



October 10, 2006

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan:

AMGA is an association that represents medical groups, including some of the nation's largest, most prestigious multi-specialty practices and integrated health care delivery systems. AMGA members' 65,000 physicians deliver health care to more than 50 million patients in 40 states, including 15 million capitated lives. Thank you for the opportunity to comment on the proposed rule regarding revisions to the payment policies under the Medicare Physician Fee Schedule (PFS) and other changes to payment under Part B.

Reassignment and Physician Self-Referral

The issue of "condo" laboratories in the realm of anatomic pathology is a focused problem and appears to be the genesis of proposed changes to the Stark regulations and reassignment rules. The nature and scope of changes proposed stands to interject additional complexity into an already highly intricate set of laws and rules. While CMS seeks to clarify existing rules, to stem abuse and the potential for abuse, there is the real risk of unintended consequences. These may inadvertently lead to the disruption of routine, normal and non-abusive business arrangements involving the absolutely legitimate engagement of independent contractor physicians, such as the emergency department company physician arrangements you referred to.

The proposed Stark changes to the definition of "centralized building" represent yet another example of refining the Stark law exceptions for the narrow purpose of stopping impermissible referrals or other abuses in anatomic pathology practice, that make no sense in other, non-abusive settings. The 350 square foot rule may rule out otherwise legitimate ancillary buildings that simply do not need to be that large. Groups will end up buying or renting more space than they actually need to deliver some services "in-office." Furthermore requiring equipment to be in place 90% of the time will require some practices to buy or lease equipment permanently even though they only need it on a

temporary or part-time basis. It may also force them to abandon those ancillary services that currently rely on mobile equipment.

As a preliminary step, CMS could ask the Health and Human Services Department's Office of Inspector General to issue a special fraud alert specifically directed to the practice of anatomic pathology and "pod" lab practices. Furthermore, we suggest that the missing element in addressing abuses in this area lies in enforcement, not refinement of existing regulations. **We recommend that the agency employ tools already available to investigate abuses and take remedial action where warranted.**

As an additional alternative we propose that rather than risk adding unnecessary complexity, hence confusion and heightened risk of unforeseen, negative repercussions on the broader and non-fraud and abuse problematic practice of medicine, that CMS focus strengthening its interpretation to maximize the enforcement utility of 42 USC 1395 nn (g) (4):

(4) Civil money penalty and exclusion for circumvention schemes

Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than \$100,000 for each such arrangement or scheme. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

If, after due consideration CMS decides to promulgate a final rule along the lines of the proposed amendments, we believe that the best available course is to make them applicable only to pathology services, the primary source of the vulnerabilities.

IDTF Issues

Independent Diagnostic Testing Facilities (IDTF) regulations were originally put in place to secure the fraudulent and abusive practices rampant in their predecessor entities, the Independent Physiological Laboratories (IPLs). Recently, the Department of Health and Human Services Office of Inspector General (OIG) undertook and published results of an audit of claims billed by IDTFs.

The OIG's report found that Medicare IDTF services were not always reasonable and necessary, were also often not ordered by a physician, nor sufficiently documented.

Additionally, the majority of IDTFs surveyed did not operate in accordance with their initial enrollment applications and succeeding filings. The OIG's investigation estimated that over \$71.5 million in overpayments were made by the ten Carriers sampled, which it will attempt to recover.

As the Medicare Payment Advisory Commission (MedPAC) has recognized, the rate of growth in utilization for IDTFs from 2000-2002 was double that of physicians' offices. It was in part the extraordinary rate of growth in IDTF services that prompted the most recent OIG investigation.

In spite of extant rules and requirements, Medicare program integrity at IDTFs remains at risk. The expected remediation of abusive practices of the past has not happened. The creation of the IDTF entity has done nothing to ensure the quality or appropriateness of diagnostic testing. In fact, the OIG findings reveal significant failures of compliance in virtually every aspect of the IDTF regulation. The success at reducing Medicare program fraud and abuse vulnerabilities of the proposed regulations and new business practice standards for IDTFs, if implemented, will not be evaluated or known for what may be years.

In the proposed rule CMS noted that these additional standards might lead some IDTFs to withdraw from the Medicare program rather than comply adding: "... [W]e emphasize that services provided by an IDTF are also readily available to beneficiaries through other avenues such as physicians' offices, outpatient laboratories, outpatient radiology facilities, and outpatient clinics."

Given the history of this troubled entity, ongoing fraudulent and abusive practices there, and the wide availability of services offered in other quarters, we suggest that CMS fundamentally reexamine the need for IDTFs rather than prolonging existence of this source of program integrity problems.

Promoting Effective Use of Health Information Technology (HIT)

While we applaud the regulatory exceptions to the Stark II (Stark) and Anti-Kickback (AKB) laws for HIT recently issued by the Department of Health and Human Services (HHS), the new regulatory exceptions are sufficiently vague and complex to deter many potential institutional providers from utilizing them.

Legal Barriers to HIT Adoption

Increased adoption and implementation of HIT, which can range from electronic patient registries to sophisticated electronic medical record systems (EMRs), has the potential to increase quality and decrease costs. However, substantial legal barriers to encourage HIT adoption exist.

Fraud and Abuse Laws

Because HIT has the potential to dramatically improve the quality and safety of patient care, some hospitals and medical groups with sophisticated HIT systems are ready to begin exchanging clinical data with community physicians. While many hospitals and medical groups already have web portals that allow physicians access to patient data, there is little two-way exchange of data. Therefore, these providers would like to assist physicians to take the next step and adopt EMRs. Increased physician adoption of HIT begins to create a culture of use and reliance on sophisticated HIT systems, easing the transition to a wholly electronic system in the future. Of course, not all hospitals and medical groups are in a position to help physicians adopt EMRs, but those that would like to cannot, due to, in large part, to the Stark and AKB laws.

Creating links between large providers and their affiliated and unaffiliated physicians involves the provision of computer hardware, software, support, education, etc. Unless these HIT items and services meet certain criteria, including that they are provided at fair market value, these arrangements implicate federal fraud and abuse laws (e.g., Stark and AKB). Because of the draconian sanctions associated with these laws (including incarceration, financial penalties, and mandatory or permissive exclusion from Federal health care programs), providers remain reluctant to enter into these arrangements.

Notably, a number of government agencies, including the General Accountability Office (GAO), the Office of the National Coordinator for Health Information Technology, and the Congressional Research Service, have stated that federal fraud and abuse statutes present barriers to arrangements between providers that would otherwise promote adoption of HIT.

New Regulatory Exceptions to the Stark and AKB laws

On August 1, 2006, HHS issued final regulatory exceptions to the Stark and AKB statutes related to the dissemination of HIT. While these new rules represent marked improvement over the proposed exceptions, significant obstacles remain which may dramatically limit the number of large providers that utilize the exceptions to disseminate HIT. Consequently, the policy driving the issuing of these new exceptions, namely, creating usable regulations that will incentive disseminating HIT to small physician practices, will be thwarted.

Problematic aspects to the new rules include new interoperability requirements. Despite best attempts at clearly defining “interoperability”, the new rules are subject to interpretation which does not offer many large providers with the comfort needed to disseminate HIT without fear of violating Stark or AKB.¹

¹ Under the rules, providers must donate HIT that is interoperable as defined in the regulations or donate technology that is “deemed” interoperable by a “certifying body.” HHS recognized that interoperability standards are evolving and thus are requiring providers using the regulatory definition to ensure that the donated technology is as “interoperable as feasible given the prevailing state of technology at the time” the HIT is provided.

We also believe it is inappropriate to interject non fraud and abuse policy issues, in this case, an interoperability requirement, in the Stark and AKB laws. These statutes are designed, appropriately, to deter and punish fraud and abuse and should not be used to promote an altogether different policy goal.

Also, the new exceptions include a five year “sunset” provision. We are not aware of any other statutory or regulatory exception to Stark or AKB laws that includes a sunset provision. Again, addition of such a requirement will give large providers pause before they decide to invest in disseminating HIT to community physicians. Similarly, the rules do not allow providers to provide “hardware” to physicians. Solo and small physician practices may opt not to accept EMR software because of contamination issues related to downloading software into existing office based computer systems.

Provider – Physician Relationships

Another concern raised suggests that the provision and support of HIT will lead to subtle, yet preferred, relationships between hospitals, medical groups and providers. Many other factors influence hospital-physician relationships, such as patient preference, insurer restrictions on patient choice, perceived quality of the hospital, and special services that a particular hospital may have available. In any circumstance, the physician is still subject to the fraud and abuse statutes. Furthermore, a computer-based system can help federal law enforcement agencies track possible violations of law much more readily than the current paper-based environment.

HIT as a Cost of Doing Business

AMGA members have pioneered the use and application of HIT in their practices and have, by and large, made heavy investments in this important infrastructural element both as a practical matter and for philosophical reasons. The Administration has taken the stance that it supports the adoption of HIT as a normal cost of doing business and as such, does not support “paying” for physician’s to acquire HIT capabilities. The realities of the realm belie that notion and strongly suggest that this “normal” cost of doing business is deemed unnecessary or unaffordable by most physician Medicare providers. It is in any event, not being done.

We believe that appropriate incentives will have to be forthcoming to advance broad adoption and implementation of HIT to realize its potential for reducing medical errors, improving patient safety, enhancing care coordination, etc. **However, we believe that any financial support, direct or indirect, that may evolve over time, must take into consideration the investments and leadership demonstrated by those entities,**

including many AMGA members, by recognizing and repaying them for having had the vision to install and apply HIT.

Healthcare Information Transparency Initiative

AMGA has taken no position *vis a vis* health care information pricing transparency. We echo cautions offered by many that making publicly available prices of physician services must be done in such a way to make the information understandable and useable for consumers. That suggests providing context, education, and full comparisons of costs, i.e., charges, reimbursement levels, and some method by which the full course of treatment costs may be known, a formidable challenge given the fact that intensity and breadth of services are often impossible to determine on a prospective basis.

We support efforts to reward physicians and medical groups for delivering quality care. The probable vehicle for data gathering is the Physicians Voluntary Reporting Program (PVRP). Currently, participation by physicians is elective and involves the use of HCPCS G-codes, or as an alternative, submission of already existing data via the Doctor's Office Quality - Information Technology (DOQ-IT) vehicle available via Quality Improvement Organizations (QIOs).

There are barriers, impediments and limitations inherent in both of these approaches that pose problems for our members and other medical groups and may preclude participation in the PVRP. Retooling existing sophisticated, and often unique electronic capabilities to accommodate the keying of G-codes on each generated bill is prohibitively expensive and administratively burdensome.

The DOQ-IT vehicle has too many limitations to make it a broadly available alternative. While technical capabilities may indeed exist, structural limitations caused by funding limitations, make this approach "hit or miss". Depending on local QIO capacity, some of our members, although willing to submit their data, may be unable to take the DOQ-IT route.

We realize that PVRP is a building block, a first step, in the development of Medicare value-based purchasing and we look forward to continuing the dialog on its evolution into P4P or whatever precursor pay-for-reporting systems that may emerge.

Large multi-specialty group practices are quite different from other types of physician practices. They are, by and large, organized care delivery systems, and as such have built into their fabric an advanced model for performance measurement, quality control and continuous quality improvement. Some are members of fully integrated delivery systems and have hospitals already participating in the hospital voluntary reporting program, in various CMS demonstrations and other projects dealing with "quality" and related matters. They are integrated groups providing integrated care, furnished by a team rather than by an individual physician. Within this kind of delivery, multiple physicians, and

other health care professionals, provide care that crosses traditional specialty lines—it is truly coordinated care, internally.

These groups have in place internal systemic quality controls, based on continuous peer review and unified medical records, for most, an electronic medical record (EMR) and other infrastructural support systems. Such groups perform as a single entity and therefore should be measured as a single entity. They are large enough for sampling to provide sufficiently robust data to measure quality. They also have a proven track record as efficient providers of care. **As such, we request that CMS allow us, along with other medical groups that want participate in PVRP, to submit aggregated, group statistics and receive aggregated, group feedback reports.**

Finally, medical groups have existing mechanisms to distribute data and rewards. As the PVRP develops into P4P, we would also like any incentives they earn to be rendered in an aggregated form, with distribution and allocation decisions, left to extant group processes.

We recommend that PVRP be revised to include a mechanism to allow multi-specialty group practice physicians to submit data directly. For many of the groups, the reporting would initially involve manual abstraction from the patient medical record, similar to what is currently done for the hospital quality reporting, but could eventually be converted to automated reports. Most group practice physician organizations would be able to participate in the PVRP if the quality data could be collected and submitted manually or electronically and periodically in one of two ways:

- 1. Submit Directly to CMS.** The easiest and least intrusive approach would be to create a separate file that would be submitted directly from the group practice to CMS. This file could be submitted quarterly. It would contain patient-level information for all relevant patient encounters during the quarter. The information would be organized so that the encounter, the patient, the physician could be tied back to the specific billing, if required.
- 2. Submit to Carrier.** The second approach would also involve periodic reporting, but in this case to the carrier. For many medical groups, four of the sixteen measures could be automatically extracted from the group practice EMR on an interim basis, without additional physician administrative work. Nine of the measures could be reported with additional chart abstractions, but would require additional staff (approximately 1 FTE per group practice).

AMGA appreciates the opportunity to offer its perspectives for CMS' consideration. Any questions about our comments should be directed to George Roman, Director, Regulatory Affairs, at (703) 838-0033, extension 342.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald W. Fisher". The signature is fluid and cursive, with a prominent initial "D" and "W".

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