can hope to find them. Not only would this make one aspect of the rules easier to understand and apply, it would also conform the regulatory structure to the evolving reality of how physicians relate to hospitals and other DHS entities. That reality is that groups contract on behalf of their physicians as often as, if not more frequently than, physicians contract directly.
There are very likely other aspects of the rules that could be made more straightforward by changing the terms of certain exceptions, e.g. to accommodate “mission support” payments that defy fair market value analysis, rather than trying to apply “stand in the shoes” in some cases but not others in order to achieve a particular policy result.

We understand that this different approach might require a considerable amount of review and redrafting, and that some of the complexity inherent in the current approach might still need to be retained to deal with indirect financial relationships through entities other than group practices. We also understand that the history of Stark rulemakings is fraught with the “law of unintended consequences,” and this alternative approach might have some. However, we think it is time to look at fresh approaches to ensure that groups can understand and comply with their regulatory obligations without constant resort to their “Philadelphia lawyers.”

As the current proposal to define different “periods of disallowance” for different types of non-compliance highlights, the financial consequences of violating the Stark law can be severe. When Stark violations are prosecuted as False Claims Act violations, these consequences become even more severe. Given those consequences, physicians, groups, and the DHS entities with which they do business need understandable rules. Indeed, one of the original purposes of the Stark law was to provide “bright lines” in contrast to the uncertainties providers historically faced under the intent based Anti-Kickback law. After almost 20 years of Stark, that clarity remains elusive. Indeed, the whole regulatory scheme gets less understandable as it gets more and more refined.

**MGMA urges you and your staff to undertake a comprehensive review of the current rules before making any other changes. The goal of this review should be administrative simplification. If the Agency is willing to embark on such a review, MGMA commits its resources and that of its members to cooperating with you.**

**Hospital Acquired Conditions (HACs)**

**Application of Nonpayment for HACs to Other Settings**

Although CMS lacks statutory authority to expand the approach of Medicare not paying for preventable health-care associated conditions to Medicare payment settings other than hospitals, the agency has requested public comment about the prospect of applying this approach to other settings. MGMA would be extremely concerned if Medicare expanded the non-payment strategy for preventable health conditions acquired beyond the hospital setting, especially to physician practices. Not only is the physician payment system different from the hospital setting, but the attribution issues alone would make this approach nearly impossible to accurately and fairly implement at the physician level. We believe this punitive policy is totally contrary to current efforts to implement a lasting patient safety system in this country as envisioned in the Patient Safety and Quality Improvement Act of 2005.
Adoption of ICD-10-PCS to facilitate more precise identification of HACs.

CMS has solicited public comment on a potential move to ICD-10-PCS to more granularly identify HACs. We would like to take this opportunity to raise concerns regarding any rapid timeline for adopting the ICD-10 code sets. Complex software and business process changes must be completed before ICD-10 could be utilized. Transitioning too rapidly to ICD-10 would create significant problems for the entire health care industry, especially providers. Before any move to ICD-10, there must be a national implementation plan, a cost-benefit analysis, code set crosswalks, and full implementation of the HIPAA 5010 standards. We recommend mandating extended compliance timelines in recognition that the transition to ICD-10 will be extremely challenging and costly for the entire industry, particularly small and medium-sized physician practices.

Should you have any questions concerning these comments, please contact Anders Gilberg at 202-293-3450.

Sincerely,

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President and CEO

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