August 28, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201


Dear Acting Administrator Weems:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the proposed rule entitled the “Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generation Facsimile Transmissions; Proposed Rule,” as published in the July 7, 2008 Federal Register. We appreciate the Centers for Medicare & Medicaid Services’ (CMS) outreach to the provider community and its willingness to participate in constructive dialogue to improve the Medicare program. We look forward to continuing to collaborate on these and other administrative simplification issues.

MGMA, founded in 1926, is the nation’s principal voice for medical group practice. Today, MGMA’s 21,500 members lead 13,500 organizations nationwide in which some 270,000 physicians provide more than 40 percent of the health care services delivered in the United States. MGMA’s core purpose is to improve the effectiveness of medical group practices and the knowledge and skills of the individuals who manage and lead them. Individual members, including practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently, so physician time and resources can be focused on patient care.
Key recommendations

MGMA offers a number of critiques and recommendations related to this rule, as outlined below. Here, we provide a summary of our key recommendations. CMS should:

- Implement the 1.1 percent Medicare physician payment update in 2009 using the current 2008 conversion factor as the base rate.

- Withdraw its proposal to require physician offices providing diagnostic imaging services to enroll as independent diagnostic testing facilities (IDTFs), especially in light of the imaging accreditation provisions contained in the Medicare Improvements for Patients and Providers Act (MIPPA).

- Delay in implementing any changes to the Medicare enrollment process until a web-based enrollment system is ready for use by providers and is in place.

- Create extensive educational programming on provider enrollment for both its contractors and providers to ensure that both sides thoroughly understand the process and expectations.

- Extend the Jan. 1, 2009, compliance date for the exemption for computer-generated facsimiles until the great majority of medical groups have transitioned to the NCPDP SCRIPT standard. CMS should also augment its educational activities and regularly assess the readiness level of the industry.

- Withdraw the complex and confusing proposals relating to the anti-markup rule and instead focus on implementing the requirements in MIPPA.

- Allow an appeals process for the 2007 Physician Quality Reporting Initiative (PQRI), provide medical associations with the 2007 and 2008 PQRI data set files, withdraw proposed changes to the group measure participation option, and only publish on its website the names of clinicians and group practices that satisfactorily participate in PQRI and earned the bonus incentive.

Medicare physician reimbursement

The proposed physician fee schedule confirms the 5.4 percent reduction in Medicare physician reimbursement levels for services rendered on or after Jan. 1, 2009 as forecasted by CMS in the February 29, 2008 letter to the Medicare Payment Advisory Commission (MedPAC). MedPAC estimates that payment will be cut every year for the foreseeable future — a trend that will have grave consequences for the entire health care system without legislative action – and has recommended that the current system be replaced with one that reflects the need for annual increases.

The Medicare Improvements for Patients and Providers Act (MIPPA) reverses the 10.6 percent physician payment cut that took effect July 1 with a continuation of the current 0.5 percent
payment rate. MIPPA also halts the estimated 5.4 percent cut scheduled for Jan. 1, 2009 and replaces it with a 1.1 percent rate. To be consistent with both congressional intent and with the Jan. 2008 MedPAC physician payment recommendation, MGMA strongly urges CMS to implement the 1.1 percent Medicare physician payment update in 2009 using the current 2008 conversion factor as the base rate.

Though MIPPA provides for eighteen months of Medicare physician payment stability, MGMA encourages CMS to take administrative steps within its authority to mitigate future Part B reductions. MGMA believes the agency could significantly reduce the cost of a long-term solution to the sustainable growth rate (SGR) formula by retroactively removing the costs associated with physician-administered drugs from physician expenditure targets in previous years — thus budgeting more accurately for physician services. MGMA and congressional leaders have repeatedly urged CMS to retroactively remove increases in Medicare spending attributable to physician-administered drugs when calculating the SGR. Because CMS combines the costs of provider services with Medicare Part B drugs, a wider gap between SGR targets and actual provider spending occurs. The statutory language of the Social Security Act (SSA) defining the payment update formula requires CMS to assess the allowed and actual expenditures of the Medicare program. MGMA maintains that the definition CMS uses for “physician services” in the SGR formula is inappropriate because it includes the cost of physician-administered outpatient prescription drugs.

Additionally, CMS continues to disregard requests to classify new national coverage decisions (NCDs) as changes in law and regulation. The agency’s proposal to continue funding new NCDs with limited Part B funds leads to an increase in medical visits and generates additional tests and treatments not accounted for in the formula. MGMA urges CMS to include these in the SGR calculation as required by law.

**Budget neutrality adjustment**

Sec. 133 of MIPPA requires CMS to apply the budget neutrality adjuster to the conversion factor instead of work relative value units (RVUs) in 2009. During the 2006 discussion regarding the shift in application of the budget neutrality adjustment from the conversion factor to the work RVUs, CMS failed to provide an adequate rationale for shifting the budget neutrality adjustor to the work RVUs in 2006, resulting in an overwhelmingly negative response from the provider community. The placement of the budget neutrality factor on the work RVUs has contributed to tremendous variation in the impact of the provision among specialties because of the different levels of work involved. Constant variation in the work RVUs from budget neutrality adjustments hinders the process of establishing work RVUs for new and revised services.

As required by MIPPA, CMS must apply the budget neutrality adjustor to the conversion factor in order to make the calculations more equitable and understandable to the provider community. MGMA believes that applying the budget neutrality adjustor to the conversion factor will have less impact on other payers who use the Medicare resourced based relative value scale as a benchmark and will still be consistent with the statutory requirement of budget neutrality. In order to achieve CMS’ goal of transparency of pricing information, the budget neutrality adjustments should be made to the conversion factor. MGMA urges CMS to make information
available regarding the proposed 2009 budget neutrality adjustor and the new conversion factor immediately.

**Resource-based practice expense RVUs**

MGMA brings a particularly valuable perspective to this issue because we have collected practice expense data since 1955. Our data collection involves group practices ranging in size from two to several hundred physicians. As such, we understand the magnitude and complexity of CMS’ task. In addition, MGMA represents an equal proportion of primary and specialty care practices. Consequently, we are able to detach ourselves from the “outcome” and focus primarily on the “methodology” applied.

**Methodology**

MGMA supports CMS’ decision to implement a bottom-up methodology as opposed to the previous top-down approach. While the results of both approaches depend on the quality of the medical practice expense data collected, MGMA believes the bottom-up approach has a greater likelihood of resulting in accurate values. History has shown that calculating practice expenses using a data based methodology is more accurate when compared to a method that uses estimates of actual inputs.

**Data Source**

As in previous comments, MGMA maintains its concern that the practice expense methodology is based on the American Medical Association’s (AMA) Socioeconomic Monitoring System (SMS) data, which is dated, and the Clinical Practice Expert Panel’s (CPEP) data, which is extremely subjective. The SMS data used to calculate practice expenses is from 1995-1999. MGMA is aware of and supports efforts by the AMA to conduct a new survey in order to provide more up-to-date information for this calculation. Given the AMA’s experience with surveys of this nature, MGMA is hopeful that the data collected will provide CMS with current and accurate information regarding the cost of practicing medicine. MGMA appreciates CMS’ support for this effort and looks forward to the inclusion of this data in future proposals.

**Geographic Practice Cost Indices (GPCIs)**

As noted in our previous comments, MGMA remains opposed to CMS using inappropriate data sources to calculate the GPCIs. This includes the use of census data to calculate GPCI values. The very nature of the data render the values outdated by the time CMS is able to use the information. Additionally, although the statute mandates updating the GPCI values every three years, they are in essence updated only every 10 years since the census is collected once every decade. MGMA maintains that this is unacceptable. A separate source with more timely data must be identified to adhere to the three year update schedule that Congress intended. MGMA recommends that CMS work with other government agencies, including the Bureau of Labor Statistics, and private organizations to identify alternative data sources. Alternatively, CMS should work with these groups to identify an appropriately indexed data source to meet the statutory requirements.
Of particular concern to MGMA is that employee wages used in the GPCI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. While it remains true that the 2000 census definitions of certain medical professionals are more expansive than the 1990 definitions, limited improvements result for the updated GPCI values. The wages of several prominent professions continue to be excluded, including physician assistants, occupational and physical therapists, certified practice managers, information technology professionals, transcriptionists and certified coders. MGMA recommends that CMS revise the GPCIs to include these employees to ensure that the occupations used in the formula reflect the numerous categories of medical workers found in modern practices.

As in years past, the office rental indices used to calculate the practice expense GPCIs are based on the Department of Housing and Urban Development’s residential apartment rent data. While MGMA is sympathetic to the difficulty CMS has in identifying alternative sources for pricing medical office space, MGMA remains opposed to the use of residential, and not commercial data, for this purpose. Such use is inconsistent with the core objective of the Balanced Budget Act of 1997 to make Medicare payments resource based.

MGMA is pleased to see that CMS is examining appropriate methods of determining locality configurations and looks forward to reviewing the study and the ensuing report.

**Medicare telehealth services**

MGMA applauds CMS for proposing to add HCPCS codes for “Follow-up inpatient telehealth consultations;” however, there are several concerns regarding the semantics used to title and describe the codes. After the deletion of these codes in 2006, the Office of Inspector General (OIG) conducted a study on issues associated with billing and payment for consultation services. In the ensuing report, the OIG found that 95 percent of the “Follow-up inpatient consultation service” codes were billed in error, with 79 percent of these services actually inpatient visits for daily care, not consultations. CMS attempts to delineate a true subsequent consultation from the rest of the 99231 to 99233 codes by referencing the codes as “Follow-up inpatient telehealth consultations.” This is the same language that CMS used prior to the deletion of the codes.

MGMA recommends that CMS change the title to “Second or subsequent inpatient telehealth consultations” in order to provide a clearer indication of the services not considered “Follow-up inpatient telehealth consultations.” The narrative descriptors that CMS proposes to use for these codes do not resolve issues that arose when the codes were previously in existence. In the description, CMS clearly expresses the expectation of having two of the three key criteria (i.e. history, exam, or medical decision making) in the documentation to determine the level of service; however, the “typical times” are listed in the proposed description, which makes it appear to be a time-based service. MGMA recommends taking the “typical time” out of the narrative description and including the time parameters in the expanded description as it is
described for the 99231 to 99233 codes currently. Additionally, MGMA believes that CMS should include in the description an explanation of “floor time” given the technical and physical nuances of telehealth services.

It remains unclear to MGMA if all of the criteria for a consultation need to be met prior to billing for one of these new codes. MGMA is uncertain if there needs to be additional documentation for a subsequent request for advice or opinion by the on-site physician who is providing the daily care services. Also, it remains unclear as to whether the telehealth consultant needs to provide a written report of findings, advice and/or opinion to the requesting physician or if documentation in the medical records is sufficient to demonstrate a medical necessity for the telehealth consultation.

**HPSA Bonus Payments**

MGMA appreciates CMS’ proposal to clarify that physicians who furnish services in areas that are designated HPSA as of December 31 but are not included on the list of zip codes for automatic bonus payment should use the AQ modifier to receive bonus payment. This clarification will lessen any unnecessary administrative burdens resulting from the lack of a modifier as in the past.

**Part B drug issues**

**Intravenous immune globulin (IVIG) provisions**

MGMA is concerned with the proposal to discontinue the pre-administration payment for G0332 that has existed for the past three years. Ensuring patient access to IVIG and fairly reimbursing providers for administrative costs could be achieved by continuing payment for G0332, and MGMA urges CMS to reconsider the proposed IVIG policy.

**Competitive Acquisition Program for Drugs and Biologicals (CAP)**

The CAP, required by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and implemented by CMS in 2005, was conceived as a potential alternative to the Average Sales Price (ASP) payment methodology for physician administered drugs and biologicals. MGMA remains concerned regarding the capability of the CAP to replace ASP given the program’s significant limitations and unnecessary administrative complications. The current and single CAP vendor, Bioscripts, Inc. has publicly indicated its intentions to withdraw from the program, further illustrating the program’s questionable future.

Though MGMA continues to have concerns with the CAP, the association applauds the apparent steps CMS has taken in the proposed rule to increase provider participation in the program. MGMA commends the proposal to allow nurse practitioners, clinical nurse specialists and physician assistants to participate in the CAP. This proposed policy change reflects the modern level of support staff that includes these highly skilled professionals who are essential for the delivery of medical services.
MGMA also supports the proposed policy changes that would allow a participating CAP provider to transport CAP drugs to multiple practice locations. However, this would still subject a group practice’s decision to approval from the CAP vendor. MGMA recommends the agency allow physicians to transport CAP drugs to settings other then the participating CAP physician’s office and not grant the discretion to the CAP vendor. Medical providers are well trained professionals and are knowledgeable about drug stability and handling, rendering them capable of this responsibility.

**Independent diagnostic testing facility (IDTF) issues**

CMS’ proposal to apply the IDTF standards to physicians and nonphysician practitioner organizations is unnecessary and overly burdensome for providers who are already subjected to myriad levels of regulations on both the federal and state levels. CMS states that the performance standards applicable to IDTFs were established to improve the quality of diagnostic testing services and to ensure that suppliers of such services meet minimum enrollment criteria to enroll in the Medicare program. With passage of MIPPA, Congress has aimed to address quality issues by establishing accreditation requirements for suppliers of the technical component of diagnostic imaging services by 2012. In light of this requirement and given the fact that existing physician offices will have already enrolled in the Medicare program, CMS’ concerns have been addressed and it should refrain from adding additional enrollment requirements on these providers. As stated elsewhere in this comment letter, enrolling in Medicare once can be a daunting experience; enrolling twice could be devastating.

The regulatory designation of IDTF was meant to apply to entities that are independent of physician offices or hospitals. To modify the category to now include physician offices, even down to the level of basic services like ultrasound, will create an overwhelming administrative burden. On a state level, physician offices that enroll as IDTFs could be subjected to a new set of facility-related regulations within each state, including certification and certificate of need requirements. On a carrier level, different carriers have different requirements for the supervising physician. There is no national standard, and physician practices across the country will scramble to comprehend and then comply with these carrier-specific requirements. In many cases, these requirements are based on specialty, rather than physician expertise in a particular procedure. A physician office that is expert in one specialty-specific diagnostic test may not have a supervising physician meeting the contractor-specific requirements and would either need to forgo providing that test to its patients or hire a new physician to supervise some of the procedures being performed. Both options could have a negative impact on a patient’s ability to receive the proper care that he or she needs.

The new requirements and administrative hassles that would result from this proposal would be in addition to the newly-passed accreditation requirements that will affect these providers. We urge CMS to withdraw this proposal and instead focus its attention on implementing Congress’ mandates in MIPPA.

With respect to CMS’ proposal to restrict the billing rights of an IDTF whose Medicare billing number has been revoked, we refer to the general enrollment section in this comment letter below.
Physician and nonphysician practitioner (NPP) enrollment issues

To say that the Medicare enrollment process is broken only minimizes the significant ripple effect caused by its deficiencies. The current process is overly burdensome, and decisions made by Medicare contractors frequently tend towards arbitrary and inexplicable. Its complex nature has created confusion for providers and contractors alike. Confusion has spurred additional work as providers and contractors strive to correct applications that would have been completed correctly the first time if it were not nearly impossible for providers and contractors to understand the associated rules and forms.

Rather than simplifying the process or providing additional education for practitioners struggling to complete the process correctly, this latest proposal will generate additional work for both physician practices and CMS contractors because it only adds to the layers of complexity already built into the system. In fact, the enrollment process could well serve as a deterrent to practitioner enrollment in the Medicare program, especially in light of declining reimbursement. As it stands today, the Medicare enrollment process discourages providers from participating in the Medicare program. MGMA routinely fields calls from physician practices expressing their extreme frustration with the process after months and months of attempting to complete an enrollment application, whether for an individual practitioner or physician practice. Despite their best efforts, it has taken quite a few practices well over a year to enroll some providers.

In the past 12 months alone, CMS has issued new regulations, made form changes and issued 11 transmittals in the last 12 months. In this most recent publication, CMS proposes even more revisions, including potential changes to a final rule published only three days prior to this proposed rule. It is inconceivable to expect that anyone, let alone a physician practice that enrolls new practitioners infrequently, could possibly keep up with this many changes occurring on a rolling basis and successfully enroll a practitioner successfully on a second attempt, never mind a first.

With each iteration of these rules, the process and procedures for enrolling a practitioner in the Medicare program have become increasingly draconian and punitive. While MGMA concedes that there may be a few bad actors, the sweeping nature of these changes appears to suggest that CMS has convicted the entire physician and nonphysician practitioner community because of the actions of these few individuals. CMS already has the tools to sanction those bad actors, including the False Claims Act and a host of other laws designed to punish those who defraud the government. Additionally, CMS has issued regulations allowing it and its contractors to conduct unannounced site visits to address concerns that are never specified and for which no proof is required. If these methods are inadequate protections against fraud or if the government cannot afford to use these laws and regulations, these provisions should be examined and altered, rather than adding layers of complexity to the process.

CMS continues to unfairly penalize providers for problems in the Medicare enrollment process that are largely the creation of the agency and its contractors. CMS is well aware of the difficulties medical practices have faced with the enrollment process. Some of the Medicare contractors seem to have difficulty completing even the most basic task – mailing information or
requests for additional information to the correct address. MGMA has received numerous reports of circumstances where the correct address has been provided to the contractor, and the contractor mails the important communication, such as a request for further development of a provider enrollment application, to a completely different address. It is only months later when the practice inquires regarding the status of the application – and after numerous phone calls and refusals by the contractor to divulge any information – that the practice learns that the application has been closed as a result of its failure to respond, and it must start all over again. MGMA urges CMS to require Medicare contractors to communicate requests for additional information in such a manner that the communications can be easily tracked. Additionally, MGMA urges CMS to require contractors to provide accurate and complete information to applicants, allowing them practices to complete their enrollment applications in an easy and efficient manner. Contractors need to provide practices and practitioners with information regarding the names of the contact person and authorized officials contained within the contractors’ files.

Practitioners and contractors both struggle to understand this overly complex and burdensome process; however, given the uneven playing field, the contractor is left with all of the power and none of the punishment when errors are made. Many physician practices report having difficulty obtaining accurate information from their Medicare contractors with regard to the CMS-855 form. As one would expect, the lack of qualified contractor staff has already led to additional work for both the physician practices and the CMS contractors. Recognizing this difficulty, many physician practices make inquiries and requests for assistance before they even begin to complete the forms and throughout the process. MGMA members report contacting Medicare contractors with questions at least three times because they expect to receive a different answer each time. While relying on this method of obtaining information does not guarantee the correct end result, there is a greater likelihood of success for practices that follow this philosophy than those who only contact the contractor once. However, that means that contractors are fielding an increasing number of calls from physician practices distrustful of the information being provided. And this burden will only increase if CMS adopts its misguided and overly burdensome proposal requiring physician practices performing diagnostic imaging services to enroll not only as a physician practice, but as an IDTF as well. If the Medicare contractors cannot understand and explain the CMS-855 forms, how can CMS expect providers to complete the forms accurately and efficiently?

To date, CMS has complained that providers fail to conduct Medicare provider enrollment in a responsible fashion; however, the agency has yet to make available any data regarding enrollment. Agency officials frequently discuss the failure of providers to respond to requests for further development of their applications, but have provided no statistics to date. Another popularly cited failing is that providers fail to submit complete applications; again, no information has been provided to justify such a statement. Even when pressed for information regarding breakdown of the application itself, that is, information on frequent errors, CMS has declined to provide hard evidence of this problem in order to address it in MGMA education materials or in those produced by CMS. MGMA urges CMS to produce educational materials beyond the vague tip sheets located at the beginning of each application. Instead, or in addition to those tip sheets, MGMA recommends that CMS develop a series of frequently asked questions
on Medicare provider enrollment and would welcome the opportunity to work with CMS to develop such a document.

Web-based provider enrollment

In this latest attempt to fix the enrollment process, CMS appears to suggest that all problems will be resolved with the advent of the web-based enrollment system. After years of promises to resolve the numerous difficulties with the provider enrollment process, this new promise is received by the physician community with much skepticism. After all, it was last year’s final fee schedule that informed practitioners of CMS’ intention to release this product in March 2008. In fact, the provider community has been told for a number of years that a web-based enrollment system for Medicare would be available “soon.” It is unclear why CMS has taken so long to develop an entirely new web-based enrollment system when the private sector has had one in the form of CAQH’s Universal Credentialing Database (UCD) since 2002.

CAQH has sought input from the provider community and has worked with the provider community to build and improve its UCD in order to ensure usability. Providers are required to certify the accuracy of their information every 120 days – more frequently than is currently required by CMS – through a process that requires very little time. The information is provided by practitioners in one place and can be accessed by appropriate payers. These payers each individually verify the information contained within the database.

To date, CAQH has over 600,000 providers in its database and is working with hospitals and state Medicaid programs as well. The UCD has been endorsed by a wide variety of organizations, including MGMA, the AMA, the American Academy of Family Physicians and others. MGMA strongly urges CMS to adopt the UCD as its provider credentialing information gathering tool.

Based on the track record of CMS and its contractors in this arena, MGMA is concerned regarding their ability to implement a new system with a smooth transition, without systems issues and with the appropriate education and adequate notice for providers and contractors. The Medicare web-based provider enrollment process will first require registration in Individuals Authorized to Access CMS Computer Systems (IACS). It is of great concern that a Medicare web-based enrollment process will first require registration in IACS, based on the experiences of group practices attempting to retrieve their Physician Quality Reporting Initiative (PQRI) reports. According to MGMA members, this registration process is time-consuming and confusing. CMS delayed posting instructions, which caused some difficulties, but it also failed to conduct education for practitioners on this system, other than providing some vague information in a Special Open Door Forum on the PQRI generally. Practitioners were not informed until after the fact that individuals could not be both the Security Official and an authorized user, nor could those designated as security officials access the reports or other components that IACS is designed to allow individuals outside of CMS to access. These difficulties will continue to cause problems for providers as they move to the web-based enrollment process upon its rollout.

Given the magnitude of these concerns and the education hurdles facing physician practices as a new provider enrollment system is implemented, MGMA urges a “timeout” on the release of
new rules and regulations surrounding the Medicare provider enrollment process. CMS should wait until the implementation of a new system before making any additional changes to Medicare enrollment. MGMA recommends that CMS hold an open and thorough dialogue with CMS, its contractors and the provider community regarding the enrollment process as it currently stands and the problems encountered by all. MGMA would welcome the opportunity to participate in such a discussion. As the representative for group practice administrators, the individuals given the responsibility for completing provider enrollment activities on behalf of providers, MGMA is ideally situated to provide information and expertise in this area.

Electronic signatures and attachments

MGMA appreciates the opportunity that CMS gave to MGMA members earlier this year when they beta tested the web-based enrollment system and provided their analysis based on a real-world application of the system. However, MGMA remains concerned about the failure of CMS to permit the use of electronic signatures and electronic documents. Providing practitioners and practices the opportunity to complete and submit the entire application package online with the appropriate security measures in place would streamline the process and decrease the opportunity for errors to be made by both the contractors and practitioners. Under the current system, Medicare contractors have experienced a great deal of difficulty matching documents submitted to further develop applications with previously submitted applications. There is no reason to believe this difficulty will decrease in a system where all applications will require matching with separately submitted documents.

Revalidation

In the final provider enrollment regulation published in the Apr. 26, 2006, Federal Register, CMS formally established a revalidation process. Since that time, only once has CMS instructed contractors to use the formal revalidation process. A lack of contractor funding is the supposed reason for the agency’s failure to use this newly established process. However, the agency has used every other means within its power, even those having nothing to do with the current enrollment process, to force them to complete new CMS-855 forms. This still translates into an increased number of provider enrollment applications without any changes in funding.

In every instance where practitioners have encountered problems, the “solution” seems to be for the physician practice to complete a new CMS-855 form. For example, practitioners that encountered difficulties in the transition to the National Provider Identifier (NPI) were frequently told that the only way to resolve a Medicare NPI crosswalk problem was to complete a new enrollment application. Unfortunately, many practitioners in this situation did not become aware of this problem, despite repeated testing, prior to May 23. Given that it takes a minimum of 60 days to process a Medicare enrollment application – and frequently, it takes much longer – many of these practices had to forgo payment for some time until their applications were processed and the crosswalk problem was resolved.

Practices that did not encounter difficulties with the transition to the NPI have not necessarily come out unscathed. Those practices that participated in the PQRI and are interested in reviewing the feedback reports are first required to become authorized through IACS. Before
they can access their reports, they must verify that they have completed an enrollment application since 2003. If they have not, they must first complete the CMS-855 form and have it processed – again, a minimum of a 60-day wait – before they can access those reports. This has only served to further increase contractor workload.

The burden of the revalidation process would be lessened if CMS followed through with promises made in the commentary to the final provider enrollment regulation. Specifically, CMS promised that the agency or its contractors would provide practitioners with pre-populated forms to make the process less cumbersome for practitioners and their practices. Issuing pre-populated forms would decrease the burden of revalidation in a number of ways. It would allow practices to determine the identities of long-forgotten designated authorized and delegated officials who have the authority to sign the applications. Under the current system, many practices have no idea who these individuals are and waste precious time attempting to identify them. Medicare contractors, acting under instructions from CMS, make it very difficult to determine who these individuals are and generally refuse to answer such questions over the telephone.

Practices would also be able to complete the revalidation process more quickly because they could simply verify correct information or correct incorrect information, rather than completing the entire application from scratch. Additionally, with the application pre-populated, practices would be less likely to submit incomplete applications, since all they would be required to do is validate and update information already maintained in CMS databases.

In the final provider enrollment appeals rule published in the June 27 Federal Register, CMS states that the Apr. 2006 regulation served as notice that providers should begin the revalidation process, and if they have not yet done so, they should do so immediately. This flies in the face of the 2006 regulation’s commentary on this subject, indicating that practitioners should wait to revalidate their information until notified to do so by their contractor. If CMS wishes providers to revalidate their enrollment information, it should use the formal process established by the 2006 provider enrollment regulation. If contractor funding is an issue in the agency’s failure to use the formal revalidation process, then it must be an issue in these ad hoc efforts, given that these efforts increase the number of enrollment applications that must be processed by the contractors. MGMA urges CMS to clarify its apparently inconsistent policies on revalidation as set forth in the commentaries to the Apr. 2006 provider enrollment regulation and the recent June provider enrollment appeals regulation.

**Effective date of Medicare billing privileges**

CMS justifies a number of changes in its policies by noting that contractors will be required to process the bulk of web-based provider enrollment applications within 30 to 45 days. However, CMS fails to recognize that this system change and subsequent processing timeframe change will not solve the problems in the enrollment process, nor will it appease practitioners angered by the end of their ability to retroactively bill. This new system will fail to solve the problems because practices will still be limited to completing and submitting CMS-855 applications no more than 30 days prior to a physician’s start date or the formation of a physician practice. Additionally, as discussed above, there is no guarantee that the web-based provider enrollment system will be available by the general timeframe given within the proposal, not to mention the fact that the
proposal makes no provision for a delayed start date in the event of further delays in the implementation of the new system.

Should CMS adopt either of its proposals to establish an effective date for Medicare billing privileges, physician practices will be forced to begin paying new practitioners before they are able to treat actual patients. Private payers typically require physicians to start before they will allow them to begin the credentialing process. If Medicare adopts such a policy, practitioners will be able to treat very few patients, certainly not enough to pay for expenses, such as professional liability insurance and their share of practice overhead. In the face of declining physician reimbursement from the Medicare program and private payers alike, the situation will become even more untenable.

While at first glance the second proposal appears to be more workable than the first, it is equally problematic. Physician practices that allow new practitioners to treat Medicare patients before their applications are approved run the risk of submitting an application that is ultimately returned on a technicality, forcing them to begin the application all over again.

The second proposal is also unworkable for new physician practices. These organizations must begin paying rent, salaries and other expenses the minute they become operational, if not before. Many are already forced to take out loans to pay expenses in the early days of operations until they are enrolled and can bill for services provided in the interim. This proposal will inhibit the ability of physicians and non-physician practitioners to create their own organizations; instead, it will force them to join already existing entities. Essentially, this is yet another example of the government dictating practice operations.

This change also sets up a conflict with the implementation of the web-based enrollment system. Where a user is new to IACS, before the individual or practice is able to enroll as a Medicare provider, registration will inevitably delay the enrollment process, which, in turn, will delay the practitioner’s ability to provide services to Medicare patients. Additionally, users are required to access their account every 60 days. Most users do not have reason to do so, which will create difficulties and delays when they do need to access the web-based enrollment system, PQRI reports or other such systems that will be accessible via the Internet. MGMA urges CMS to reexamine the various components of the enrollment process, their interactions and their effect on the ability of health care professionals to treat Medicare patients.

Medicare billing privileges and existing tax delinquency

Pursuant to the Taxpayer Relief Act of 1997 and the subsequent congressional mandate in Sec. 189 in MIPPA, CMS plans to implement the Federal Payment Levy Program (FPLP) to collect overdue taxes owed by providers and suppliers enrolled in Medicare Part A and Part B. Such providers and suppliers frequently reassign their billing rights to a third party, and the FPLP does not allow the agency to offset payments that have been reassigned. Consequently, CMS is also considering proposals that would prohibit payment to providers and suppliers when benefits have been reassigned to a group practice or other entity.
MGMA is supportive of the federal government’s interest in collecting tax delinquencies. We also appreciate CMS’ recognition that it is not appropriate to take action against a group practice or other entity when a tax delinquency is owed by one of its physicians. To address this situation, CMS is considering proposing to either 1) revoke the billing privileges of such individual physicians or 2) revoke the billing privileges of organizational entities when the owners of the entities have tax delinquencies.

With respect to the first option, MGMA does not believe it is wise to revoke the billing privileges of a physician member of a group practice simply because the agency cannot directly levy future Medicare payments. This proposal is counter to the agency’s stated goals if it hopes to ensure a revenue stream to fulfill the tax obligation, especially when credentialing with other private and government payers can be conditioned on Medicare enrollment. Eliminating the means to earn income will not help the federal government recoup tax liabilities. In addition, we are concerned that the move would penalize physicians practicing in group practices by revoking their enrollment privileges where the same physician practicing as a solo practitioner would only be subjected to a 15 percent offset. Similarly, the second option has the potential to negatively affect group practice members who do not owe the IRS but who have entered into business with those who have. While we recognize CMS’ concerns and the careful balancing that will be required in implementing this program, we urge the agency to proceed with caution on any proposal that might eliminate the ability of otherwise qualified physicians to practice medicine under the Medicare program or discourage such physicians from adopting a group practice model.

Maintaining ordering and referring documentation

CMS continues to increase the amount of documentation required to justify payment for medical services, which will increase the amount of storage space practices are forced to obtain. Even electronic storage comes with associated costs. Increasing the length of time that providers must maintain ordering and referring documentation will only serve to increase these costs, without any corresponding increase in payment. MGMA urges CMS to reconsider this unfunded mandate.

Reporting requirements for providers and suppliers

CMS’ proposal to revoke billing privileges where a practitioner has failed to notify a Medicare contractor of a change in location assumes that physicians, nonphysician practitioners and the organizations in which they practice are seeking to defraud the Medicare program. CMS would apply an overly harsh punishment in response to what in most cases amounts to a failure to meet requirements based on a technicality, rather than a real attempt to commit fraud. In most cases, the failure to notify CMS of a change in practice location is an oversight or an inadvertent error. CMS is overreacting to a problem created by the failure of its contractors to adequately educate practitioners and staff, as well as their spectacular inability to perform the tasks with which they are charged as they relate to Medicare provider enrollment.

CMS notes that it plans to conduct overpayment actions against practitioners and practices that fail to notify contractors within 30 days of a location change where the location change would
have resulted in a decrease in payment. It fails to comment on its plans to reimburse practitioners for any potential increases in payment if the location change results in an increase in payment. A failure to notify Medicare contractors of a change in location is an oversight rather than a true attempt to defraud the Medicare program, and the Association urges CMS to take this into consideration when drafting the interim final rule.

**Denial of enrollment in the Medicare program**

Additionally, CMS’ proposal to impose a payment suspension on a practice suspected of wrongdoing is a denial of due process and is in conflict with the principle of innocent until proven guilty. There are many practices where Medicare patients make up the bulk of the patient load. A payment suspension would cripple the ability of these practices to fulfill their financial obligations, such as paying suppliers, making payroll and other such regular expenditures. It would even make it difficult for a practice to obtain a loan to cover such obligations during the time of the investigation. CMS must not deny practices their due process rights, nor should the agency be permitted to curtail them prematurely.

**Revocation**

It is of grave concern to MGMA that CMS proposes to significantly curtail the amount of time a practice or practitioner whose billing privileges have been revoked has to bill the Medicare program for services provided prior to the effective date of the revocation. Given the new and overly broad reasons CMS has proposed revoking billing privileges, this provision would unfairly target individuals who may have only committed a technical violation of the Medicare provider enrollment regulations, as opposed to committing fraud or other intentional wrongdoing. Additionally, CMS’ proposal fails to take into account the time it will take for the practice or practitioner to receive the notice. Thirty days is simply not enough time to wrap up all of the details of a practice, in addition to the other circumstances associated with a revocation of Medicare billing privileges.

**Other issues – Revisions to final appeals rule**

It is inherently problematic that the public is forced to comment on proposed changes to a rule released only three days after the proposed changes were issued. CMS does a disservice to practices and practitioners when it creates policy in this fashion. It is not the first time this has happened in recent memory. Last year’s proposed fee schedule contained proposed changes to the Stark regulations. Only two weeks prior to the end of the comment period, the Stark II, Phase III final regulations were issued, meaning that the proposed changes were to be applied to the new final rule. This pattern suggests either poor planning or a desire to foil the intentions behind the notice and comment process. MGMA urges a delay in the effective date of the final rule until the web-based enrollment process can be implemented and a thorough discussion is held between all affected parties, as recommended above.

Obviously, it is impossible to reverse an adverse legal action or a change in practice location. However, group practices should be permitted to remedy a failure to notify CMS or its contractors of such a change in circumstances through an administrative remedy where the
failure to provide this information was a mere oversight. In these situations, it is in the best interests of patients and the Medicare program to allow the practices and practitioners to file a corrected CMS-855 form. To revoke their billing privileges would attach a stigma to them and make them ineligible for reenrollment for a minimum of one year, based on the final provider appeals rule published on June 27. Because of this, MGMA opposes the proposed changes to this provision.

According to the proposed rule, the revocation would be effective based on the date the letter was mailed by the contractor. This approach fails to account for potential problems with the US Postal Service. Instead, any notice of such grave consequence should be sent in such a manner that it could be tracked and that the contractor could know who received the notice and when it was received. Additionally, any revocation should be based on the date of receipt, given that it can take some time for mail to reach the appropriate person in a medical practice. Because of this lost time, it may be only one to two weeks before the effective date of the revocation that the affected party is actually aware of the revocation. This does not allow the affected practice or practitioner enough time to react and prepare such information. MGMA urges CMS to require contractors to send such notices in an effective manner that will establish a date of receipt and the recipient.

CMS’ proposal to make revocations effective with limited notice and appeal rights in certain situations is a violation of due process. It is imperative that all practices and practitioners be provided with full appeal rights. If CMS does adopt this proposal, an expedited reconsideration process is the minimum that should be provided to practices and practitioners; however, it does not begin to compensate for the rights diminished by this proposal. Once again, the agency has made a proposal without providing evidence that such a problem actually exists, which it only serves to make an already untenable situation even more unsustainable.

**Electronic prescribing**

MGMA is strongly supportive of electronic prescribing (e-prescribing) and other health information technology (HIT) initiatives. We believe utilization of HIT generally and e-prescribing specifically will improve clinical care and reduce administrative costs. The challenge for medical groups, however, continues to be how best to adopt this technology in the most cost-effective manner.

We are well aware that e-prescribing offers a number of important opportunities to prescribers and pharmacists. From the clinical perspective, e-prescribing can permit the clinician and pharmacist to review allergies, drug-drug interactions and contraindications that, if not identified, could have an adverse impact on the patient. E-prescribing can also facilitate enhanced administrative functions, including access to information related to formulary and benefit management. Fully integrated e-prescribing systems have the potential to limit the time prescribers and pharmacists spend on formulary management issues, create efficiencies in the delivery of health care, and provide enhanced access to electronic patient health information.

As evidence of our strong commitment to the use of e-prescribing technology to improve clinical care and administrative functions, MGMA and several leading provider organizations founded
the Center for Improving Medication Management. Additionally, MGMA recently collaborated with a number of leading professional medical societies to develop the www.GETRXConnected.com website and educational campaign that assists physician practices in determining if their electronic health record system has e-prescribing capability and outlines the steps their organization needs to take to integrate e-prescribing into their patient care workflow.

E-Prescribing challenges

Despite the promise that e-prescribing offers, practices face a number of challenges that continue to prevent the full implementation of this technology. These challenges include:

- Costs – Potential e-prescribing adoption expenses include: license fees; hardware purchases (desktop computers, laptop computers or personal digital assistants); high-speed Internet connectivity; and staff training.

- Workflow changes – In order to integrate this new technology in the organization’s care delivery process, significant practice workflow changes are necessary before e-prescribing can be utilized in physician practices and pharmacies.

- Internet accessibility – There is a lack of wide accessibility to broadband Internet. To be an effective clinical tool, e-prescribing systems should be connected to pharmacies via a secure high-speed Internet connection.

- Adoption by community pharmacies – It is estimated that approximately 30 percent of pharmacies nationwide do not currently have e-prescribing capabilities. Many of these pharmacies assist underserved populations. The lack of access to broadband Internet and the costs associated with e-prescribing transaction fees (fees charged to a pharmacy for e-prescribing transactions to and from the pharmacy) need to be addressed.

- E-prescribing of controlled substances – The Drug Enforcement Agency (DEA) currently prohibits the e-prescribing of controlled substances. Their recently released Notice of Proposed Rulemaking outlines a complex and comprehensive set of requirements that would need to be adopted prior to prescribers being able to transmit controlled substances electronically. Providers are concerned that the proposed rule does not strike an appropriate balance between security and usability and would discourage many physicians from adopting e-prescribing.

E-prescribing recommendations

As the federal government and the health care industry move toward adoption of standards for e-prescribing, we recommend the following issues be considered:

- Standards to be Flexible, Scalable and Promote Interoperability– E-prescribing standards must be both flexible and scalable to encourage adoption by both small and large health care organizations and physician specialties processing both low and high volumes of
prescriptions. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility, combined with a high level of interoperability, will allow physicians to consider critical factors, such as clinical quality, safety, efficiency and integration with existing practice management software and electronic health record systems when making an investment.

- **CCHIT Certification for stand-alone e-prescribing software.** MGMA contends that the Certification Commission for Health Information Technology (CCHIT) has assisted physician practices in selecting the appropriate ambulatory electronic health record system. The CCHIT has tremendous credibility and support within both the physician practice and EHR vendor communities. In order to provide physicians with that same level of confidence, CMS should work with CCHIT to ensure that a stand-alone e-prescribing software certification process is in place prior to the compliance date for the final rule.

- **Promote the Security and Privacy of Patient Data** – Patients are more concerned than ever about maintaining the security and privacy of their health information. At the same time, providers are embracing the new standards in these areas as mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). E-prescribing systems utilizing the medication history standard must maintain these HIPAA standards as part of their core operating features. CMS should provide guidance on the critical issues surrounding the protection of patient health information during the prescription transmission process.

- **Incentives for Providers** – While medical practices typically absorb the cost of purchasing the hardware, software and training necessary for e-health transactions, many of the benefits accrue to others in the system. The greatest cost relative to benefit – in time and money – is borne by clinicians. Even an extremely effective means of prescribing new drugs or authorizing refills will have at least a short-term adverse impact on office workflow and expenses. Although there may be significant nationwide savings from the adoption of e-prescribing, relatively little of that financial benefit is passed to the clinician in the current environment. Incentives should be directed toward resolving the relative misalignment of costs and benefits. MGMA believes there should be a “realignment” of these incentives by promoting appropriate public and commercial reimbursement programs.

- **Expansion of the Stark/OIG Exception/Safe Harbor** – MGMA congratulates CMS and OIG for their important step in this direction through the creation of HIT exceptions and safe harbors that went into effect Oct. 1. 2006. However, despite these having now been in effect for some time, very little e-prescribing or other health information technology has been donated. We believe that these safe harbors and exceptions must be expanded to encourage donations. For example, the requirement that recipients cover at least 15 percent of the cost of the software and the prohibition against hardware donations should be eliminated.

- **Continued Consultation with the Physician Practice Community** – Physician practices must play an integral role in the development and deployment of any standardized e-prescribing system. Since the vast majority of all health care is delivered in these practices, the success or failure of these initiatives will depend heavily upon physician acceptance of
this new technology. MGMA encourages CMS to continue its outreach to this community to ensure that the needs and concerns of physicians are addressed.

- **Industry Outreach** – The successful adoption of e-prescribing will depend, in part, on the ability of the federal government and the industry to encourage all covered entities to understand and support the standards and the technology. CMS should also communicate with the software vendor community, through town hall meetings, open door forums and other such avenues. Vendors must be encouraged to move forward with the development of low cost and compliant e-prescribing products as quickly as possible. In addition, MGMA recommends that CMS work with the appropriate industry associations to deliver a consistent message on this important change in the health care system.

**Facsimile Exemption**

In this rule, CMS proposes the elimination of the exemption for computer-generated facsimiles to adhere to the NCPDP SCRIPT standard. While we are generally supportive of the elimination of the exemption for computer-generated facsimiles, we urge caution in moving too quickly to mandate use of the SCRIPT standard. Recent history has shown that the health industry in general, and providers specifically, have struggled to meet HIT-related compliance dates. MGMA strongly recommends extending the Jan. 1, 2009 deadline.

In the rule, CMS suggests that the fax exemption might encourage those without such NCPDP SCRIPT capabilities to upgrade their current software products, or, where upgrades are not available, to switch to new products. Purchasing this software, in turn, would increase the number of NCPDP SCRIPT transactions fairly significantly in a relatively short time period, and this could, in turn, create a "tipping point" that could create economic incentives for independent pharmacies to adopt NCPDP SCRIPT capable software to begin exchanging true e-prescribing transactions with their prescriber partners. However, CMS should recognize that transitions of this nature, relying on non-covered entities to supply products and services and providers to incur all costs for software, hardware, workflow modifications and staff training, are often protracted.

CMS has proposed to further amend the computer-generated facsimile exemption to also allow for an exemption from the NCPDP SCRIPT standards for electronic prescription refill request transactions that are conducted by computer-generated facsimiles when the prescriber is incapable of receiving electronic transmissions using the NCPDP SCRIPT standard. MGMA supports the continuation of the current exemption in instances of temporary network transmission failures. This is a critical provision that should be retained. Should medical practices experience temporary network failures, they should retain the ability to send non-standard electronic prescriptions as opposed to reverting to paper.

In the proposed rule CMS states, “We will periodically revisit the exemption for the purpose of ultimately eliminating it for the prescription refill request transaction as described in Sec. 423.160(b)(1)(vii), and solicit comments regarding what constitutes an adequate time to allow the industry to transition to the use of the NCPDP SCRIPT standard.” MGMA strongly supports this additional exemption and recommends that CMS evaluate industry readiness to send and
receive e-prescriptions using the NCPDP SCRIPT standard on a periodic basis. MGMA also recommends that CMS not sunset this exemption with an arbitrary date. Rather, we suggest that once industry readiness has reached an acceptable level, the exemption should be phased out after adequate notice has been provided to the industry.

In the e-prescribing realm, a large number of smaller practices in particular rely on computer-generated facsimiles to send prescriptions to pharmacies, although some do not currently use the SCRIPT standard. While MGMA agrees that full implementation of the SCRIPT standard will result in an increased level of administrative simplification, the benefits of sending a computer-generated facsimile, even for those that do not utilize the SCRIPT standard, are well documented. Medical errors caused by illegible handwritten prescriptions are eliminated, faster processing of prescriptions occurs at the pharmacy and record keeping at both the medical group and pharmacy locations is improved. Many of these benefits are reduced or lost when paper prescriptions are utilized. MGMA is concerned that if medical practices are unable to upgrade software to the SCRIPT standard by the proposed Jan. 2009 deadline, they may revert to paper prescriptions.

The following recommendations may offer an approach that meets the government’s desire to move the industry toward full adoption of the SCRIPT standard, yet takes into account the realities that medical practices and others must rely on non-covered entities to comply with the standard.

- **Increase the level of CMS provider educational activities.** CMS should consider augmenting its current level of educational outreach on HIT and e-prescribing. This outreach should focus on the steps necessary to implement and achieve a return on investment from utilization of the SCRIPT standard. This outreach should: 1) target small and medium-sized physician practices; 2) target rural providers, community health centers and other “safety-net” organizations; 3) expand the current, very successful face-to-face and conference call activities and 4) coordinate closer with industry to ensure that a unified message is communicated.

- **Increase the level of CMS vendor educational activities.** As the industry experienced during the implementation of the numerous HIPAA provisions, providers and others must rely on non-covered entities to achieve compliance. CMS should work more closely with the vendor community to ensure that they understand the regulation and the government’s expectations for their covered-entity customers. CMS should partner with industry organizations such as MGMA, other provider organizations, the Workgroup for Electronic Data Interchange and other industry groups to conduct face-to-face vendor forums across the country. CMS should offer vendors technical assistance to facilitate the development of appropriate products for all covered entities.

- **Conduct regular assessments of industry progress.** CMS, perhaps with the assistance of the National Committee on Vital and Health Statistics, the Agency for Healthcare Research and Quality, MGMA or other government agency or industry organization, should survey the industry on a regular basis after effective date of the final rule. These regular surveys should not only include all provider types and pharmacies, but also the vendors themselves.
Ascertaining the number of vendors that have updated their products and the number of medical groups and pharmacies that have adopted the standard will be critical to ensuring that physicians do not revert to paper prescribing.

Overall, MGMA supports the proposal to eliminate the exemption for computer-generated facsimiles, but we urge CMS to augment its educational activities and regularly assess the readiness level of the industry. The Jan. 1, 2009 compliance date should be extended until the great majority of medical groups have transitioned to the NCPDP SCRIPT standard.

Similarly, on the issue of the exemption for practices that cannot accept NCPDP SCRIPT standard refill transactions, MGMA recommends surveying the industry on a periodic basis and eliminating this exemption should an appropriate level of compliance be achieved. Prior to ending this exemption, CMS should conduct a comprehensive outreach effort to ensure providers are well aware of the change in policy and the compliance date.

We believe that it would be more advantageous to extend these compliance dates than to penalize practitioners and potentially adversely impact patient safety by forcing physicians to revert to paper prescriptions.

**Physician self-referral and anti-markup issues**

The Stark law and its accompanying regulations represent a complex and comprehensive regulatory scheme aimed at eliminating improper referrals for designated health services. MGMA has, on many occasions, conveyed to CMS that the Stark law, with its constant revision, has become too complicated for even the most sophisticated medical group practices to navigate without the help of even more sophisticated attorneys. Over the last two years, CMS has proposed modifying a separate and unrelated Medicare billing rule (referred to as the anti-markup rule) in an attempt to curb what it sees as program abuses allowed to exist because of the Stark law centralized building definition under the in-office ancillary services exception. We once again renew our objection to the ever-changing web of regulation and the amendment of Medicare billing requirements to produce a change in the Stark law regulatory scheme. The current proposals are overlapping and varying. Some contain proposed regulatory text and others do not. This format makes commenting on and fully understanding their impact almost impossible.

The proposed rule states that anatomic pathology diagnostic testing arrangements precipitated the original proposal to revise the anti-markup provision, and, at least through publication of the “delay rule” published on Jan. 3, 2008, remained CMS’ core concern. To the extent that CMS has sought to make “pod labs” for anatomic pathology services unattractive business enterprises, it has done so through publication of the 2008 final rule applied to certain anatomic pathology diagnostic testing services.

CMS further states in the current proposal that it has concerns with overutilization of diagnostic testing services. With passage of MIPPA after the release of the current proposed rule, Congress has addressed its concerns regarding overutilization and quality of imaging by directing the agency to develop a demonstration project to determine the appropriateness of advanced
diagnostic imaging services furnished to Medicare beneficiaries and requiring accreditation of advanced diagnostic imaging suppliers by 2012. Congress has provided two very clear directives to CMS on how to address concerns it may have regarding diagnostic imaging tests. In contrast, CMS’ current proposal relies on an unprecedented, and we think untenable, interpretation of the statutory language of the anti-markup rule at Sec. 1842(n) of the SSA to expand its application. Rather than further complicate an already incomprehensible scheme, CMS should observe the much clearer legislative directives on the issue. After last year’s proposal and the subsequent delay, Congress was well aware of the concerns over the anti-markup language at 1842(n). Rather than taking CMS’ lead and amending the anti-markup statute, Congress took a clearer path. We thus believe that CMS is obligated to defer to Congress on this matter.

Notwithstanding the above-mentioned objections, we offer the following in response to specific requests for comments:

“Sharing a Practice”

CMS has asked for comment on its “all or nothing” approach to determining whether physicians “share a practice” for purposes of Sec. 1842 (n) of the statute, and for possible exceptions to the “all or nothing” approach.

As a preliminary matter, we note that when Sec. 1842 (n) was enacted, Congress had not yet defined the term “group practice” in the Medicare statute. We believe the “share a practice” concept was simply Congress’s short hand version of what later became the lengthy definition of “group practice” in section 1877 (h)(4) of the statute. That definition is, in turn, implemented in elaborate detail through CMS regulations at 42 CFR § 411.352, and supplemented in Sec. 411.351 by definitions of what it means for a physician to be either a “member” of a group or “in” a group. With a detailed statutory and regulatory scheme now in place for determining when physicians practice together for purposes of the self-referral law, we cannot believe Congress would have intended the concept of “sharing” a practice to have a different and more restrictive definition for purposes of determining whether diagnostic tests – now heavily regulated under Stark – were provided by a group as opposed to being purchased from “outside” the group.

In addition to several examples set forth in the preamble (providing services at a “free clinic” or moonlighting in an ER or as a hospitalist), there are many other circumstances in which group practice physicians provide services to or through entities other than their primary group affiliation:

- Serving as a locum tenens for another practice on a temporary basis;
- Covering a service for another practice while it recruits to replace a retired or deceased physician;
- Providing specialty services at hospitals or primary care clinics in areas (often rural but not always) that would otherwise not have those specialties available and convenient to patients; and
- Providing specialty services to a different practice that has a part-time need for the service; but where it would not be efficient to recruit a full time physician to the second practice.
That the Stark regulations have evolved over the last 15 years to accommodate many of these arrangements, while incorporating features that disqualify a physician (or would-be “group”) that does not meet rigorous definitional tests, is ample testament to the fact that a physician can share his or her practice with others in a group practice setting, while still providing some services outside that group with which he or she is primarily affiliated.

*Calculating a “Net Charge”*

If CMS allows last year’s rule to go into effect or promulgates final rules based on either of the alternatives discussed this year, a significant amount of technical and professional component services provided by and through group practices will become subject to the anti-markup rule for the first time. However, CMS has not yet even proposed a definition of “net charge,” without which MGMA does not see how the anti-markup rule could be fairly and consistently applied to testing provided inside groups. For this reason, MGMA believes that any implementation of changes to the anti-markup rules must be deferred.

Currently, groups do not “charge” themselves for either technical component (TC) or professional component (PC) services provided through the group. They do, of course, have standard fees for these diagnostic test components that they charge to patients and payers. The only simple method for determining an inside charge would be to recognize the group’s usual and customary external charges. These will, in most cases, be higher than the Medicare fee schedule amount. Any other approach based on trying to calculate the group’s costs for individual TC and PC services will be fraught with difficulty both conceptually and in application. And no method would compare to the process by which a true “outside supplier” bills for services, calculating its direct costs and overhead to determine a viable charge for services.

CMS has suggested that it might look to the cost of the professional personnel involved. This approach would capture only a small portion of the true cost of service, especially with respect to the TC. Any fair method would need to include the cost of equipment, supplies, technical personnel, related benefits, and allocated space, utilities, taxes and general overhead. Since physicians do not keep or file cost reports, this would be a monumental burden on practices, and the likelihood of consistency in application across practices, or across carriers at the enforcement stage, seems remote.

*Office of the Billing Physician*

MGMA continues to believe that site-of-service distinctions are not relevant to determining the appropriate scope of section 1842 (n) of the SSA. Physicians in bona fide group practices share in a common professional enterprise whether that enterprise has one building or ten, and if ten, regardless of the particular geographic configuration of the ten buildings. Once again, CMS has developed a regulatory scheme for determining when a service is provided “in-office” for Stark purposes, and we see no legal or policy justification for applying different site-of-service rules for purposes of the anti-markup provision. MGMA is particularly concerned about distinctions that treat groups differently from solo practices and that discriminate between different types of groups.
As we understand CMS’ proposal, a solo practitioner could have five offices with an x-ray machine in each. As long as he or she regularly practiced in each, he could order tests at all five locations, or from any one of them, and have them treated as “furnished” inside the practice rather than “purchased.” A group practice, on the other hand, that has primary care physicians in one building and specialists in another, either has to have x-ray machines in both buildings, to be used only by the physicians in each building, or do testing in only one and treat the group practice members in the other as “purchasing” the tests. When tests are provided in a centralized building by a non-profit multi-specialty group, they are considered “furnished,” but the same tests provided by a physician-owned group that is otherwise comparable in size and scope would be considered “purchased.” Cardiologists in a single-specialty group seeing patients in one building and ordering “low tech” tests there, but doing “higher tech” services and testing in another may be deemed not to meet the “full range” test at either so that tests performed at both will be considered “purchased.”

These distinctions, and many others like them that reflect the diversity in group practice arrangements, have little if anything to do with quality, convenience, efficiency, utilization or potential abuse. Rather than lowering the cost of testing, arbitrary site-of-service distinctions may instead lead to greater duplication of testing equipment and personnel at multiple locations, increasing the ultimate costs of service.

Direct Billing Option

MGMA opposes any proposal to require physicians performing either the TC or the PC of diagnostic tests to directly bill for such services. At the time Congress developed the anti-markup rule, it had already established a direct billing requirement for clinical laboratory services. Rather than adopt the same approach for diagnostic tests, it chose to enact the anti-markup rule in Section 1842(n) of the SSA. CMS should not now second-guess Congress’ decision and choose to eliminate the system of assignment and reassignment that is currently in place.

Allowing reassignment has benefits to both physicians and patients. It provides physicians with the flexibility to establish the most appropriate employment or contractual relationships for their life and lifestyle. Patients benefit by having medical services combined on one bill, which avoids confusion and additional paperwork. Given that there is currently a mechanism by which physicians can reassign their right to bill, it would be unfair to deny that convenience and flexibility to a physician simply because he or she performs diagnostic tests.

Status of 2008 Rule and Other Effective Dates

As noted elsewhere in these comments, MGMA does not believe that the delayed portions of last year’s rule should go into effect on Jan. 1, 2009, or that either of the alternative approaches discussed in this year’s proposal should be finalized. To the extent that changes to the anti-markup rule were motivated by a desire to regulate so-called “pod labs,” CMS has achieved its purposes with those aspects of last year’s rule that were not delayed. Extension of those or similar rules based on site-of-service beyond the pathology laboratory context risks disruption to a wide variety of diagnostic testing services that are genuinely “inside” group practices. These
arrangements have enhanced quality and served patient convenience. Congress has recently enacted additional measures to ensure quality in the future. Stark regulations continue to regulate “in-office” testing. Changes to the anti-markup rules to extend their scope beyond tests purchased from outside group practices are simply not needed.

Exception for Incentive Payment and Shared Savings Programs (Proposed § 411.357(x))

MGMA appreciates CMS’ efforts to develop an exception to the physician self-referral (Stark) law to allow physicians and hospitals to enter into arrangements where each would mutually benefit from improved quality and reduced costs. We view the current proposal as a tentative step in the right direction. We are generally concerned, however, that the proposal (with its 4 ½ columns of Federal Register text) is too complex and too restrictive for the average group practice or hospital to want to participate. Additionally, the requirements relating to the “participating physicians” further restrict a group’s willingness or ability to participate by requiring at least five physicians in the participating physician pool. As CMS evaluates the results of the current demonstration projects, we hope it will use that information to inform the development of a simplified Stark law exception.

Physician Quality Reporting Initiative (PQRI)

MGMA continues to support quality improvement activities that focus on improving patient care and clinical outcomes and studying the cost-effectiveness of resource use. The Association remains committed to assisting CMS in achieving the laudable goal of learning how to pay for high quality services. As discussed with CMS Administrator Mark McClellan in May 2006, MGMA has repeatedly asked for and looks forward to working with the agency to develop an appropriate sampling method that allows group practices a new means of reporting in the PQRI.

The Association is currently finalizing an analysis of MGMA member’s experiences with the PQRI, including 2007 and 2008 PQRI participation rates and motivations, methods used to capture the data, total time and costs incurred with involvement, frustrations associated with accessing the 2007 PQRI feedback reports and attitudes towards posting PQRI participation data online. MGMA looks forward to partnering with the agency to improve the PQRI upon completion of this research.

According to CMS, approximately 16 percent of eligible providers participated in the 2007 PQRI, and yet, only half of these participants received the 2007 bonus incentive. This clearly indicates significant confusion and hesitation regarding the PQRI. MGMA advises CMS to facilitate PQRI participation through extensive education and outreach. MGMA urges CMS to provide practices that reported quality measures in the 2007 PQRI but did not receive a bonus incentive with the ability to appeal the ruling. Detailed confidential interim feedback reports should be provided by the agency as it continues to evolve the PQRI. These reports should clearly identify to PQRI participants their reporting errors and should also provide clear instructions on how to correct these mistakes.

In the spirit of improving PQRI participation, MGMA urges CMS to provide MGMA and other medical associations with the 2007 and 2008 PQRI data set files, so we can analyze this
information, help CMS improve physician quality measures and better understand potential barriers to successful reporting.

MGMA supports a measurement development process developed through a transparent, multispecialty consensus process such as the AMA-convened Physicians’ Consortium for Performance Improvement (PCPI). Many eligible providers were prevented from PQRI participation because CMS did not include measures applicable to their specialties. When CMS requested 2009 PQRI measures in March of 2008, the PCPI submitted measures that would have addressed this issue, yet peculiarly, CMS did not include these measures in the proposed rule. MGMA requests that CMS provide an explanation in the final rule and reconsider this proposed policy.

In 2008, CMS announced additional reporting periods and options within the 2008 PQRI, which MGMA supports because they allow providers greater flexibility and opportunities to participate in the PQRI. However, by increasing the reporting options and making midyear PQRI announcements, the agency is increasing provider uncertainty, frustration, and apprehension with the entire program.

Currently, CMS allows providers the ability to report on PQRI group measures for either 15 or 30 consecutive patients. Without knowing the outcome of this specific 2008 PQRI reporting option, CMS proposes to arbitrarily change the consecutive patient PQRI group reporting option to 30 consecutive patients for the half year reporting period. MGMA urges CMS to reconsider and allow practices the ability to report a PQRI group measure on 15 and 30 consecutive patients that have a condition specific to the PQRI group measure for both the full and half year reporting periods.

MGMA commends the agency’s incorporation of qualified clinical registries, including electronic health records, into the PQRI, as stipulated by the Tax Relief and Health Care Act of 2006 and the Medicare, Medicaid, and SCHIP Extension Act of 2007. These methods of PQRI reporting allow greater flexibility in reporting and also allow participants the ability to submit PQRI data separately from Medicare claim forms. However, the proposed rule does not outline specific procedures and requirements that registries must meet to ensure that the data providers submit to the registry are properly transmitted to CMS. MGMA recommends the final rule specifically outline registry requirements for successful integration into the PQRI.

MIPPA requires CMS to post online the list of PQRI participants that have “satisfactorily submitted data” on quality measures. Medicare beneficiaries deserve to know whether their provider demonstrated this commitment to performance measurement and quality improvement. Accordingly, CMS must adhere to the statutory authority and congressional intent of the term “satisfactorily” provided in MIPPA and must only publish on its website the names of clinicians and group practices that satisfactorily participate in PQRI and earned the bonus incentive. MGMA is concerned that CMS will post PQRI provider participation information that would mislead patients regarding physician quality. Considering the problems the agency has had with 2007 PQRI data, it would be unfair to post online the names of practices that attempted to successfully participate, yet were ultimately unable to earn the PQRI bonus incentive due to reporting complexity. MGMA urges the agency to notify potential PQRI participants well in
advance as to whether participants’ names will be listed on a CMS website and to only post the names of PQRI participants that successfully earn the bonus incentive. MGMA also urges CMS to provide PQRI participants that did not earn the bonus incentive with a confidential feedback report that includes the reason they were not named on a CMS website and the opportunity to correct errors.

Prohibition concerning providers of sleep tests

CMS has proposed to prohibit payment to a supplier of continuous positive air pressure (CPAP) devices used to treat obstructive sleep apnea (OSA) when the supplier has a direct or indirect relationship with the provider of the sleep test used to diagnose the OSA. Categorized as durable medical equipment (DME), CPAP devices are currently designated health services which fall under the physician self-referral (Stark) law. Physicians that diagnose OSA have a limited ability to supply such devices – it is our understanding that they may currently only supply such CPAP devices when the device is personally provided by the referring physician and not his or her employees, independent contractors, or group practice members. Given that the Stark law currently addresses the situation of physicians supplying CPAP devices, it is redundant and potentially confusing to also place governing regulations in 42 C.F.R. § 424.57.

MGMA appreciates your consideration of these comments and looks forward to collaborating to educate medical group practices on the numerous Medicare program changes. If you have any questions, please contact Leah Cohen in the Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and Chief Executive Officer