



August 29, 2008

Kerry Weems, Acting Administrator
Department of Health and Human Services
Center for Medicare and Medicaid Services
Attention: CMS-1403-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20210

Submitted electronically by e-Rulemaking

Re: [CMS-1403-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E- Prescribing Exception for Computer Generated Facsimile Transmissions; Proposed Rule.

Dear Mr. Weems:

The American Medical Group Association (AMGA) represents multi-specialty medical groups and other organized systems of care, including some of the nation's largest, most prestigious integrated health care delivery systems. AMGA represents more than 320 medical groups in 47 states with 88,000 physicians treating over 80 million patients. Average group size is 283 with 16 satellite locations. AMGA medical groups serve 1 out of 4 Americans. AMGA advocates for continuously improving patient care through innovation, information sharing, benchmarking, and creation of sound public policy.

PHYSICIAN SELF-REFERRAL AND ANTI-MARKUP ISSUES: *AMGA favors narrowly drawn remedies that target areas of program risk. Because CMS has already applied the Anti-Markup Provision (AMP) to "pod" labs, AMGA recommends that CMS proposed changes either be withdrawn or incorporate changes reflecting logistical/operational realities in large medical groups and organized systems of care.*

As CMS is aware, entrepreneurs conceptualized and actuated enterprises in the field of anatomic pathology that utilized a loophole in the Stark provisions. This loophole allowed physician offices to place an anatomic pathology laboratory at a site distant from the practice and have it administered by a contractor as long as it was designed for the continuous and exclusive use of the practice. Thus were born so-called "pod" labs.

In a typical pod lab configuration a third party established a location of “pods”, cubicles or contiguous offices, each putatively for the sole use of a different group. A single pathologist, working as an independent contractor for each group practice/“pod” office “owner”, moves from office to office to serve each practices pathology laboratory. Financial arrangements are structured to allow “profit” to be generated for each “pod owner”.

To address this issue, CMS issued a final rule (72 Fed Reg 66222) requiring all diagnostic services to be performed in the same office in which the ordering physician provided the full range of medical services. CMS delayed implementation of its rule until January 1, 2009, save for anatomic pathology services, in response to concerns expressed by many including AMGA, that such an action would effectively shut down or severely curtail diagnostic operations in many of America’s largest and most highly regarded medical groups, that were not engaging in untoward practices. AGMA sincerely appreciated CMS’ willingness to consider our concerns at that time.

In the current Notice of Proposed Rule Making (NPRM), CMS offers new changes to the AMP and proffers three alternatives. Under the first proposal, the physician practice is subject to the AMP if the diagnostic test is purchased or if the professional component or supervision of the technical component is not done by a physician who “shares a practice”, i.e., works solely for the single (one) practice. Compliance with this may be possible by some medical practices, those with the capital and testing volumes sufficient to warrant engaging or contracting for exclusive physician services needed to perform or supervise diagnostic testing. However, this proposal may be burdensome to many physician offices.

The second alternative requires that substantially the full range of services be provided in the same building of the ordering physician. This variant makes compliance for many practices with campus arrangements impossible. If the physicians’ office building(s) does not share the same street address as the building housing the diagnostic testing, the transaction would be deemed a purchased diagnostic test, even if the diagnostic center is located around the corner. This would punish those with large campuses with several buildings.

Thus a highly integrated multispecialty group practice with a centralized building(s) for diagnostic testing would be treated the same way as an anatomic pathology laboratory in another region of the country for purposes of billing diagnostic services. With the limitation on “net” charges, physician offices may not be able to recoup the costs of equipment, space and related administrative burdens for services performed within their practices, often rendering important diagnostic tests financially unfeasible.

We suggest that this alternative be reworded to accommodate practices that have “campuses”, i.e., several buildings on the same grounds, not necessarily on the same street, but otherwise integrated into the practice. This might be accomplished by expanding the definition of a campus to include activities fully integrated into the overall practice, by geographic proximity, ownership, and governance.

To be considered “on campus”, the following criteria may apply: the diagnostic center/building/entity must be located within the main building(s), or located in the physical area immediately proximate to the provider’s main building(s), or in other areas or buildings that are not proximate to the main building(s) but are fully integrated, i.e., financially integrated and administered in concert with overall operations standards, guidelines, rules and directives, with governance and operations functions determined by central administrative processes and structures. In plain language, they are part and parcel of the organization, structurally, financially, operationally, in terms of governance and philosophy.

Proposed Exception to Anti-Markup Provisions for Non-Profit Entities

In the third alternative, CMS proposes an exception for tax-exempt entities to the AMP. This exception widely misses the mark as we are unaware of any evidence suggesting tax-paying medical groups behave, or are likely to behave, in a manner substantially different from tax exempt medical groups. As an illustration we cite a current example, the much heralded, and rightly so, results of the second year of the CMS Physician Group Practice Demonstration. Among the ten participants was a variety of groups with varying structures and characteristics, representing academia, rural communities, urban settings, geographic dispersion, for-profit and non-profit tax status, among others ([This link is to the CMS press release of August 2008 about the findings](#)). All participants, regardless of ownership and other differentiating factors, demonstrated adaptability and flexibility to change and to produce high quality medical care that was both effective and efficient.

Moreover, we are not aware of any instances where the Medicare program differentiates policies based solely on institutional mode of ownership, incorporation or tax status. To base public policy on such criteria and to do so haphazardly is inflammatory and unreasonable on its face. Additionally, it is not clear to us whether CMS has statutory authority to create such a distinction related to ownership type.

We agree with CMS, however, that certain entities deserve exemption from the AMP and other Medicare rules. We elaborate on this issue immediately below.

EXEMPTION FOR MERIT: CARVE-OUT FOR MULTI-SPECIALTY GROUPS/ORGANIZED SYSTEMS OF CARE: *AMGA recommends an exemption from anti-markup and IDTF rules for large multi-specialty medical group and other organized systems of care based on the inclusion of certain, characteristics, attributes, infrastructural elements and behaviors (desired actions). These entities distinguish themselves by delivering high quality services to patients in the most cost-effective model of care currently available.*

Instead of trying to bootstrap any of the proposed exemptions, none of which would fully meet the needs of large, multi-specialty medical groups or organized systems of care, or completely address CMS’ stated objectives, we suggest a multispecialty medical group “carve out”, i.e., exemption from rules (anti-markup and independent diagnostic testing facilities and others in the future) based on delivery of health care services in the multispecialty/organized system of care model. Because the potential and risk for inappropriate actions is outweighed by attributes and

actions of merit, special exemption should be available as a facet of public policy in the rulemaking realm.

Indeed, Congress has provided recognition of the coordinated approach to patient care that multi-specialty medical groups provide in the recently passed Medicare Improvements for Patients and Providers Act (MIPAA). Section 131 requires CMS to accept quality measures from medical groups that target high-cost, high-volume, chronic conditions through a statistical sampling model, similar to the one being used in the Physician Group Practice demonstration project, beginning in 2010.

Because such groups distinguish themselves in the provision of quality, efficient patient care (the growing body of evidence was bolstered by the recent, strongly positive findings of the second year results of the CMS Physician Group Practice Demonstration project), it is good public policy to foster desired behaviors and mechanisms of delivery. A creative and constructive opportunity presents itself in this NPRM by exemption of members of multispecialty group practices and other organized systems of care from certain rules, anti-markup and independent diagnostic testing facility (IDTF) standards, for example, should these proposals become final.

Typically such capacity comes with practice size of 25 or more physicians, but we do not believe that size alone should be the criterion for inclusion, rather that it should be a demonstration of numerous other facets of advanced practice that should pertain.

Below are listed some principles and criteria for entities that would qualify for such exemptions for merit based on their model of health care delivery which engage in desired activities:

Guiding Principle

Integrated delivery systems of health care are the most effective and efficient vehicle to provide the highest quality of medical services to Americans. The strongest underpinning of truly integrated delivery systems is the multi-specialty medical group or other organized system of care. As such, it should be a significant national health care policy to stimulate formation, foster growth, and support development of organized systems of care.

Multi-specialty Medical Groups/Organized Systems of Care: Definition

An organization which provides a coordinated continuum of health care services and is willing to be held clinically accountable for the health status of the community served which subscribes to the core values and demonstrates attributes enumerated:

Core Values of Organized Systems of Care

- Quality—continuous striving to improve patient care through measuring, reporting, and application of findings using evidence-based clinical and service quality measures and tools such as benchmarking, best practices, and peer review;

- Patient-centered care—timely information sharing by patients and physicians allowing patients to become active participants in their own care to receive services for their individual needs and in consideration of their preferences;
- Care coordination—supporting collaboration and communication among medical specialties and non-physician care givers;
- Accountability—shared physician responsibility and accountability for patient care;
- Innovation—openness to adoption and adaptation of evolving health care delivery models, and a modern infrastructure (electronic medical records, patient registries, electronic prescribing, secure electronic communication with patients, and electronic claims submission. etc.);
- Physician self governance—support of professionalism, physician participation in group governance and independence of clinical decision-making;
- Leadership development—creating a practice environment supportive of and seeking to enhance skills, knowledge and experience of physicians’ management and executive abilities.

Attributes

- The organization is a multi-specialty group medical practice or other organized system of care;
- The organization has a stable governance structure;
- The organization has a stable financial structure;
- The organization has a centralized administration;
- The organization possesses a quality driven mission statement.

INDEPENDENT DIAGNOSTIC TESTING FACILITIES (IDTFs): *AMGA recommends that CMS focus on the upcoming implementation of the accreditation requirement per MIPAA. To impose the IDTF standards on physician offices at the present time would be redundant and is unnecessary.*

The proposed rule would apply the established operating standards for IDTFs to physician organizations, with some exceptions. CMS’ stated rationale is founded on the assumption that physician groups are enrolling as participants in Medicare as group practices to circumvent the performance standards for IDTFs. CMS is also concerned about the quality of testing done in physicians’ offices.

In the same stroke however, CMS exempts doctors’ offices from a number of IDTF requirements because CMS acknowledges that physician organizations already exceed some some IDTF standards. We can find no basis for CMS’ assumptions regarding imaging in doctors’ offices, in particular, quality issues. The notion that physician groups enroll as group practices to avoid the standards required of IDTFs is simply unfounded. They enroll as group practices because they are group practices.

AMGA is deeply concerned about the IDTF requirements regarding supervision of diagnostic testing facilities. Some Medicare Administrative Contractors (MACs) or carriers, have made local coverage determinations requiring supervisory physicians to be radiologists or to effectively be radiologists, i.e., have training essentially equivalent to that of radiologists, a norm that might be, and has been misconstrued to unnecessarily and unproductively restrict capabilities by specialty rather than by training, education, and experience. This restriction is undesirable for many reasons, not the least of which is the nation-wide shortage of radiologists.

More importantly, the practical result of this proposed rule change will be to bring the Federal government into the credentialing business, making determinations about scope, competence, sufficiency of medical school and residency training, etc. This authority is traditionally and, most appropriately, left to State medical boards. Moreover, many medical groups have already obtained accreditation by independent accrediting bodies, rendering the compliance with additional standards unnecessary.

AMGA recognizes that program integrity concerns exist in the area of IDTFs, and we suggest closer oversight and enforcement of those facilities that raise concerns. However, we question whether application of the IDTF regulatory framework on all physician offices will further CMS goals of controlling abuse and over utilization. This is especially true in large integrated multi-specialty medical groups and other organized systems of care that typically have internal and external counsel to ensure program compliance.

Finally, the recently passed Medicare bill, MIPPA, calls for accreditation of all facilities providing advanced diagnostic imaging services, beginning in January of 2012, rendering the proposed application of IDTF performance standards to medical groups redundant, wasteful, and unnecessary. IDTF standards should not be applied to doctors' office settings and the proposal should be withdrawn.

PHYSICIAN QUALITY REPORTING INITIATIVE (PQRI): *AMGA strongly supports expanding the options for reporting under PQRI, including expansion of measures groups, and we encourage adoption of EHR-based reporting of measure groups as soon as possible. AMGA also proposes an attestation process as an alternative means of reporting structural measures (#124 and #125) for medical groups that meet certain requirements, thus eliminating the barrier to participation that claims-based reporting through G codes presents.*

EHR-based Reporting of Measures Groups

AMGA strongly supports the concept of EHR-based submission of PQRI data and is pleased to see CMS consider this option for a subset of measures for 2009. Claims-based reporting has always presented a major barrier to participation in PQRI for multi-specialty medical groups and other organized systems of care with existing EHRs. As a result, many leading medical groups are not participating in the program.

AMGA also supports the expansion of measures groups as a step “toward a more holistic and comprehensive assessment of patient care” (73 FR 38560), focusing on high-cost, high-volume disease states. We recommend CMS accept EHR-based reporting for measures groups as soon as it is feasible, since AMGA member groups are already using EHRs and embrace broader clinical accountability to the communities they serve. Allowing this form of reporting will stimulate PQRI participation.

Claims-based reporting was and remains the only reasonable approach to accept quality data from solo physicians and small group practices. For large multi-specialty medical groups, however, retooling existing, sophisticated, often proprietary software, modifying business processes, and training personnel is expensive and disruptive. It competes for resources and attention with quality improvement efforts to improve patient outcomes. Estimates range in the hundreds of thousands of dollars to create the necessary interfaces for medical group EHR systems to abstract the required data and to place the corresponding G codes onto claims.

Group Practice-Level Reporting (MIPPA)

Many medical groups are large enough for statistical sampling to provide sufficiently robust data to measure quality. They also have a proven track record as efficient providers of care. By and large, such medical groups perform as a single entity, should be measured as a single entity, and have any bonuses or rewards paid as a single entity, allowing use of their existing mechanisms to efficiently distribute feedback reports and incentive payments.

Congress has recognized the importance of including a mechanism in the PQRI program that would allow for group practice-level reporting done through an EHR-based statistical sampling methodology to report on high-volume, high-cost disease states. This was included in the 2008 Medicare bill (MIPPA) passed after the current fee schedule proposed rule was published. The mechanism is to be modeled on the one successfully being used in The Physician Group Practice Demonstration. MIPPA requires CMS to have this system in place beginning in 2010; therefore, AMGA urges CMS to begin accepting data through EHR as soon as practicable.

Quality Measure Development

AMGA supports CMS’s efforts to promote a “robust marketplace for development and review of quality measures” (73 FR 38567), since EHR-based reporting will enable new measures that allow more accurate characterization of population health and more sensitive tracking of changes over time. Both statute and common sense require endorsement/ approval by a respected and broadly representative organization such as NQF or AQA, but CMS should encourage receptivity to new measures that may be easier to report via an EHR without manual intervention and measures that provide additional insight into the quality of care being received by Medicare beneficiaries.

eRx Measure Definition

Although removed from the PQRI program by MIPPA, reporting the use of electronic prescribing (eRx) depends on submission of G code data for PQRI Measure 125, HIT-Adoption/Use of e-Prescribing. As currently specified, this measure requires providers to have a qualified e-prescribing system that is capable of: generating a complete active medication list incorporating data received from applicable pharmacy drug plan(s) if available; selecting medications, printing prescriptions, electronically transmitting prescriptions, and conducting all safety checks; providing information related to the availability of lower cost, therapeutically appropriate alternatives (if any); and providing information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan.

Unfortunately, full compliance with this measure depends on many factors external to the medical group, such as the availability of detailed formulary and cost data for individual health plans or the ability of drug plans to process authorizations electronically. In surveying AMGA members, among the largest medical groups in the country, many of whom have pioneered eRx (and other sophisticated HIT), we learned that many groups could not meet, in the strictest sense, all four numerator elements of this measure. Yet these medical groups are achieving substantial benefits, in terms of patient safety, overall practice efficiency, and even physician and patient satisfaction, from their eRx systems, even though external factors preclude their full compliance with measure 125.

If these AMGA member medical groups, leaders in the realm of HIT adoption and use, cannot strictly meet this measure, then few practices in the country will be able to comply. We believe the measure sets the bar too high. We support the legislative intent of MIPPA, to stimulate acquisition, implementation, and use of eRx. We strongly urge CMS to set performance measures at achievable levels, in order to have the maximum effect in terms of promoting policy objectives.

Attestation Mechanism for Reporting Structural Measures

AMGA is pleased to see that CMS proposes retaining Measure 124, HIT-Adoption/Use of Health Information Technology (Electronic Health Records), as a structural measure within PQRI.

However, since both the eRx and EHR measures (#125 and #124, respectively) are structural measures, it is not optimal to report them on a per-encounter basis. Moreover, the current specifications for both of these measures focus on the *capabilities* of the respective systems, not how they are actually used.

Attestation is a more logical and efficient way to report structural measures, and it could be structured to allow CMS to assess the use of these technologies, not merely their capabilities. AMGA proposes that an attestation process be developed and made available to practices that meet certain criteria, as mentioned earlier and fleshed out below. There is a well-

established precedent for attestation in other areas of the Medicare program (including provider-based entity attestation and therapy cap exceptions). CMS should use the criteria offered by AMGA in this letter to determine medical practice eligibility to attest to their use of eRx and EHR. This eliminates the barrier to participation that claims-based reporting at the encounter level, using G codes presents, and it also allows CMS to recognize advanced modes of practice.

Proposed Attestation Criteria for eRx Adoption and Use

Attestation should be submitted annually to aver and avow that prescriptions are written electronically in at least 50% of instances where permissible by Federal and State law; that the volume of monthly scripts written exceeds 2,000 per medical group or organization; that safety checks are routinely used (i.e., available in the software and not disabled) to address potentially inappropriate dosages, routes of administration, and contraindications; that the system maintains an active list of patient allergies and cross-checks prescriptions against allergies; that the system is capable of generating an active medication list and is capable of incorporating electronic data received from pharmacy drug plans, if available; that information is provided to patients about the availability of lower cost, therapeutically appropriate alternatives, as available; that formulary medications, patient eligibility and authorization requirements are received from the patient's drug plan electronically, or by other timely means, as available.

We recommend that a similar attestation process and criteria be developed for Measure 124, HIT-Adoption/Use of Health Information Technology (Electronic Health Records), as well as any other structural measures that are added to the PQRI program.

MIPAA Provision for Reporting eRx Through Part D Claims

AMGA would also like to comment on other avenues of reporting e-prescribing. One such alternative exists in the MIPPA language, in Section 132(a)(2)(B)(iii), as follows:

“REQUIREMENT FOR ELECTRONICALLY PRESCRIBING UNDER PART D.—The requirement described in this clause is that the eligible professional electronically submitted a sufficient number (as determined by the Secretary) of prescriptions under part D during the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year).”

This language provides the authority for CMS to utilize Part D claims data to determine if physicians are prescribing a sufficient number of prescriptions electronically. AMGA urges CMS to move forward with implementation of this provision, either in parallel with our proposed attestation mechanism or as an alternative to it.

This would be an elegant system, a “passive” approach that would allow CMS to gather and extract needed data without PQRI participants having to key, code or submit data and not requiring per-encounter HCPCS codes for this structural measure. This broadly phrased

statutory text implicitly suggests modification of the claims form to accommodate fields that would meet the data requirements needed to accomplish such a “passive” system of quality reporting.

COMPUTER-GENERATED FAX TRANSMISSIONS: *AMGA recommends that in cases when the receiving pharmacy does not have a fully operational eRx system, that the computer-generated fax exemption also be available for initial prescription orders.*

AMGA is very pleased to see that CMS has extended the computer generated fax exemption for refill requests and for instances when transmission isn’t possible due to network outages. CMS is specifically soliciting additional information on any other eRx transactions that may be adversely affected by the elimination of computer-generated faxes. AMGA therefore suggests that in cases when the receiving pharmacy doesn’t have a fully operational e-prescribing system, that the computer generated fax exemption also be available for initial prescription orders.

We are confident that with the financial incentives provided through MIPPA for eRx that more widespread adoption will be stimulated.

Thank you for the opportunity to present AMGA’s perspectives on these matters. Among our members and staff there exists broad expertise in the matters under discussion. We would be pleased to assist CMS in its pursuits of alternative means of data reporting, acting as a sounding board to offer “real world” perspectives on contemplated regulatory actions and their consequences. Should you have questions or require additional information, contact Karen Ferguson, Assistant Director, Regulatory Affairs, of my staff at 703-838-0033x349 or kferguson@amga.org.

Sincerely,



Donald W. Fisher, Ph.D.
President and CEO