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May 15-16, 2004
New Orleans, LA

ANNUAL MEETING

May 15-20, 2004
New Orleans, LA

OFFICIAL PUBLICATION

Gastroenterology
Editor: David A. Brenner, MD

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October 9, 2003

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1229-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Payment Reform for Part B Drugs;
Proposed Rule; 68 *Fed. Reg.* 50,428 *et seq.* (August 20,
2003).

Dear Sir or Madam:

The American Gastroenterological Association (“AGA”) appreciates the opportunity to comment on the proposed revisions to payment policies for Part B drugs. 68 *Fed. Reg.* 50,428 *et seq.* (August 20, 2003). 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 Centers for Medicare & Medicaid Services’ (“CMS”) proposal on AGA members, and AGA’s ongoing interest in the matters discussed therein, AGA is providing these comments.

A. Proposed Approaches to Revising the Current Payment Methodology for Part B Drugs

AGA commends CMS for devising and proposing for comment four options for revising Medicare payments for Part B drugs. We recognize the difficult and controversial nature of this matter, and the challenge that CMS has before it. However, because of the controversy surrounding this issue, and the fact that Congress at this moment seems poised to revise the statutory payment formulas for Medicare Part B drugs,

we encourage CMS not to finalize any of these proposals, and instead allow Congress ample opportunity to act.

Should CMS feel compelled to proceed, AGA urges the Agency to adhere to two general principles in evaluating the best alternative for reimbursing for drugs. 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. It is widely understood that physicians rely on positive margins from drug reimbursement to cross-subsidize negative margins from program reimbursement for these other services. Without the positive margins to cross-subsidize, many physicians would be unable to furnish drugs to beneficiaries.

With respect to the proposals themselves, AGA has concerns about each of the proposed changes. For example, AGA is concerned that CMS is granting too much discretion to carriers under the comparability proposal. If carriers are given discretion to set reimbursement rates for prescription drugs for both Medicare and private plans, they would have a strong incentive to understate regional reimbursement rates, and lower payment rates, to maximize their own profit margin.

AGA has concerns about CMS's competitive bidding proposal, too. Competitive bidding models induce suppliers to compromise quality as they race other suppliers to a bottom price. In the case of drugs, cutting corners on quality – *e.g.*, such as inadequate temperature control during storage and drug dilution – can have devastating, even deadly results for patients.

While using an average AWP discount approach also is not problem free, it appears to be the least problematic of the four proposals. This proposal is most similar to current reimbursement methodology, and we anticipate that it would therefore cause the least reimbursement fluctuation on a drug-by-drug basis, and the least disruption for physicians who administer drugs.

B. Payments Related to the Administrative Costs of Furnishing Drugs

AGA appreciates that CMS is proposing to revise payments to physicians to reflect changes to payments for drugs that CMS may implement, as described in the proposed rule. Overall, we support the concept of adjusting payments to physicians in this manner. Under current reimbursement methodologies and rates, Medicare payments to physicians for the work associated with infusing drugs is too low: Medicare pays only approximately \$43 for CPT code 90780 (IV infusion therapy, 1 hour), and \$21 for CPT code 90781 (IV infusion therapy, additional hour). Few gastroenterologists can afford to offer infusion therapy to Medicare beneficiaries at these payment levels. Those gastroenterologists who do offer infusion to beneficiaries do so at a loss with respect to the overhead reimbursement.

While AGA recognizes that there are problems inherent in the current reimbursement methodology for drugs, the margin physicians are able to potentially make on the drugs themselves, albeit not nearly as great as CMS purports, is the only way that physicians can cross-subsidize the losses they incur reimbursements for the other practice costs of furnishing drugs. The current system functions because AWP reimbursement enables physicians to furnish drugs without losing money on every patient. As such, AGA is delighted that CMS is proposing to increase practice expense relative value units to accommodate for anticipated reductions in drug acquisition cost.

However, AGA is concerned that CMS may not be proposing adequate increases. Compounding this concern is the fact that the Proposed Rule does not define what the increase in practice expense would be for non-oncologists, or for that matter give any specialty-level impact for any specialty other than oncology. Given what we know to be the current disparity in reimbursement between oncology and non-oncology services, we are concerned that CMS's proposals will undervalue non-oncology services, and fail to adequately adjust payments for non-oncology services to offset decreases that are anticipated in drug acquisition cost reimbursement. Cutting drug acquisition cost reimbursement without a corresponding increase in the amount allowed for the physician work likely will lead many physicians to stop offering infusion-type therapies to Medicare beneficiaries.

AGA encourages CMS to first publish proposed practice expense reimbursement increases for non-oncology services, before proceeding with any physician service or drug acquisition cost reimbursement changes. Specifically, CMS should release an interim final rule with comment period once it has chosen a drug payment option, and include in this interim final rule specialty-level impacts and practice expense RVUs for all the CPT codes that will receive an adjustment as part of this proposal. Additionally, AGA urges CMS to ensure that reductions to the drug reimbursement methodology be offset by corresponding increases in physician service reimbursement to ensure that physicians are capable of continuing to provide infusion services to program beneficiaries.

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

Very truly yours,



Daniel K. Podolsky, M.D.
President

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