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AGA WEB SITE

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September 21, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1429-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Medicare Program; Revisions to Payment Policies Under the
Physician Fee Schedule for Calendar Year 2005; Proposed Rule;
69 *Fed. Reg.* 47,488 *et seq.* (Aug. 5, 2004); CMS-1429-P.

Dear Sir or Madam:

The American Gastroenterological Association (“AGA”) appreciates the opportunity to comment on the proposed revisions to payment policies under the Medicare Physician Fee Schedule for Calendar Year (“CY”) 2005. 69 *Fed. Reg.* 47,488 *et seq.* (August 5, 2004).

The AGA is the nation’s oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 13,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system. In light of the implications of the proposed changes on AGA members, and AGA’s ongoing interest in the matters discussed therein, AGA is providing comments on the following topics:

- Practice Expense;
- Section 303; and
- The Sustainable Growth Rate.

A. Practice Expense

The comments in this section pertain to the proposed changes to the resource-based Practice Expense Relative Value Units (“PE-RVUs”).

1. Discharge Management Clinical Staff Time

AGA strongly objects to the Centers for Medicare & Medicaid Services’ (“CMS”) proposal to eliminate the discharge management clinical staff time from all 0-day global procedure codes. This proposal would adversely affect virtually all gastrointestinal endoscopy codes.

CMS is underestimating the role of clinical staff in post-procedure discharge management. Clinical staff play an extensive and vital role in post-procedure discharge management, particularly where anesthesia has been used during the procedure. Clinical staff routinely educate the patient on the stages of anesthesia recovery and how to monitor for signs of anesthesia-related complications, instruct the patient on which foods and medicines are safe following surgery and which should be avoided during anesthesia and surgery recovery periods, schedule follow-up visits, as necessary, for further testing, arrange for pathology tests to be conducted and results to be delivered, and inform the patient about pending pathology tests and results. Oftentimes, the clinical staff must undertake these steps twice, once with the patient, and once with the patient's caregiver. Clinical staff also routinely field post-discharge telephone calls from patients and their caregivers with additional questions. Moreover, these functions are most often performed by a registered nurse, which means that these services are furnished at a relatively high cost to the physician practice.

CMS is proposing to make this change without providing any rationale whatsoever to support the revision. Before making such a change, CMS should at the very least articulate a basis for concluding that the entirety of post-procedure discharge management can be fulfilled through one post-service phone call. Moreover, CMS should be able to explain a rationale for distinguishing between 0-day global codes and 10 and 90-day global codes, for which CMS proposes to retain the post-procedure discharge management time. In fact, the post-procedure discharge management activities associated with 0-day global codes are virtually the same as those associated with 10 and 90-day global codes.

AGA believes that CMS already is understating the time and cost involved with post-procedure discharge management, and that CMS would be further damaging the integrity of the RVUs by eliminating post-procedure discharge management clinical staff time from 0-day global codes. As such, we strongly encourage CMS to retain the post-procedure discharge management clinical staff time presently in 0-day global codes.

2. Acid production stimulants used with CPT codes 91011 (Esophagus motility study) and 91052 (Gastric analysis test)

The Practice Expense Advisory Committee ("PEAC") recommended that CMS include a supply input for methacholine chloride as the injected stimulant for CPT codes 91011 (Esophagus motility study) and 91052 (Gastric analysis test). CMS notes that a gastroenterology specialty organization subsequently advised the Agency that the PEAC's recommendation was incorrect, because an injected form of methacholine chloride is not currently available. Instead, CMS is proposing to include edrophonium, 1 ml as the drug used for CPT 91011. For CPT 91052, CMS notes that it was unable to identify the single drug that is most typically used with this procedure. CMS requested that commenters provide information on the drug that is most typically used with CPT 91052, including the drug dosage, so that it can be included in the practice expense database.

AGA agrees with CMS's proposal to identify supply inputs other than methacholine chloride as the injected acid production stimulant for CPT codes 91011 and 91052. While edrophonium, 1 ml may be an appropriate supply input proxy for CPT 91011, in practice few practitioners use edrophonium when performing this procedure. Rather other agents are more commonly used.

With respect to CPT 91052, the most commonly used drug is pentagastrin in 6mg/kg sq dosage. Alternatively, betazole or histamine may also be used as acid production stimulating agents.

3. CPT code 91065 Breath Hydrogen Test

AGA encourages CMS to revisit proposed PE-RVU adjustments to CPT 91065 (Breath hydrogen test). If finalized, CMS will have reduced the PE-RVUs associated with this service by more than 60 percent in two years, from the 2003 technical component PE-RVU value of 3.81 to the proposed 2005 technical component PE-RVU value of 1.40.

CMS provides no explanation for this proposed change. Nonetheless, we suspect that CMS is responding, at least in part, to new analyzers that have been introduced into the market since this code was initially defined. While it is true that QuinTron, a leading manufacturer of breath hydrogen test analyzer equipment, now manufactures several models of microlyzers, and that some of the newer models are priced less than the original models, CMS should take note of several important facts. First, some of the newer models of microlyzers are priced less than the original models because they offer fewer capabilities than the original models. For example, some models measure H₂ (hydrogen), while other, more expensive models, also measure CH₄ (methane) and CO₂ (carbon dioxide), which is important to correct the results for possible dead space contamination of the sample. Physician practices are still purchasing the more sophisticated microlyzers for these tests.

Second, while the cost of equipment may have decreased in recent years, the cost of the reagents necessary to conduct the tests has increased. As a result, the per-service cost has remained relatively constant over the past five years.

Finally, the American Medical Association's CPT Editorial Panel recently approved a substantial revision of the code definition for 91065 to be effective in 2005. Beginning next year, CPT code 91065 will be defined as "Breath hydrogen test (e.g., for detection of lactase deficiency), fructose intolerance, bacterial overgrowth, or oro-cecal gastrointestinal transit)." This revised definition represents a substantial expansion of the types of services defined by this code. In light of these forthcoming changes, and the increased costs that will be incurred when using this code to define other tests, AGA urges CMS to not further reduce the PE-RVUs for this procedure, at least at this time.

B. Section 303

CMS's proposed implementation of the changes made pursuant to section 303 of the *Medicare Modernization Act* are relevant for gastroenterologists for two reasons.

First, gastroenterologists who provide infusion services with infliximab are affected by proposed reimbursement changes for Remicade. According to CMS, the allowed payment amount for Remicade, a drug occasionally administered by gastroenterologists, would drop by approximately 9 percent, from \$58.79 to \$53.32, as a result of the new payment methodology. Second, payments for certain drug administration services also will be affected pursuant to section 303(a)(1) of the MMA, which requires CMS to increase work and practice expense RVUs for drug administration services to offset the decline in payments for the drugs themselves. According to CMS, the volume-weighted average permanent increase in payment among drug administration services is approximately 105 percent (109 percent for oncologists and 94 percent for other physicians).

In light of the implications of these changes on reimbursement for services commonly furnished by gastroenterologists, AGA appreciates the opportunity to participate in the process established by CMS for implementing these changes. As CMS continues to implement changes concerning drug and administration service reimbursement, AGA urges the Agency to adhere to two general principles. First, Medicare payments for drugs should fully cover the acquisition cost for such drugs. Physicians should not be left to make up gaps between cost and reimbursement, nor to pass along such costs to their patients. We also urge CMS not to take any action that will force more physicians to discontinue furnishing drugs to their patients, and that would limit site of service options for program beneficiaries. Second, any reductions in Medicare payments for drugs must be accompanied by corresponding increases in program payments to physicians to administer those drugs. When furnishing drugs to program beneficiaries, physicians incur costs well beyond just the acquisition cost of the drug. For example, physicians must store the drug, prepare the drug for delivery, and administer the drug, a process which often can take hours. There are costs associated with each of these steps which can be substantial. CMS must take full account of these costs when considering drug administration reimbursement changes.

C. Changes to the Physician Fee Schedule Update Calculation and the Sustainable Growth Rate (“SGR”).

AGA commends CMS for making changes to the formula used to determine annual Medicare physician payment updates. Changes recently made to the productivity factor and data errors for 1998 and 1999 were important and welcome steps toward improving the fairness of the formula. However, this formula remains flawed and in need of further refinements. Updates mandated by the *Medicare Modernization Act* only serve to mask and postpone systemic problems that will undoubtedly resurface when the MMA provisions expire.

AGA believes that CMS has the authority to fix certain aspects of the update formula, and urges CMS to address the problems that are clearly within its discretion to fix. Specifically, AGA urges CMS to exclude the cost of outpatient drugs for purposes of establishing the physician target. The statute specifies that CMS is to estimate allowed and actual expenditures for “physician’s services.” In so doing, CMS includes in the calculation the cost of drugs. While the physician’s administration of the drug is

a physician service that is required by statute to be included in the pool, the drugs themselves are not. Including drugs in the calculation is not only inappropriate, because drugs are not a physician's service *per se*, but also because the rising cost of drugs is due in large part to the introduction of costly new cancer and biological drugs, and not because physicians failed to control service expenditures. Including the costs of drugs in the calculations results in a lower SGR. AGA encourages CMS to eliminate from the SGR the cost of drugs given by injection in the office.

Additionally, CMS should ensure that the impact on utilization and spending resulting from all national coverage decisions and benefit changes are taken into account for purposes of the SGR spending target. Beneficiary demand for physician services increases for a variety of reasons, including legislative actions and regulatory decisions that expand benefits and coverage. AGA supports these initiatives, which clearly are good for patients. However, these changes must be appropriately reflected in the target. For example, the new prescription drug benefit enacted under the MMA will significantly expand expenditures for physician services because beneficiaries who previously could not afford to purchase drugs will visit physicians to get prescriptions. Moreover, these patients will have to be monitored by the physician for the impact of the drugs and may need to be seen for other conditions discovered at the time of the visit. Additionally, the MMA allows for an initial preventive physical exam by a physician. While these benefits will increase physician spending, additional spending will occur since these new services are certain to trigger ongoing care for a chronic condition or surgery for an acute condition. These additional costs must be included in the calculation of the SGR target.

Gastroenterologists have been disproportionately impacted in recent years by these problems. In CY 2002, physicians incurred a 5.4 percent across-the-board payment cut, the largest payment cut since the Medicare physician fee schedule was developed. Gastroenterology procedures sustained even deeper cuts in part because of changes to resource-based PE-RVUs. CMS reduced payments for gastroenterology by 7 percent in CY 2002. For CY 2003, CMS proposed to cut physician payments by 4.4 percent. Had Congress not stepped in with a temporary adjustment, gastroenterology reimbursements would have been reduced by approximately 6.3 percent. The proposed physician fee schedule update for 2004 would again have reduced Medicare payments for gastroenterology procedures beyond the reductions sustained by most every other specialty. Had Congress not specified an update for 2004, the projected reimbursement cut for most gastroenterology procedures would have been 4.8 percent, whereas the overall anticipated reimbursement cut for CY 2004 would have been only 4.2 percent.

In light of these concerns, AGA urges CMS to take action to fix those aspects of the SGR that are clearly within its legal authority to do so, and to take these steps immediately to prevent further substantial erosion of Medicare physician payments in the future.

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We appreciate your consideration of these comments. If you have any questions, please call AGA's Vice President of Public Policy and Government Affairs, Michael Roberts, at (301) 654-2055.

Very truly yours,

A handwritten signature in black ink that reads "Emmet B. Keeffe". The signature is written in a cursive style with a large initial 'E' and a long, sweeping tail on the 'e'.

Emmet B. Keeffe, MD
President

cc: Michael Roberts, Vice President of Public Policy and Government Affairs