AMERICAN COLLEGE OF GASTROENTEROLOGY

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(87)

September 14, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Re: *Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Rates; Medicare and Medicaid Programs; Proposed Changes to Hospital Conditions of Participation; proposed Changes Affecting Necessary Provider Designation of Critical Access Hospitals*

Dear Mr. Kuhn:

The American College of Gastroenterology is pleased to provide these comments with respect to CMS' proposed rule, published in the *Federal Register* on August 2, 2007, on proposed changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Proposed Changes to the Ambulatory Surgical Center (ASC) Payment System and 2008 rates and other related topics.

INTRODUCTION

The American College of Gastroenterology is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers more than 9,500 physicians among its membership of over 10,000 health care providers of gastroenterology specialty care. Although the vast majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists, and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology – the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be, educational efforts directed at promoting and optimizing quality care.

Rate-Setting Methodology

As the agency states on page 42796 of the proposed rule, GAO's statutorily-mandated report "Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System," GAO-07-86, played a key role in informing CMS' decision to use the HOPPS payment methodology as the basis for the new ASC payment system. The ACG is concerned that this reliance, given the agency's failure to provide timely access to the report to all affected stakeholders prior to the November 6, 2006 comment

deadline on the proposed rule, potentially violates the Administrative Procedures Act as well as general principles of fairness and transparency in government decision-making. This injustice is all the greater given that the report was submitted to Congress way past its January 2005 deadline, depriving affected stakeholders of time to analyze and respond to its data and analysis. Instead, the GAO report was available only to the agency and a few stakeholders. Further, ACG's request for advance access to the report was denied, harming our ability to comment on the rule on equal footing with those who had seen the report.

Further, the College respectfully disagrees with the GAO/CMS conclusion that a uniform percentage of the HOPPS payment rate is appropriate in the ASC setting. CMS provides scant evidence at best on the relation between actual ASC costs relative to HOPD rates, and hence any justification for a single payment across specialties and/or procedures. For GI, as indicated in our attached November 2006 comments, the HOPPS payment clearly does not reflect costs in the ASC setting. Our previous comments and that of other key GI stakeholders, as well as presentation to the agency in a November 2006 meeting prior to the close of the comment period, all showed that HOPPS is not a relative cost proxy for GI ASCs costs. For example, as we stated in 2006, a study of hospital costs, derived from HOPD costs and payment data, shows that among eighteen 40000 series GI CPT codes, four codes [45378 (diagnostic colonoscopy), 43239 (EGD with biopsy), 43247 and 43450 (two much lower volume codes)] had HOPD payments in excess of the hospitals reported costs, while for the remaining fourteen GI procedures Medicare payments were less than the hospital's reported costs. Based on this-- 77% of GI cases have a negative margin *even* when paid at 100% of the HOPD facility fee payment. Therefore, the rule's 65-67% of HOPD percentage will result in these procedures being severely underpaid, projected by the Lewin Group at Medicare GI ASC payments being –20% below actual costs.

Conversion Factor

Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit. Sadly, and whether intentionally or inadvertently, CMS has consistently emasculated the effectiveness and utilization of that benefit, by relentless and devastating cuts to physician payment for colorectal screening and now, through an unfair and grossly inadequate conversion factor that was reduced by 2.68% from the $42.542 level in the final ASC rule to the $41.4000 level announced in the proposed OPPS rule. CMS's decision to maintain a site-of-service differential for facility and non-facility payments to GI have also contributed to this GI underpayment. (For more information, please see the attached ACG 1998 comments on the Medicare Physician Fee Schedule.)

Budget Neutrality

Reverse Migration

The ACG continues to be mystified by CMS' budget neutrality calculations, whose shortcomings will result in higher costs to the Medicare Part B Trust Fund and to Medicare beneficiaries. As the College argued in its comments in its proposed rule , CMS limited its analysis to new ASC

procedures added and did not recognize savings that will accrue to Medicare with procedures already on the ASC list when large payment shifts trigger volume moves from the HOPD to the ASC for many non-GI procedures, or costs that will be incurred when volume in GI procedures, which will now be reimbursed below costs in the ASC, move back to the HOPD when payment is too low, and does not cover the costs of the procedure. In an alternative analysis in the proposed rule, CMS did consider the effect of migration but analyzed the migration that could occur only as the 14 new codes that CMS is proposing to implement. However, ACG argued that if CMS defined budget neutrality to include all outpatient sites, this could generate savings to the Medicare system and still maintain a reasonable revised ASC facility fee cost structure for GI procedures. The extensive Lewin Group analysis confirms that many non-GI cases would migrate from the HOPD to the less expensive ASC, thereby creating savings to Medicare, for which CMS is not accurately accounting in its rulemaking proposal.

In the final rule, while CMS did a more expansive analysis of case migration and chose to estimate budget neutrality using case migration, it explicitly failed to reference the Lewin data, or that submitted by others on reverse/negative migration. Instead, the agency appears to have instead simply stated that the phenomena would be offset by positive migration, but provides no evidence for this conclusion.

Also in the final rule, CMS specifically concentrated its migration analysis for the 793 new procedures added to the ASC list, assuming that any shift in site traceable to the wide shift in payment rates for procedures such as colonoscopy and EGD and other procedures already on the ASC list would be negligible. CMS' actuaries also concluded, and factored into the agency budget neutrality calculations, that it would incur costs when eventually 15% of cases now done in physician offices move over to the ASC, even though the final rule assures that the payments would essentially be cost-neutral, since the new facility fee for cases now done 50% in the office would never exceed the practice expense component under the Medicare physician fee schedule. These two conclusions appear to be logically inconsistent. Finally, as stated above, the final rule states that agency actuaries determined that any negative migration will be offset by positive migration but provides no evidence or detailed analysis to support this conclusion or to counter the Lewin analysis. In fact, the agency makes no mention whatsoever of the Lewin analysis, a substantial body of evidence which the agency, by all appearances, completely ignored.

The budget neutrality baseline was established based on 2003 law. Subsequently, interpreting P.L. 109-71, CMS extracted significant early savings (i.e., mandating that the ASC facility could never exceed the facility fee in the HOPD). CMS's budget neutrality calculation should have been interpreted to consider this early savings installment in ASC payment reform. Those savings should have been considered as part of the pool for computing budget neutrality (and not excluded just because after MMA 2003 CMS undertook ASC payment reform in two steps—one through interpretation of P.L. 109-71, and the second step via the adoption of the ASC payment reform rulemaking first published in August 2006) and a higher conversion factor would have resulted.

Other Analytic Errors

In addition to these problems in the rule's budget neutrality calculations, ACG has identified the following flaws with the agency's analysis which first, uses the wrong baseline by not accounting for post-Medicare Modernization Act changes to the payment system and the significant expansion of the ASC list. First, the rule fails to account for any migration among procedures that have been paid in ASCs, before CY 2008, despite the fact that major changes in payment triggers substantial swings in site of service. Second, contrary to Congressional intent, the Agency's ASC rulemaking included not just the payment reform mandated by MMA, but also the addition of 793 new services without the addition of new monies. CMS interpretation that the same pool of money should be used for a far larger universe of services is inconsistent with the words, "for such services" invoked by Congress in its MMA budget neutrality mandate. The result CMS has created could not possibly be what Congress meant by budget neutrality; rather, ACG firmly believes that the term "budget neutrality" should have been applied as to costs only for those services that existed on the ASC list in December 2003 at the time MMA passed.

Physician Payment for Procedures and Services Provided in ASCs

The proposed rule states (pages 42791-92) that for services performed in ASCs, physicians will be paid for the professional work and facility PE associated with performing the procedure but not the Technical Component (TC) of payment. Given that reimbursement for most GI-procedures, particularly screening colonoscopy, has fallen precipitously since Congress enacted the screening benefit in 1997; ACG once again warns that the profession cannot afford any further reimbursement cuts without affecting beneficiary access. It is particularly perplexing to see policies, such as the refusal to pay for the TC service, when no significant policy rationale is articulated.

Annual Updates

Ironically, while the agency states that the HOPPS is an appropriate payment methodology for the ASC setting, CMS declines to provide the same inflation update for both systems going forward. Under current law, CMS is required to annually adjust ASC payments by the consumer price index for urban areas, although inflation adjustments were suspended under the MMA through 2009. The same law requires CMS to inflate HOPD payments by the hospital market basket index, a separate inflation adjustment. This hospital market basket is traditionally higher than the CPI-U, and the gap between ASC and hospital payments would continue to diverge because of this disparity. This is likely to result in further significant underpayments to ASCs, compared to hospitals and exacerbate the underpayment to endoscopy centers. ACG urges CMS to instead use a market basket update for ASC payments.

Payment for Colonoscopies

ACG is also mystified as to why the relative weights in the proposed rule are different for HCPCS 45378 (diagnostic colonoscopy) and G0127 (colon cancer screen; not high risk individual) in Addendum BB of the rule. The CY 08 relative payment rate for the former is 8.8143 while for the latter it is 7.8134. Both these procedures have the same relative value units and are clinically identical, and there is clear legislative history in OBRA 1997 compelling that payment for 45378 (diagnostic) and GO127 (screening) are mandated to be identical, i.e., the

higher 8.8143 rate must apply to all without discount for screening cases. They differ only in the indication for the procedure.

A Longer Transition Period Is Insufficient

As CMS has itself acknowledged, GI is a net loser under its new ASC payment policies. The agency states in its commentary on the final ASC rule that, "[O]ur final policy of a 4-year transition to phase in the revised ASC payment system should mitigate the potential disruption in care that could be associated with significant increases or decreases in payments for specific surgical procedures under the revised payment system. Individual ASCs will have a longer period of time to evaluate and potentially modify the breadth of surgical procedures they provide based on the expanded list of covered surgical procedures and the final policies of the revised ASC payment system." This appears to suggest that the agency believes that the hit that endoscopic centers and other negatively affected ASCs suffer under the final rule can be offset if the affected ASCs change their business model. The idea that GIs can broaden their service offerings is naïve as best because: (1) many states have certificate of need laws, which would make it impossible to offer a new line of services; and (2) specialties that are "winners" under the new policies are unlikely to wish to join up with GI, given the payment hit they would take in doing so. The only other alternative for many GI ASCs is to limit or exclude treatment of Medicare beneficiaries. Surely, this cannot be the agency's aim in creating the new ASC payment system.

ACG urges the agency to provide an even longer transition period for GI or some sort of stop-loss protection or payment floors as the agency has in the past for device-intensive procedures under previous years' HOPPS rules.

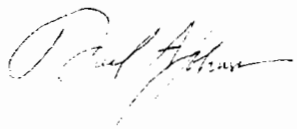
Conclusion

We are deeply concerned that the cumulative cuts from the SGR, and the pending reform to the ambulatory surgery payment system will drive many gastroenterology practices and ASCs out of the Medicare system and/or out of business and compromise their ability to continue to provide gastroenterology specialty care to Medicare beneficiaries. Indeed, surveys of our members found that under the proposed ASC rule, one-third of GI ASCs would stop seeing Medicare patients or close, and a Deutsche Bank analysis found that any GI ASC that provides fewer than 3,500 procedures per year will be put out of business This downward spiral must stop. The potential negative implications for patient access to quality gastroenterologic service are frighteningly apparent. If this policy is to go forward in its present form, it is implicit with such a decision – which is not supportable by data or expert input, that the agency accordingly accepts and is held responsible for the consequent implications threatening patient care and outcomes.

The College urges the agency to go back to the drawing board to develop a new system as it applies to gastroenterology services. These changes should be made in a way that will not impair beneficiary access to colorectal screening and recognize that the negative migration is truly budget neutral in the way that Congress intended. We appreciate the opportunity to submit our comments on this proposal, and we would be pleased to answer questions or otherwise engage in dialogue with the agency about how to revise the proposal in a way that protects

taxpayers and Medicare beneficiary access and does not penalize physicians and ASCs and the patients who need these services.

Respectfully submitted,



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AMBULATORY SURGERY CENTER RULE

Leslie Norwalk, Esquire
Acting Administrator
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Department of Health & Human Services
Attention: CMS-1506-P
P.O. Box 8014
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Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Ms. Norwalk:

The American College of Gastroenterology is pleased to provide these comments with respect to the proposed rule issued August 23, 2006, by the Centers for Medicare and Medicaid Services' (CMS), on revisions to the payment policies relating to the Ambulatory Surgery Centers PPS Proposed Rule (to begin Calendar Year 2008) and other related topics.

INTRODUCTION

The American College of Gastroenterology (ACG) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers nearly 10,000 physicians among its membership. While the majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists and other specialists who focus on the various aspects of treating digestive diseases and conditions. The College focuses its activities on clinical gastroenterology, i.e., the issues confronting the gastrointestinal specialist in treating patients. The primary activities of the College have been and continue to be educational.

A significant number of physicians practicing gastroenterology perform most of their GI procedures, including life-saving colorectal cancer screenings, in GI ambulatory surgery centers (ASCs). In some cases, the physicians have an ownership interest in those ASCs. In other cases, the physicians may not have an ownership interest, but the centers provide the most accessible, convenient, reliable, and cost-effective location in which to perform their endoscopies.

It is exceedingly important for CMS to recognize that the vast majority of the ASCs where GI procedures are performed are single specialty ASCs, dedicated solely to GI. GI ASCs are not profoundly a corporate environment or multi-specialty in nature. CMS's proposal to change the ASC payment system would visit tremendous damage upon GI ASCs and this damage will not be spread across a diversified

corporate portfolio, or among winners and losers in a multi-specialty ASC format. If CMS reduces the margin in GI ASCs by roughly negative -22% for Medicare patients, as the proposed rule stipulates, the losses will stay right in the GI ASC. Those ASCs will be forced to lay off support staff, go out of business, and profoundly limit access to Medicare beneficiaries solely because of the draconian, survival-threatening, economic imperatives CMS plans to impose on them.

Overview

ACG wishes to express our grave concerns with CMS's recent proposal to change the way the agency pays ambulatory surgery centers for their services, via facility fee payments.

Physicians in the clinical practice of gastroenterology see a large number of Medicare patients. Treatment for a substantial percentage of these patients includes performing screening colonoscopies for those who are at average risk or high risk for colorectal cancer, as well as surveillance colonoscopies for those who already have been identified as having either polyps, or who have had cancerous lesions excised previously. Additionally, we see a very significant number of patients with other conditions: GI bleeding, inflammatory bowel disease, gastroesophageal reflux disease (GERD), and/or Barrett's esophagus. Patients with these diseases require ready access to an appropriate, safe, and cost-efficient site for GI endoscopy if we are to maximize our ability to treat them.

On August 23, 2006, the CMS issued a proposed rule setting forth a draft policy scheduled for implementation on January 1, 2008, for a new prospective payment system for ASCs, required by the Medicare Modernization Act (MMA) of 2003. Major features of the proposed rule include but are not limited to: the addition of 14 surgical procedures in 2007; a new payment system that pegs procedure payments to approximately 62% of the hospital outpatient department amount to be fully phased in by 2009; and a larger expansion of procedures approved to be performed in an ASC. This proposed rule would reduce the ASC payment for GI services by a remarkable 25-30%. The effect of cutting ASC payment rates by 25-30% will prove completely draconian, especially since they would be on top of the existing cuts of nearly -40% to Medicare physician fees for colorectal cancer screening colonoscopies since 1998.

There are ten major aspects of the CMS proposal the effects of which need to be better understood by CMS, as well as by Members of Congress:

I. CMS's definition of budget neutrality fundamentally undercuts the fairness of the rule and diminishes the prospect for survival of many ASCs if the CMS proposal is implemented.

CMS's proposal has interpreted the MMA 2003 provision to mean that it must take the single pot of funds that were expended on ASC services in 2003 to pay for all costs associated with reform of the ASC payment system, which would also include the total

costs of expanding the ASC list of approved services. That is not the construction required by the MMA, as we will demonstrate below. CMS has presented an "alternative" which does contemplate the possible role for migration, and this can certainly be interpreted to indicate that the agency recognizes that there is a solid legal argument that a broader view of budget neutrality is justified.

We believe that the broader view of budget neutrality which allows a full incorporation of potential savings from case migration is the correct approach. We will endeavor in this section to explain both the legal arguments as to why CMS has the authority already to adopt a broader view of budget neutrality (and we do this at the risk, perhaps, of being a bit redundant if in fact the "alternative" approach demonstrates that CMS already recognizes that there is a sound legal basis for this broader approach), and then through our discussion of migration, underscore why we believe it is essential for CMS to adopt that broader approach.

The unfairness of this CMS approach is demonstrated by two factors. First, there is no explicit evidence Congress intended for CMS to add a significant number of additional services to the ASC list and still pay for all of those additional services out of a single pot of funds which had originally excluded all of those new services. Second, CMS has not recognized that migration of cases from one site to another, a shift that is already ongoing to a limited degree, from the more expensive HOPD to the less expensive ASC, saves Medicare a great deal of money. Savings or expenditures from resulting changes in patterns due to the proposed rule should be included in the budget neutrality definition. Current migration patterns, from the HOPD to the ASC, result in more expenditures each year from the ASC pot, and correspondingly fewer expenditures from the HOPD pot.

Congress not only would want to encourage this tendency, but would want it counted. CMS cannot fairly and legitimately put on its blinders to exclude from the budget neutrality equation all the savings in terms of relatively fewer services being done at the HOPD level. Those savings belong in the same budget neutrality calculation. CMS should be looking at budget neutrality, not just in the ASC pot of funds, but across the entire outpatient system, so that savings from the ASC pot are computed into the overall savings and budget neutrality picture.

We developed the attached projected "fact sheet" which demonstrates the sizeable savings which are excluded, based on just a few procedures, by CMS' refusal to count savings from the relative reduced number of services in the HOPD which occur as a result of the ongoing migration for cases from the HOPD to the ASC (Attachment 1).

The agency's concept of budget neutrality in this proposal is incorrect and unfair for multiple reasons. First and foremost, the agency proposes to increase markedly the number of procedures, from a variety of different specialties, that are performed in the ambulatory surgery center. By markedly raising reimbursement for vascular, orthopedic and urologic services, much larger numbers of these services will be performed in ASCs. But in computing budget neutrality, CMS appears to believe that exactly the same pool of dollars should fully cover the new payments. When the ASC list is expanded, millions of

procedures that once were performed in other settings (HOPD, physician office) will be reimbursed under the ASC payment policy. Congress could never have intended that CMS would secure twice as many services for the same number of dollars. Under this interpretation, every new service that is added to the ASC list will force the facility fee payment for a GI endoscopy performed in an ASC that much lower, as will each procedure that migrates from the HOPD to the ASC. This approach is unfair, unsubstantiated, and bad health policy.

For every single case that moves from the HOPD to the ASC under this expansion of the ASC approved list, the Medicare program will save money because at the current rates, ASC payments are always lower than, or at least never greater than, the facility fee that CMS pays to HOPDs. If the pool of dollars for ASC payments remains fixed despite a large increase in the number of cases done in the ASC (because of expansions to the ASC list), then the pool of dollars paid out to HOPDs will decline, because fewer cases are likely to be performed there. So, the only rational accurate approach to budget neutrality is to consider the impact on the total pool of both ASC facility fee payments and HOPD facility fee payments. In summary, the agency needs to expand its definition of what payment "pots" comprise budget neutrality for ASCs: (1) you cannot expect the same pool of funds to cover all costs when the expansion of the ASC approved list will likely result in millions of additional cases moving to the ASC; and (2) CMS must take into account, and not ignore, the savings that are generated in HOPD payments because of the cases that will move from the HOPD to the ASC.

Legal Issues Relating to the CMS Interpretation of Budget Neutrality

CMS has already received an extensive and well-documented legal opinion which demonstrates that the agency has the legislative authority and precedent to adhere to the clear intent of MMA 2003, and take a broad and aggregate view of budget neutrality across the outpatient payment system. We have attached a copy of that document to these comments, and we have extracted below some of the key findings of that opinion, which concludes that the CMS' current view of budget neutrality is neither what the law requires, nor what Congress intended when it passed MMA in 2003 (Attachment 2).

"To achieve the policy goals set forth above, however, it is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from the inevitable shift of services currently performed in HOPDs to lower cost ASCs following implementation of the new payment system. (Legal Opinion, Attachment #2, , final para, on p. 1)

"As technology and practice protocols have advanced, ASCs can now safely perform many procedures that are currently not covered by the Medicare program when performed in an ASC. Therefore, these procedures continue to be provided in HOPDs, in most cases at greater cost to the Medicare program, as well as to beneficiaries. Under the statute, Medicare beneficiaries pay a 20% copayment for all services received in ASCs. However, under the statute, beneficiary copayments for HOPD services can be as high as

40%, and, according to the Medicare Payment Advisory Commission (MedPAC), in 2004 were as high as 34%.. (Legal Opinion, Attachment #2, , second para, on p. 2)

"If HHS develops an ASC payment system that substantially underpays ASCs relative to HOPDs, market forces will work to keep procedures in the hospital setting. The end result will be continued barriers to effective competition and reduced access for Medicare beneficiaries. . (Legal Opinion, Attachment #2, , final para, on p. 2)

"Section 626 of MMA directs the Secretary to consider the budgetary baseline impacts of the revised ASC payment system. Specifically, that section provides that:

"(ii) In the year the system described in clause (i) is implemented [i.e., the revised ASC payment system], *such system shall be designed to result in the same **aggregate** amount of expenditures for **such services** as would be made if this subparagraph did not apply, as estimated by the Secretary."* (Emphasis added.). . (Legal Opinion, Attachment #2, , second para, on p. 3)

"The key to interpreting this budget neutrality provision is the underlined phrase. Looking only at the statutory text, the most logical reading of the term "such services" is that it relates to "such system" referenced in parallel form earlier in the same sentence, thus meaning the services covered by the new ASC payment system. With that established, "aggregate" expenditures then refers, by its plain meaning, to "total" or "overall" Medicare expenditures for the services covered by the new system. In other words, under this provision, budget neutrality is to be measured by reference to the impact the new ASC payment system will have on overall Medicare expenditures for the total package of services covered by the system. Thus, if, as we anticipate, the new payment system will expand coverage to include additional procedures not currently on the Medicare ASC list, the budget impact is to be evaluated to include any savings that will be achieved through the performance of those procedures in ASCs, rather than in HOPDs. . (Legal Opinion, Attachment #2, , third para, on p. 3)

"Unfortunately, CMS has at least initially selected the alternative way to measure budget neutrality by referencing ASC payments only – that is, the new payment system could not result in overall ASC expenditures being greater than they would be without the new system. The problem with such an approach is that if CMS significantly broadens the list of covered ASC procedures, as Secretary Leavitt indicated is the plan (in a December 2005 letter to Senator Mike Crapo), ASCs will be able to perform hundreds of additional procedures for Medicare beneficiaries that currently are performed only in HOPDs. Thus, budget-neutrality, if applied to avoid any aggregate increase in ASC payments, would necessitate drastic, across-the-board reductions in payments for all ASC services to a level that would not be sustainable for the ASC community. Many ASCs could be forced to discontinue providing Medicare services, thus reducing patient choice and

harming beneficial competition for outpatient surgery. . (Legal Opinion, Attachment #2, , final para, on p. 3)

"Fortunately, the statute does not compel this result. By its plain language, Section 626 calls for budget neutrality to be measured by reference to the new ASC payment system, and that system's impact on "aggregate" Medicare expenditures for all of the services it covers, "as estimated by the Secretary." . (Legal Opinion, Attachment #2, , first para, on p. 4)

"In short, the MMA should be read in the context of Congress' goal to modernize Medicare, improve patient choice, and lower the cost of services, including outpatient surgery, to the program and its beneficiaries. The Secretary's own Inspector General noted that the majority of procedures currently performed in ASCs and HOPDs can be performed at a lower cost in the ASC setting. A revised ASC payment system that ensures reasonable reimbursement rates will reduce the costs of those outpatient procedures to Medicare, thus fulfilling the intention of Congress when it sought to modernize payments for ASCs. Moreover, improved patient access to ASC services will result in lower out-of-pocket costs for beneficiaries. ASC copayments are 20% of the service's cost; copayments for the same service in the HOPD can be as high as 34%. . (Legal Opinion, Attachment #2, , first full para, on p. 5)

"The MMA was designed to modernize Medicare, lower cost, and improve patient choice through increased competition. Thus, the proper lens through which a revised ASC payment system should be viewed involves lowering the cost of outpatient surgery. (Legal Opinion, Attachment #2, , second full para, on p. 5)

"Congress enacted the MMA to modernize Medicare, improve patient choice, and lower costs. Outpatient surgery is recognized as a valuable, high quality service for Medicare beneficiaries. Congress acted upon the opportunity to modernize and lower the cost of outpatient surgical services by encouraging competition between sites of services for such services, namely, ASCs and HOPDs. The Secretary should adhere to Congress' intent by designing a payment system that improves patient choice and lowers program costs, by improving and enhancing access to outpatient surgical services in ASCs, and by applying the budget neutrality provision in a broad and dynamic way – consistent with these policy goals and the language of the statute – that recognizes the new payment system's effects not just on payments to ASCs, but also its overall cost savings to the Medicare program." (Legal Opinion, Attachment #2, , final para, on p.9)

The budget neutrality adjustment is too narrow. CMS interpretation of budget neutrality under the 2003 MMA provision does not yield rational results or sound outcomes for the health system. CMS would apply budget neutrality to each individual site of service such as the ASC, HOPD, or office setting. Because of the steady shift in procedural services from the HOPD to the ASC, the ASC budget must fund an increasing number of services while the HOPD budget funds fewer services.

It would be more appropriate for budget neutrality to be applied across all three sites of service because there will be savings to the Medicare system for each case that moves from the more expensive HOPD to the ASC. Currently, CMS does *not* count those savings in the CMS budget neutrality equation because these will be attributed to the excluded HOPD sector, and not within the narrowly described ASC sector. ACG believes, under a payment structure created using this broader view of budget neutrality, many cases would migrate from the HOPD to the less expensive ASC, thereby creating savings in Medicare. The correct analysis for CMS is to see budget neutrality in terms of the entire outpatient payment system, including both ASC and HOPD. Any reductions to the facility fee for GI procedures and screening colonoscopies will simply exacerbate already low payment rates for these services. Again, if these CMS proposed ASC changes are implemented, it will reduce access to GI procedures, including colon cancer screenings, in the ASC setting.

II. CMS Migration Analysis Is Understated and Far Too Limited

CMS must recognize that significant migration will occur because changing the ASC price structure will trigger major shifts in whether procedures are performed in the HOPD or the ASC.

The second flaw in the agency's analysis is its failure to seriously consider the potentially enormous impact of case migration under its proposal. There is currently approximately a 50 point spread between the biggest potential loser (GI) and the biggest potential winner (orthopedics) in light of CMS's proposed rule to bring ALL subspecialty procedures to a single percentage level, 62% of the HOPD payment. If GI is to take a cut in the range of 25-30%, it is inappropriate for CMS not to factor into its analysis the inevitable impact this will have in reducing the number of GI Medicare patients who will receive their procedures in the GI ASC. Likewise, it is equally naïve for CMS to think that, if orthopedics is going to get a payment boost in the range of 25%, it does not need to factor into its analysis the inevitable impact this will have in increasing the number of orthopedic Medicare patients who will receive their procedures in the orthopedic ASC. As is noted below, positive migration of cases from HOPD to ASC in orthopedics may be mitigated somewhat as long as CMS continues to refuse to provide for the pass-through, and Medicare reimbursement of device and similar costs that are now reimbursed in the HOPD, but not in the ASC.

CMS provides an exceedingly simplistic alternative analysis on migration which the agency purports to apply to only the 14 procedures being added to the ASC list. This is merely the tip of the iceberg—the real dollar shifts are going to occur with respect to the many more procedures that are, and have been, on the ASC-approved list--ones which have developed a natural pattern of volume in the respective ASC and HOPD settings. In its very limited alternative analysis, CMS simply plugs in its own convenient ballpark numbers and says, "oh, it works out to be a wash." That absolutely will not be the case when one looks at the shifts that will occur in the large number of procedures across all specialties that have been on the ASC list.

Orthopedics, which currently represents about 13% of the ASC payment pool, is likely to experience some positive case migration, likely some more cases being done in the ASC if the rule were adopted. But CMS has not included a critical component of parity with HOPD, the ability to receive reimbursement for pass-through costs and devices, in this proposal. As long as this situation prevails, the shift in orthopedics from HOPD to ASC will be muted and modest. Conversely, GI and ophthalmology represent over 70% of the current ASC payment pool; with major reductions in payment to both specialties, much deeper for GI than for ophthalmology, clearly there is not going to be any positive migration of cases from HOPD to ASC in these fields. Being paid less, there is no reason for these specialties not to shift more commercial cases to fill their ASCs, thereby costing Medicare very significant amounts of money.

CMS's analysis is deficient as: (1) the agency has not factored this case migration for services already n the ASC list AT ALL into the computation of budget neutrality, despite huge potential swings in total Medicare outlays; and (2) the agency has completely failed to even consider this huge economic variable which argues compellingly against the agency's proposal to bring all specialties to a single payment level, as a fixed percentage of HOPD payments.

ACG joined with a coalition of other interested parties in commissioning an in-depth study conducted by the Lewin Group into the potential impact of this critical, but heretofore ignored, case migration. We anticipate Lewin's being able to brief the agency on its findings, and you will find attached to these comments some key summaries demonstrating the potential huge impact of case migration. (Attachment 3)

a. CMS must recognize "negative migration" because deep cuts in GI and pain management facility fees will result in significant numbers of cases migrating from ASCs to HOPDs, which will increase Medicare costs.

As noted above, the alternative analysis that CMS has proferred regarding the 14 new procedures, is spectacularly deficient in giving significant credence to this compelling economic factor. The agency has completely glossed over or ignored a critical case migration component that it is the agency's duty, as the steward of the Medicare fund, to evaluate, namely, the entire topic of negative case migration.

If the proposed rule is enacted, it is inevitable that GI ASCs will react to the huge cut in Medicare payment (Attachment 4). Their reaction, according to data we have collected, will almost certainly fall into a mixture of two behaviors. We should start by clarifying that GI physicians will almost certainly continue to treat Medicare physicians in their practices. When these patients need a colonoscopy or other endoscopic procedure, the question arises whether, in the face of the very strong economic imperatives this proposed rule would generate, GI physicians will be able to perform these procedures themselves in their ASCs, or refer them for a procedure by another physician (within the

original gastroenterologist's practice, or beyond) who would provide that service in the hospital outpatient department.

Expressing the alternative response to this question in broad general terms, on the one hand, GI physicians could shift their Medicare patients from the ASC back to the HOPD, with each and every case where this happens resulting in higher cost to the Medicare program. Alternately, some GI physicians find doing procedures in the hospital outpatient department so inefficient, in terms of travel time, uncontrolled waits in the HOPD and other factors that those physicians may simply decide that they cannot themselves perform the procedures on Medicare patients, and refer them to another physician who does perform procedures in the hospital outpatient department (HOPD).

The extent of this latter reaction will probably depend on the commercial volume. If every Medicare procedure under this proposed rule loses substantial amounts of money for the ASC because the actual costs exceed the Medicare payment, GI ASCs (and other losing specialties like pain management and ophthalmology) can be expected to populate their ASC scheduling first and foremost with as many commercial pay patients as possible. If there are gaps, weeks when commercial demand falls short of capacity in the ASC, these centers ***may*** proceed to schedule a modest number of Medicare patients. So, negative migration, ignored entirely by the agency, leaves two unhappy outcomes in GI and elsewhere: (1) CMS will expend significantly more money on each and every case where doctors choose to transfer procedures for their Medicare patients back to the HOPD; and (2) with respect to a potentially large number of doctors who simply will not do GI procedures in the HOPD, CMS's policy of huge payment cuts per case in GI (and potentially other losing specialties), ASCs will reduce access and increase waiting time for Medicare patients.

b. 62% is probably not the accurate Budget Neutrality number

The entire ASC community was shocked when CMS, using a narrow definition of budget neutrality, arrived at a budget neutrality number of 62%. As mentioned above, ACG and others have commissioned the Lewin Group to look at the overall case migration situation. Part of the Lewin analysis resulted in their conclusion that there were flaws in CMS' computation of budget neutrality. Even when they accepted all of CMS' assumptions regarding case migration, limitations to the ASC pot only, etc., Lewin still arrived at a budget neutrality figure of approximately 65%. We commend this analysis to the agency in the anticipated briefing by Lewin, and for consideration as part of the rulemaking.

Some interesting factors came to light in September when CMS officials (Ms, Sanow, Dr. Simon, and Ms. Burney) provided a briefing on the ASC rule at the AMA headquarters in Washington. Ms. Sanow revealed that in addition to the "wash" analysis on case migration for the 14 new codes which CMS had provided as an alternative in its rulemaking announcement, the agency had also looked at what the budget neutrality number would be if they did NOT factor in any migration of cases from the physician office to the ASC on the 14 new codes. The result announced by CMS at the AMA

meeting of that analysis was that it would have increased the budget neutrality number but it would still be below 70%. CMS has drawn a very tight net around those fourteen new codes, by providing that the total payment in the ASC cannot exceed what the payment had been in the physician office. So, it is reasonable to believe that given the prohibition on any financial payment difference between physician office and ASC, there is strong basis for excluding any physician office to ASC migration costs. As noted above, CMS has missed the bigger picture, as well as the huge significance of case migration, but it would make sense for the agency to correct its alternative analysis to reflect this "no cost for physician office to ASC migration" conclusion, and raise the budget neutrality number accordingly.

Another issue was raised at that same AMA meeting. Namely, the question was asked, "What would budget neutrality be if the 14 new codes had not been added to the ASC list?" This may seem like the above question stated in a different way, but it brings to bear another major problem with the CMS exceedingly narrow view of budget neutrality. It is inconceivable to us that Congress could have intended in MMA 2003 that CMS should, through additions to the ASC list, load into the ASC pot a sizeable number of additional codes, ***but*** pay for all of those new codes out of the same pool of funds, essentially mandating that every new code added would serve to dictate a corresponding reduction in the payment level for every other procedure already on the ASC list. Even in the CMS' narrow reading, and its unfortunate exclusion of case migration, it needs to separate in concept (and budget neutrality): (a) the reform of the payment system; and (b) the additions to the ASC list. The additions to the list, as constructed by CMS do not really cost Medicare any new money. Those funds are already being expended under the physician fee schedule for these services in the physician office. But CMS insists on driving down budget neutrality by counting these as new expenditures, not for the Medicare program, but simply because of the administrative decision by CMS to shift these payments from the physician fee schedule to the ASC pot. Fairness demands that CMS, at least, interpret the budget neutrality provisions of MMA 2003 as applying only to the payment reform component. No costs for payments on the fourteen (14) new codes should be included in the budget neutrality computation, as these exact dollars have already been counted elsewhere.

III. CMS's fundamental assumption that the HOPD payment system is reasonably aligned to ASC actual costs is incorrect for many GI procedures.

The CMS proposal for a single HOPD to ASC payment conversion factor assumes that the costs of most procedures bear a comparable relationship to the relative payment structure in the HOPD payment system. This is not true for many GI procedures.

a. HOPD cost data, as reported by hospitals do not bear out CMS' implicit assumption that costs for GI ASCs bear a comparative relationship with payments in HOPD

However, there are some contrary indications. In fact, a study of hospital costs, derived form HOPD costs and payment data [Attachment 5], shows that among eighteen 40000 series GI CPT codes, four codes [45378 (diagnostic colonoscopy), 43239 (EGD with

biopsy), 43247 and 43450 (two much lower volume codes)] had HOPD payments in excess of the hospital's reported costs, while for the remaining fourteen GI procedures Medicare payments were less than the hospital's reported costs. Based on this-- 77% of GI cases have a negative margin when paid at 100% of the HOPD facility fee payment rate. This disparity will be exacerbated if the proposal to reduce payment for all GI procedures performed in ASCs to 62% of the HOPD payment is implemented as is..

b. Lewin Data on ASC Costs

Lewin has reached a similar conclusion based on an independent analysis of costs for GI procedures performed in ASCs. The purpose was to see how the actual costs would match up with the proposed CMS ASC payments at full implementation of the proposal in 2009. According to this Lewin data, in 2007, Medicare ASC payments will be about 11% higher than actual costs for GI procedures, but in 2008 under the proposed rule, GI payments would drop to around 7% below costs. In 2009, with full CMS ASC payment reform implementation, GI ASC payments would drop dramatically to 22% below actual costs. (Attachment 6)

Further validation of the Lewin cost analysis is the 2003 American Society for Gastrointestinal Endoscopy (ASGE) cost study which determined that costs for GI procedures in an ASC were in the range of $320, With inflation increases, as well as the higher costs of sedation medications, a current day projected cost is in the range of $390 per case. The Lewin information shows costs at $400.50 for 2007, increasing to $416.52 for 2008, and again to $433.18 in 2009. Compare these costs to the dismal projected payment of $349.62 per GI case upon full implementation of the CMS proposal in 2009, for a loss on each case of $83.56.

More broadly, Lewin's data indicating the **negative –22%** in GI, such losses do not reflect any arguable fairness in the envisioned new system. Some have suggested that CMS use cost data, and instead of finding a single percentage of HOPD, focus on a single target profit margin by adjusting the payment structure to reflect the necessary spread between actual payments and actual costs to attain that net profit margin percentage parity. CMS may be reluctant to venture into the arena of profit, but the disconnect between the agency's proposed new payment system and actual costs in GI is so broad and distorted that the agency clearly MUST evolve to a modified or alternate approach for GI ASCs. Fairness demands it.

c. GAO data should NOT be considered in this rulemaking unless it is released to the public, and public comment on it permitted before the end of the comment period. CMS should not utilize information that was in its possession but not shared with the public for comment.

We are compelled to comment on the legal status of the long-overdue GAO report. The GAO report, which Congress directed be published by January 1, 2005, was not published in a timely manner that would have allowed it to be considered by all stakeholders in this rule-making. CMS issued its proposed rule without the benefit of the

GAO report, and welcomed comments on that proposal without anyone having the benefit of seeing any GAO cost analysis. If the agency wanted to factor the GAO report into its analysis of these questions, and into this ASC rulemaking, CMS could have deferred publishing this proposal until after a final GAO report was released to the public. CMS chose to proceed without the GAO report and we believe is now bound to exclude that report completely from all consideration in this rulemaking.

We have been informed that within the final three weeks of the comment period, GAO shared with CMS a "draft"of its report for agency review and input. While GAO made provision for a very small number of people outside CMS to see this draft proposal, we have not seen it (in fact, despite our request to GAO, we have affirmatively been denied access to review it), do not know its contents, and so cannot factor it into our response to the CMS proposal. We believe at this juncture, CMS should be constrained from considering the GAO report in any way in this proposed rulemaking. CMS cannot have the benefit of information in an NPRM, under the Administrative Procedure Act, that is not made available to all stakeholders and interested parties. Legally, the agency has only two choices: (1) eliminate the GAO report entirely from all consideration in this ASC payment reform rulemaking, since this information is not available to the public now, or at any time during the comment period; OR (2) withdraw the current proposed rule, await the dissemination of the GAO report for public availability, and then publish an entirely new rulemaking proposal so that right of public comment is not compromised by the lack of availability of the final GAO report.

The cost data, referenced under item (b) above, argues quite compellingly in favor of some specific intervention to address the GI disparity. In the face of this cost data, and with CMS's unsubstantiated presumption that the costs of GI ASCs bears a comparable relationship to the GI HOPD payment system having been soundly disproven with actual data, we think the agency must invoke a higher percentage payment for GI. Essentially, we are advocating a bi-level approach. Time is short, and we have pressed our efforts with Lewin to identify a bi-level structure that would make for either no loss, or the smallest possible loss to GI, while still maintaining all other specialties at roughly the budget neutral level. While this work is still ongoing, we believe a bi-level approach will fall somewhere in the range of 81% for GI and 65% for all other specialties. **This would still mean a reduction for GI, while avoiding the precipitous decline that the data demonstrates would uniquely drive GI *only* into *huge* negative margins of negative – 22% or more. Such a plan could be budget neutral if CMS adopts the broader view of budget neutrality across the entire Medicare outpatient system as envisioned and authorized by Congress in MMA 2003, and outlined in #I above.**

IV. The proposal to bring all ASCs to a single percentage of HOPD generates too many big winners and losers. A bi-level approach will better reflect actual costs AND can assure the best outcome in Medicare savings by reducing potential profound negative migration among the big losers

Initially, virtually the entire ASC community (except GI and perhaps pain management) thought that moving all specialties to a single percentage of HOPD was the fair and

correct approach. Many had also hoped that a combination of a stop loss provision and long phase-in could save GI from huge immediate losses. But over time, the CBO estimate on the Herger-Crapo bill showed that the cost of this was fairly high. Therefore, the legislative approach to ASC reform stalled. In our discussions with Lewin, we have asked them to evaluate the merit of a bi-level payment structure, that would avoid the huge "winners and losers" implicit in moving across what was a 48 point spread between GI (where estimates of current payment as percentage of HOPD range from 89% to 83.4%) and orthopedics currently at 36% of the HOPD payment.

CMS indeed had a suitable model to examine for at least some of the issues it faces related to ASC payment reform. The **Herger-Crapo bill (H.R. 4042/S. 1884)** misses the mark although it targets a more reasonable ASC payment structure, and is certainly preferable and more realistic than the current CMS proposal. **It too insists on moving all medical services, those currently reimbursed at 34% of HOPD to those currently reimbursed at 89% of HOPD, a spread of 55%, to a single level as a percentage of HOPD payments, creating profound winners and losers, instead of moving to at least two different levels to help narrow both the losers and the winners.**

If CMS is bound to peg ASC payments at a percentage of HOPD, it must adopt a bi-level approach. The first level would consist of GI ASCs, both because of the huge negative margins (estimated at **negative –22%**), and because of the delicate impact on an already underutilized Medicare colorectal cancer screening benefit. The first level should be at a higher tier of payment, close to the current 89% GI now receives but at least no lower than 81%. If not, data show GI procedures moving into a huge negative margin that would limit Medicare access in multiple ways, including, as noted below, pushing perhaps 20% of GI ASCs out of business. A second, lower tier as the facility fee percentage should be established for ASCs in other specialties which are not involved in life-saving preventive services like colorectal cancer screening tests (Attachment 7).

V. Specific deficiencies with percentages and proposals

The uniform discount rate of 62% is too low. The payment threshold proposed by CMS is an unusually low number, both compared to the 89% currently paid by CMS for GI services, and in light of the fact that ASCs are smaller, have less purchasing power and therefore are at a cost disadvantage vis-a-vis hospitals. **This is too drastic a drop for any small business to absorb, and will likely result in reduced access by Medicare beneficiaries to life-saving colorectal cancer screening tests commonly performed in ASCs.** The Crapo-Herger legislation acknowledged these concerns, and provided a combination of hold harmless/stop loss provisions along with a longer phase-in period to prevent sharp reductions in payment, severe disruption of these small businesses and their employees, and resulting declines in access. For these reasons, we urge CMS to modify the rule to adopt a two-tiered structure. **One level would apply for GI services, projected at somewhere around 81% or modestly higher, and a second level, projected at 65% of the hospital outpatient rate, would apply to all other services provided in the ASC setting.**

The list expansion needs refinement. The expansion of procedures eligible for Medicare payment in ASCs in 2008, while an improvement over current law, does not go far enough. The proposed list expansion remains restrictive, does not provide true site neutrality with the hospital setting and thus does not offer beneficiaries and their physicians a true choice with respect to accessing outpatient surgical care.

If ASC payment is to be linked to HOPD payment there needs to be comparability. Clearly, an essential reform that is not addressed in the CMS rule is that the cost for devices used during procedures performed in the ASC must be reimbursed (they are currently reimbursed in the hospital, but not in the ASC). **This change would generate savings by opening ASCs to many services currently performed only in the more expensive HOPD setting solely because device costs cannot be fully absorbed by the ASC.** CMS needs to create some greater measure of parity between the HOPD and ASC setting. Specifically, CMS must revise this rule to permit the payment in the ASC to include, in additional to the facility fee itself, the cost of devices and other pass-through items. The current discrepancy, where these devices and pass-through items are paid in addition to the facility fee in the HOPD but not the ASC, is unfair, and is a major reason why many cases that could be cost-effectively and safely done in the ASC are not done there.

Finally, while we do not think that the current proposal by CMS linking ASC payments to a percentage of HOPD payments is a sound one, we do believe that it is essential that facility fee payments in both the ASC and HOPD settings be updated, using the same factors and formula. ASCs, like hospitals, should be updated based on the hospital market basket rather than the urban Consumer Price Index. Using the hospital market basket for annual updates as to both ASC and HOPD facility fees would achieve parity and transparency in the market. The hospital market basket is almost certainly a better indicator than CPI of inflation costs in providing medical and surgical services. Unifying the criteria for inflation updates around the hospital market basket approach would help assure that decisions regarding where services are to be provided continue to be made on the basis of what is best for the patient, and not be skewed by economic considerations.

VI. ACG survey of ASCs

We have commented above on key factors relating to GI ASCs. Among these are the expectation of a strong negative case migration from GI ASCs to HOPDs if this proposed rule were adopted, the prospect for longer waiting times and increased pressures on GI ASC access for Medicare patients, and difficulty in maintaining ASC operations will result. In addition, one very likely negative public health ramification of the adoption of this proposal is reduced utilization of the Medicare colorectal cancer screening benefit, with likely reduction in early detection, and higher total costs, both financially and in lost lives, for cancers diagnosed at more advanced stages. ACG is not making these conclusions ab initio (as CMS seems to do with its conclusion that the HOPD payment system somehow accurately reflected relative costs by specialty). Rather, ACG compiled data from GI ASCs on the likely effects adoption of this proposed rule would have. ACG initiated a survey of 105 randomly-selected GI ASCs to try to gauge anticipated actions

and expected responses by these stakeholders in the event that the CMS proposed rule is enacted with the resulting reduction in dollars paid to GI ASCs for services provided to Medicare beneficiaries. A total of 38 responses were received to this survey. The entire survey profile is attached to these comments (Attachment 8). Some of the key findings from this survey, which are shared for illustrative purposes only, are as follows.

The phenomenon of reverse migration was confirmed, but the relationship is not a linear one. With cuts of 5%, only 3.6% of GI ASCs would start refusing to see Medicare patients. When the cuts increased to between 11-20%, a total of roughly 19% of GI physicians say when their Medicare patients require colonoscopy or other endoscopic procedure, they likely are not going to continue to perform those procedures themselves in their ASCs, at least not as consistently. When the ASC payment cuts increased above the **negative -20%** mark, a full one-third of GI physicians surveyed said they would not be able to continue to perform the procedures on their Medicare patients themselves, at least not within their ASCs.

-90% of respondents said Medicare patients definitely would always wait longer than they currently do if the CMS ASC payment reform proposal were adopted.

-93% said that enactment of this proposed rule, and the resulting payment reduction, would increase the likelihood of their recommending to Medicare patients who desire to have procedures done in the ASC that they should instead have these done in the HOPD (no reference in this question to whether GI physicians would be willing to go to the HOPD themselves to perform these procedures there).

-17.9% of GI ASCs said that they would expect their ASCs to close completely if the CMS ASC payment rule were implemented as proposed. 79.3% said they expected enactment of this rule would result in fewer employees at their ASC, and 69% said there would also be a reduction in the average compensation for ASC employees. Only 7.1% said they thought this proposed rule's enactment would result in an increase in the total number of hours per week that their ASC would see patients, discounting in strong terms any concept of a behavioral offset for the dramatically reduced per patient payment this rule would portend for GI.

VII. CMS Policy will force many ASCs out of business and others to close to Medicare patients, creating an access dilemma, and more broadly eliminating a cost-effective center for health care

CMS seems to be ignoring both the stated priorities of the current Administration as well as the lessons of cost management in the private sector. President Bush and Administration officials are on record, on multiple occasions, stating that ASCs are a more cost-effective environment than the hospital to receive key medical services. When private sector insurers have sought to reduce total health care costs, they have actively sought to encourage patients to receive their services in the ambulatory surgery center, instead of in the hospital outpatient department. One recent example is Blue Cross of California's announcement that it will pay a 5% premium to physicians for every GI

endoscopy that is performed in the ASC, rather than in the HOPD. This CMS proposal, which would always pay more to HOPDs and always pay less to ASCs, is directly antithetical to the direction adopted by the private sector insurers.

The results of CMS's proposed policies would be to drive a substantial number of ASCs out of business. 17.9% of GI ASCs said they would expect to close their doors completely and go out of business if the proposed CMS rulemaking were enacted. If CMS, contrary to both the White House and most Congressional health policymakers, thinks that fewer sources of care and fewer choices for patients represent sound health policy, the agency is certainly using its power in the health marketplace to move in that direction. If CMS wants to eliminate the lower cost centers for quality care, and force more cases into the higher cost hospital centers, it has crafted a policy to accomplish this. If CMS thinks that creating an access crisis for its beneficiaries is necessary to balance the country's health care budget, it has found a policy that will indeed reduce access to critically needed medical and preventive services for Medicare beneficiaries. At the levels of the **negative –25%** in GI, CMS can cut Medicare beneficiary access to GI services by a full one-third. But frankly, we think that these are all results that CMS should want to avoid, not embrace. If CMS thinks more competition, more centers for high quality, lower cost health care, and more choice and access for Medicare beneficiaries are components that should drive the Nation's health policy, then CMS should follow what private sector health planners and insurers are doing. CMS should scrap, or radically change this proposed rule so that Medicare begins providing dollar parity in costs between ASCs and HOPD, and encourage, not penalize those in the business of providing safe, convenient and cost-effective patient care in the ASC setting.

VIII. Volume threshold for ASC services and small business issues for potential closing of ASCs with volumes below the threshold of 3,500 annual cases

A recent Deutschebank analysis was released which provides insights into the minimum number of cases that an ASC would have to perform per year in order to survive under a payment structure such as CMS proposes. Deutschebank analysts concluded that any ASC that provides fewer that 3,500 procedures per year will be put out of business--the data from the ACG survey, while a small sample, indicates that fully 20% or one-fifth of GI ASCs will go out of business based on the volume criteria. In that same survey, 18% of GI ASCs stated that imposition of the draft CMS ASC rule would cause them to go out of business. Clearly, by either of these measures, this CMS proposal would have a profound and disproportionately negative effect on small business ASCs across the country, and may well require study by the Small Business Administration before it can be enacted.

IX. What will happen to GI under the current proposal, Harm to GI as well as the public health consequences, Including Damage to the Colorectal Cancer Screening Benefit, Resultant Loss of Lives from Failure of Early Detection and Resultant Higher Medicare Costs for Patients Whose Colorectal Cancers Are Diagnosed at More Advanced Stages

Damage to the colorectal cancer screening benefit, resultant loss of lives from failure of early detection and resultant higher Medicare costs for patients whose colorectal cancers are diagnosed at more advanced stages are the results that can be expected under this proposed rule. Both the GAO and CMS itself have stated that the Medicare colorectal cancer screening benefit is underutilized. MEDPAC repeatedly has endorsed the concept that medical procedures and services should be site neutral. On its face, a proposal such as this one seems counterproductive. It institutionalizes the concept of paying significantly more to the hospital than to the ASC, and which will likely pose distinct and difficult challenges to providing GI screening colonoscopies and other GI endoscopic procedures, because Medicare's payment level will drop so precipitously that these ASCs can no longer meet their expenses and render a reasonable return on investment, seems counterproductive.

While timely screening could reduce mortality by 90% from colorectal cancer, utilization of the benefit will continue to lag, perhaps irreversibly if these additional cuts are implemented by CMS.

In the gastroenterology area, CMS's proposed policy virtually assures results inimical to the public health. Today, when a GI procedure, such as a screening colonoscopy, is performed in an ASC, that ASC receives a facility fee which on average amounts to 89% of the facility fee CMS pays to the HOPD if that same procedure is performed there. We need to provide a bit of background relating to the effectiveness of the Medicare colorectal cancer screening benefit. Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit, and again in 2005 when it waived the deductible for this important screening service. Sadly, and whether intentionally or inadvertently, CMS has diminished utilization of that benefit. Since 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%, from a little over $300, to the current level of under $200, and trending downward. No other Medicare service has been cut this much over this period. The new ASC proposal would further diminish prospects for Medicare beneficiaries to receive a colorectal cancer screeing colonoscopy. In terms of the specialty that would be hurt the most by the current proposal, once again, CMS has placed gastroenterology and colonoscopies for colorectal cancer screening in its cross hairs, as by far the biggest potential loser, with the prospect of cuts from 89% of the HOPD payment to 62%.

It is clear and relatively easy to predict what will happen if this CMS proposal is adopted

in anything close to its current form:

For Patients:

Utilization of the Medicare colorectal cancer screening benefit, under this proposed rule will decline still further, and cancers will go undetected. In life and death terms, many Medicare beneficiaries will die unnecessarily because the access to sites where colonoscopies can be performed will be reduced as GI ASCs close. Waiting times for screening will increase, and the overall rate of CRC screening will plummet farther.

For the Medicare System:

Medicare facility fee payments for GI services will increase, rather than decrease. Having dealt a death-blow to many GI ASCs by draconian reductions in payment, the access of Medicare beneficiaries to GI ASCs will be markedly reduced. CRC screening colonoscopies will be reduced, but the volume of diagnostic colonoscopies and endoscopies will not decline.

With fewer ASCs, a larger proportion of all GI procedures will need to be performed in the HOPD, where the facility fees CMS pays will be higher.

So, the inevitable result of this proposed CMS action, if implemented, will be: (a) total Medicare costs for GI facility fees will rise (although the per unit facility fee for decreased number of these performed in the ASC may well decline); (b) available access by Medicare beneficiaries for life-saving GI screening colonoscopies, other GI diagnostic and therapeutic colonoscopies and other endoscopic procedures will decline; and (c) the number of Medicare beneficiaries who will die unnecessarily from colorectal cancer will increase as screening rates decline. These cancer patients, detected at later stages, will incur increased Medicare expenditures for colorectal cancer end-stage treatment accordingly.

CMS may face a choice between which of two ways it wishes to lose money: (1) negative migration of cases from the ASC to the HOPD if GI private practice doctors are willing to go to the hospital to do the cases; or (2) reduced access for Medicare beneficiaries, later detection of many colorectal cancers with higher downstream care costs

If CMS maintains its current posture on this rule and pursues a policy that ensures big losers, like GI and huge winners, like orthopedics, the agency will almost certainly face something of a Hobson's choice between two devastating results. The Medicare budget will sustain significant financial losses in direct proportion to the percentage of physicians, who, when faced with ASC payment cuts in the range of 25-30%, choose to refer their Medicare patients to have their GI procedures performed in the hospital outpatient department. This will trigger negative migration. E ach and every case shifted from the ASC to the HOPD will cost Medicare more money. This result is a very bad

one, but even worse outcomes will await if a substantial number of GI doctors decide, with every single Medicare ASC procedure costing the practice approximately $83,-- i.e. the amount by which 2009 costs will exceed Medicare payment for each and every case--that if they cannot afford to see Medicare patients and do their procedures in the ASC, they will not indulge the further inefficiencies of seeing those patients in the HOPD, but rather simply stop being a physician who does any, or many GI procedures on Medicare patients. This behavior, the only viable alternative to shifting Medicare cases back to the HOPD, would trigger greatly reduced access for Medicare beneficiaries, with the inevitable results of later detection of many colorectal cancers, increased colorectal cancer fatalities among Medicare beneficiaries, and higher resulting downstream costs as patients with cancers detected at later stages require more cost-intensive care.

X. Additional measures that CMS needs to undertake if this rule is going to proceed: longer phase-in, hold harmless, adoption of a bi-level approach

ACG believes that this CMS proposal for ASC payment reform is seriously ill-conceived and, if adopted, would be disastrous. The agency needs to recognize the realities of this complex field, ones that are not easily assimilated at first glance, as is so clearly evidenced by the agency's initial ASC payment reform proposal. This is not a situation which can be repaired by a few palliatives. Rather, this rulemaking requires a complete re-thinking and new approach, of necessity almost certainly a bi-level one, to help compensate for the "costs exceed payments by –22%" situation in GI, as well as an approach that will expand the definition of budget neutrality, and allow for the powerful economic factors of case migration as part of budget neutrality projection. Such a rulemaking must reflect accurate cost data, and recognize that such data debunks the agency's unsupported presumption that somehow, the costs of GI ASCs bear a comparable relationship to the relative payment structure for GI procedures in the HOPD payment system. ASCs and HOPDs are apples and oranges, not oranges and oranges.. While the agency's total re-thinking is called for, our comments would not be complete unless we mentioned briefly a few additional considerations that could and should be factored into any new agency approach to the task of ASC payment reform.

The transition period is too short. The proposed transition period , essentially a one year phase in of revised rates (the rule proposes a 50/50 rate split between current law and the new amounts in 2008), is drastic and is not sustainable for ASCs. Especially as some surgical specialties confront rate cuts of up to 30% under the proposed rule, a slower transition period, gradually applying a blend of old and new amounts over a four-year period, is necessary for ASCs to prepare for and respond smoothly to the new system.

CMS also needs to adopt a key component of the Herger-Crapo approach, namely, to provide a hold-harmless so that even if the percentage of HOPD payment declines for one or more specialties as a new ASC payment structure is implemented, the losing specialties are assured that their actual dollar payments will not decline. Rather, losers can be held harmless at current payment levels until the calculation of their applicable

percentage of the HOPD payment actually exceeds the number of dollars being paid for that service today.

But clearly, the best prospect to transform this ASC payment reform process so that it does not precipitate huge case migration swings of undetermined consequences, and an extraordinarily damaging degradation of the Medicare health care and access system, is the necessity of adopting a bi-level approach. Obviously, this is the only realistic conclusion to address what would otherwise be extremely devastating losses in GI that would severely handicap the preventive screening fight against colorectal cancer.

Adopting a bi-level approach that pegged GI at about 1.25% of the payment level for other specialty ASCs would substantially diminish GI losses, save Medicare money by minimizing the costs of negative migration of GI cases from ASC to HOPD, and avoid a public health debacle in further undercutting the already seriously underfunded struggle to reduce the lethal toll of colorectal cancer through early screening. Physicians deserve fairness, and Medicare beneficiaries deserve a system that works and saves lives, while being cost efficient. We urge CMS to adopt this bi-level course in evolving this proposal.

a. Conclusion

In conclusion, CMS's proposed changes to the ambulatory surgery center (ASC) payment proposal:

(1) adopts too narrow a view of budget neutrality and does not properly count savings that accrue when services, already approved for ASCs migrate from the HOPD to the ASC. If CMS counted those savings it would allow Medicare ASC payments to be set at a higher, more realistic level. CMS ignores also, under the heading of budget neutrality, the profound cost increases for Medicare attributable to negative migration as big losing specialties predictably shift cases to the higher cost HOPD setting; a costly result that can be avoided only if the final CMS rule is fair and gives relief, most effectively through a bi-level system, to GI and possibly other prospective big losing specialties;

(2) undercuts ASCs, and would cause many of these facilities, which offer a lower cost option, to go out of business. This will cause loss of small business jobs and revenues in most Congressional districts; other ASCs would have to limit access by Medicare beneficiaries;

(3) dramatically reduces the effectivevness of the Medicare preventive colorectal cancer screening benefit, causing unnecessary deaths from colon cancer as patient access is confined to fewer screening sites, and beneficiaries wait longer or simply decide not to be screened. CMS reductions in physician payment for colonoscopies of about

40% since 1998 already have prompted consideration of federal legislative intervention via S. 1010/H.R. 1632, to try to reverse the damage to the screening benefit. If CMS does chop off another 30% from GI ASC facility fees, the colorectal cancer preventive benefit would be damaged even more dramatically.

It is hard to believe that these are the results CMS is seeking; however, the only way to avoid this outcome is to modify the proposed rule to avoid a decrease to the facility fees to GI ASCs. This could alleviate the closure of very significant numbers of GI ASCs, and thus avoid a reduction in access and CRC screening rates. It will also prevent an increase in the number of GI procedures performed in the more costly HOPD setting.

Respectfully submitted,

David A. Johnson, M.D., FACG
President

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Chair, ACG National Affairs Committee

Attachments

Attachment 1 –Fact Sheet on Prospective Savings from Case Migration HOPD to ASC
Attachment 2 –Legal Opinion Relating to Budget Neutrality
Attachment 3 –Selected Tables Reflecting Lewin Analysis on Case Migration
Attachment 4 –Lewin Case Migration Analysis Relating to Negative Migrations and Its Costs to the Medicare Program
Attachment 5 –Costs of GI Procedures as Related to HOPD Payment Structure/Amounts
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Attachment 8 –ACG ASC Survey Results Summary

Attachment 1

Fact Sheet on Prospective Savings from Case Migration HOPD to ASC

Table 1: Payment 75% - With Hold Harmless (code specific migration)

43239	GI	$446	480.03	$446	628415	$34	4%	$855,398
62311	Pain/Neurology	$333	357.9	$333	400006	$25	4%	$398,406
45378	GI	$446	509.34	$446	578795	$53	4%	$1,486,435
52000	Urology	$333	412.53	$333	128984	$80	4%	$412,398
64622	Pain/Neurology	$973	1387.71	$1,041	27723	$347	7%	$719,722
15823	Dermatology	$717	1062.84	$812	63684	$271	11%	$1,833,272
66984	Ophthalmology	$333	600.85	$451	2027195	$150	22%	$65,966,885
26055	Orthopedics	$446	930.73	$698	40006	$233	32%	$3,002,655
29881	Orthopedics	$530	1670.39	$1,253	44370	$418	53%	$9,899,563
								$84,554,724

9/5/2006

LEGAL OPINION ON BUDGET NEUTRALITY

CONSIDERATIONS FOR HHS IN DESIGNING NEW ASC PAYMENT SYSTEM

Congress has given the Department of Health and Human Services (HHS) broad authority to develop a new Medicare payment system for ambulatory surgical centers (ASCs). HHS and the Centers for Medicare and Medicaid Services (CMS) should use this opportunity to accomplish the following policy goals:

- Achieve cost savings for the Medicare program;
- Provide savings to Medicare beneficiaries;
- More closely align payments across the different sites of service for outpatient surgery;
- Promote competition among the providers of outpatient surgical services, especially ASCs and hospital outpatient departments (HOPDs); and
- Encourage increased transparency among Medicare providers, including transparency on price and quality of care.

These goals are fully compatible with the mandate given to HHS in the Medicare Modernization Act of 2003 (MMA), which simply directed the Secretary to develop a "revised" payment system for surgical services furnished in ASCs. While the MMA is short on specifics – other than that the new system be implemented by not later than January 1, 2008 – it does include additional statutory parameters to help guide HHS's development of the revised ASC payment system:

> *First*, MMA requests a Government Accountability Office (GAO) study comparing the relative costs of procedures furnished in ASCs to the relative costs of procedures furnished in HOPDs, as well as recommendations on the appropriateness of using the hospital outpatient prospective payment system (HOPPS) as the basis for the new ASC payment system. Although the GAO report was due by January 1, 2005, the report is not yet complete. Furthermore, it is unclear whether the GAO has compared relative costs between these two settings and/or whether GAO will make recommendations.
>
> *Second*, MMA provides that the revised ASC payment system should be designed to result in the same aggregate amount of expenditures in the first year of the revised ASC payment system that would have been made if HHS had not revised the ASC payment system. In addition, the Deficit Reduction Act of 2005 (DRA) caps payments for certain procedures furnished in ASCs at the HOPD amount for those procedures, beginning January 1, 2007.

These statutory parameters provide HHS broad latitude in developing a revised ASC payment system.

To achieve the policy goals set forth above, however, it is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from the inevitable shift of services currently performed in HOPDs to lower cost ASCs following implementation of the new payment system. Otherwise, if budget neutrality is applied

only to ASC services, the result will be substantial cuts in ASC reimbursement that will significantly undermine the viability of ASCs serving as an effective competitive alternative to HOPDs.

With that in mind, the remainder of this paper sets forth the case for a broad reading of the budget neutrality requirement in MMA, consistent with (1) the statutory language, (2) the legislative history and context underlying MMA, and (3) other comparable situations, where CMS has applied its budget neutrality obligations in ways that took into account anticipated changes in behavior, like the shift of procedures from HOPDs to ASCs that is likely to occur following implementation of the new ASC payment system.

POLICY GOALS

Achieve savings to the Medicare program and Medicare beneficiaries. As surgical procedures have shifted over time from inpatient to outpatient settings, the costs to the Medicare program for these procedures (by individual procedure) have decreased. However, Part B expenditures in this area have grown. A revised ASC payment system could be used as one tool to reduce the cost of outpatient surgical procedures by allowing ASCs to compete on a more level playing field with HOPDs. When outpatient surgical services are performed in ASCs, the Medicare program and Medicare beneficiaries save money.[1] As technology and practice protocols have advanced, ASCs can now safely perform many procedures that are currently not covered by the Medicare program when performed in an ASC. Therefore, these procedures continue to be provided in HOPDs, in most cases at greater cost to the Medicare program, as well as to beneficiaries. Under the statute, Medicare beneficiaries pay a 20% copayment for all services received in ASCs. However, under the statute, beneficiary copayments for HOPD services can be as high as 40%, and, according to the Medicare Payment Advisory Commission (MedPAC), in 2004 were as high as 34%.

More closely align payments across sites of service delivery and promote competition among providers of outpatient surgical services. CMS has recently observed that many small orthopedic or surgical specialty hospitals "may describe themselves as hospitals rather than ASCs, in part to take advantage of the more favorable payment rates" that apply under HOPPS, as opposed to the current ASC payment system.[2] For the same reason, many procedures that could be performed in ASCs are instead routinely performed in HOPDs because ASC payment rates do not adequately cover facility costs. By reforming the ASC payment system to diminish payment disparities that encourage artificial incentives for the creation of small orthopedic or surgical hospitals and the provision of procedures in HOPDs, CMS will lower costs to the Medicare program while, at the same time, promote healthy competition. However, if HHS develops an ASC payment system that substantially underpays ASCs relative to HOPDs, market forces will work to keep procedures in the hospital setting. The end result will be continued barriers to effective competition and reduced access for Medicare beneficiaries. Without payment parity across sites of service, potential providers of surgical services may be

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[1] The HHS Office of Inspector General (OIG) examined the costs of 424 procedures performed in both ASCs and HOPDs and determined that 66% of these procedures were performed in ASCs at a lower reimbursement rate. *Payment Procedures in Outpatient Departments and Ambulatory Surgical Centers*, OEI-05-00-00340, Jan. 2003.

[2] Testimony of Mark B. McClellan, MD, PhD, Administrator, Centers for Medicare & Medicaid Services, Before the House Committee on Energy and Commerce Hearing on Specialty Hospitals: Assessing Their Role in the Delivery of Quality Health Care (May 12, 2005).

unintentionally encouraged by the Medicare program to invest in building and expanding hospitals, rather than ASCs.

Encourage increased transparency among Medicare providers. Equal competition among hospitals and ASCs also should include price transparency, especially with regard to beneficiary co-payment obligations. This would empower beneficiaries to make more informed choices about the cost of the services they receive. CMS also should consider other opportunities to promote transparency in its development of the revised ASC payment system.

THE BUDGET NEUTRALITY PROVISION

Section 626 of MMA directs the Secretary to consider the budgetary baseline impacts of the revised ASC payment system. Specifically, that section provides that:

> *"(ii) In the year the system described in clause (i) is implemented* [i.e., the revised ASC payment system], *such system shall be designed to result in the same* ***aggregate*** *amount of expenditures for* ***such services*** *as would be made if this subparagraph did not apply, as estimated by the Secretary."* (Emphasis added.)

The key to interpreting this budget neutrality provision is the underlined phrase, particularly the words in bold – that is, what "such services" are covered by this provision and how is their "aggregate" impact to be measured? Looking only at the statutory text, the most logical reading of the term "such services" is that it relates to "such system" referenced in parallel form earlier in the same sentence, thus meaning the services covered by the new ASC payment system. With that established, "aggregate" expenditures then refers, by its plain meaning, to "total" or "overall" Medicare expenditures for the services covered by the new system. In other words, under this provision, budget neutrality is to be measured by reference to the impact the new ASC payment system will have on overall Medicare expenditures for the total package of services covered by the system. Thus, if, as we anticipate, the new payment system will expand coverage to include additional procedures not currently on the Medicare ASC list, the budget impact is to be evaluated to include any savings that will be achieved through the performance of those procedures in ASCs, rather than in HOPDs. The statute recognizes that this is not capable of precise measurement; thus, it only requires that the system be "designed" to achieve this result, "as estimated by the Secretary."

The alternative way to measure budget neutrality would be by reference to ASC payments only – that is, the new payment system could not result in overall ASC expenditures being greater than they would be without the new system.[3] The problem with such an approach is that if CMS significantly broadens the list of covered ASC procedures, as Secretary Leavitt indicated is the plan (in a December 2005 letter to Senator Mike Crapo), ASCs will be able to perform hundreds of additional procedures for Medicare beneficiaries that currently are performed only in HOPDs. Thus, budget-neutrality, if applied to avoid any aggregate increase in ASC payments, would necessitate drastic, across-the-board reductions in payments for all ASC services to a level that would not be sustainable for the ASC community. Many ASCs could be

[3] We presume that even under this alternative interpretation, CMS would make the kinds of routine adjustments for changes in case mix and volume that historically have been applied in assessing budget neutrality.

forced to discontinue providing Medicare services, thus reducing patient choice and harming beneficial competition for outpatient surgery.

Fortunately, the statute does not compel this result. By its plain language, Section 626 calls for budget neutrality to be measured by reference to the new ASC payment system, and that system's impact on "aggregate" Medicare expenditures for all of the services it covers, "as estimated by the Secretary." Under traditional canons of statutory construction, that should resolve the issue and define the approach CMS should follow. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002) (if the statutory language is unambiguous, then the inquiry ceases).

If there is doubt in that regard, then the "statutory language must always be read in its proper context." *McCarthy v. Bronson*, 500 U.S. 136, 139 (1991). While statutory interpretation begins with the express language of the statute, "[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *United States Nat'l Bank of Oregon v. Indep. Ins. Agents of America, Inc.*, 508 U.S. 439, 455 (1993) (citations omitted). In this case, we believe the overall object and policy behind MMA further supports application of budget neutrality in a way that accounts for the cost savings to be achieved through the expanded provision of services under the new ASC payment system.

THE MMA SEEKS TO PROMOTE EFFECTIVE COMPETITION

Looking at the "whole law," its "object and policy" requires a broader examination of MMA. The preamble to the law states that one of its purposes is to modernize the Medicare program. "Modernizing" Medicare includes expanding the role of private market forces in the program. Indeed, in MMA, Congress explicitly created an enhanced role for private health plans, disease management companies and private pharmacy benefit managers to compete on a local, regional and national basis to deliver enhanced Medicare benefits, most notably including outpatient prescription drugs. These entities submit bids in open competition free from government interference; health and drug plans must meet certain baseline benefit standards, but are encouraged to compete on cost and quality. These private market forces, and the value of head-to-head, level playing field competition, have served to lower the cost of health care, while at the same time increase the quality of care received by Medicare beneficiaries. Fostering competition is one of the primary tools utilized by Congress in the MMA to achieve cost savings for the Medicare program. In other aspects of the program, Congress has developed competitive bidding programs to produce savings in the areas of durable medical equipment, clinical diagnostic laboratory services, and certain physician-administered outpatient drugs.

The same approach to promoting market competition can be seen in the ASC provisions of MMA. Congress clearly recognized that many surgical procedures that are performed in HOPDs can also be performed in ASCs. Thus, Congress mandated the creation of a new payment system for ASCs and directed GAO to consider the appropriateness of basing that system on HOPPS. Congress's clear intention was to consider an ASC payment system that was similar to the HOPPS, thus providing a more level playing field between similar settings. Congress no doubt hoped this would lead to the migration of procedures from the more-costly HOPD setting to the ASC setting. The collective group of "such services" would include those procedures currently performed only in HOPDs, but that may be performed in ASCs upon implementation of the revised ASC payment system. In other words, the dynamic nature of the

HOPD/ASC marketplace should be considered, and we believe the Secretary should approach the budget neutrality provision with the same breadth Congress did when it enacted Section 626, which is to say with a depth that includes the cost impact of all outpatient surgical services performed across all service lines, not just ASCs.

In short, the MMA should be read in the context of Congress' goal to modernize Medicare, improve patient choice, and lower the cost of services, including outpatient surgery, to the program and its beneficiaries. The Secretary's own Inspector General noted that the majority of procedures currently performed in ASCs and HOPDs can be performed at a lower cost in the ASC setting. A revised ASC payment system that ensures reasonable reimbursement rates will reduce the costs of those outpatient procedures to Medicare, thus fulfilling the intention of Congress when it sought to modernize payments for ASCs. Moreover, improved patient access to ASC services will result in lower out-of-pocket costs for beneficiaries. ASC copayments are 20% of the service's cost; copayments for the same service in the HOPD can be as high as 34%.

The MMA was designed to modernize Medicare, lower cost, and improve patient choice through increased competition. Thus, the proper lens through which a revised ASC payment system should be viewed involves lowering the cost of outpatient surgery. For the majority of surgical procedures, where such services are performed in an ASC setting instead of an HOPD setting, we believe Medicare's costs will be lower; that ASCs can and will provide such services in a safe and more efficient way than other providers.

OTHER APPROACHES INVOLVING BUDGET NEUTRALITY

Numerous statutory and regulatory references to budget neutrality exist in changes to various payment systems instituted by Congress and implemented by HHS over the years. Generally, when CMS prepares to implement payment system reform through the rulemaking process, interpretations tend to lean toward a measure of the same total payment for the same class of providers. Crafting a budget neutral payment system in the instance of ASC payment reform is challenging as this payment system could affect multiple classes of providers (i.e., HOPDs, ASCs and physicians).

In general, CMS considers total payments to providers based upon a particular class of service. For example, when moving from a cost-based system to a prospective payment system, the focus is making changes to payments within that specific system (*e.g.*, inpatient rehabilitation facilities, skilled nursing facilities). Rather than renew or remake a new payment system with new money, budget neutrality provisions tend to force CMS to reconfigure old systems to pay for new ones within the narrow context of services offered by those same providers in the previous year. CMS' conclusions can be driven, however, by how it chooses to define "services" in the context of a particular issue.

Statutory budget neutrality language often includes the narrowing phrases "under this part" or "under this title" to refer to the application of the budget neutral limitation on aggregate spending. Section 626, however, does not include this language. CMS therefore has considerable latitude to define the overall dollar pool broadly in the context of a revised ASC payment system.

What follows is a selected summary of statutory and regulatory approaches to the budget neutrality concept used by CMS in implementing payment system reform. These approaches

provide further historical justification for a broad application of budget neutrality with respect to ASC payment reform.

INPATIENT REHABILITATION FACILITY (IRF) PROSPECTIVE PAYMENT SYSTEM

In the IRF PPS final rule, CMS discussed how it would adjust payments in future years in order to facilitate budget neutrality, in part by making changes to the conversion factor, wage adjustments, outlier payments, and relative weights during the transition to the new payment system.[4] CMS discussed the application of budget neutrality in broad terms, recognizing that the new IRF PPS could lead to new practice patterns – an outcome likely under Section 626 as well. Specifically, CMS recognized and discussed the implications of changes in efficiency, site utilization, and behavioral modifications providers would make in adapting to the new payment system. The behavioral offsets of physicians played an important role in this discussion of budget neutrality:

> *"This provision requires the Secretary, in establishing budget neutral rates, to consider the effects of the new payment system on utilization and other factors reflected in the composition of Medicare payments...The purpose of the budget neutrality provision is to pay the same amount under the prospective payment system as would have been paid under the excluded hospital cost-based payment system for a given set of services, but not to pay that same amount for fewer services furnished as a result of the inherent incentives of the new prospective payment system. Thus, our methodology must account for the change in practice patterns due to new incentives in order to maintain a budget neutral payment system. Efficient providers are adept at modifying and adjusting practice patterns to maximize revenues while still maintaining optimum quality of care for the patient. We take this behavior into account in the behavioral offset."* [5] (Emphasis added.)

We believe that similar behavioral offsets will occur in the presence of a revised ASC payment system. Such behavioral "offsets" will occur as the result of service migration from higher-cost HOPD settings to lower-cost ASCs. If efficient providers determine that higher quality outpatient surgical services can be delivered in ASCs at lower costs to the Medicare program and its beneficiaries, lower aggregate spending for outpatient surgical services may result – an outcome made less likely by a narrow application of budget neutrality that unduly constrains ASC payments. The IRF PPS transition accounted for behavioral changes among efficient providers. As it develops the revised ASC payment system, CMS should similarly take into account the likely migration of services from HOPDs to ASCs, which has the potential to lower "aggregate" Medicare costs.

HOME HEALTH PROSPECTIVE PAYMENT SYSTEM

[4] 70 *Fed. Reg.* 41,316 (August 7, 2001).
[5] 66 *Fed. Reg.* 41,366 (August 7, 2001).

The creation of the home health prospective payment system also offers an instructive precedent for a broad interpretation of Section 626. The Balanced Budget Act of 1997 mandated the implementation of a prospective payment system for Medicare home health services which would bundle a number of previously separately billed services into a single payment amount. Congress directed that this new system be budget neutral. This required the Secretary to develop a means of incorporating the cost of what previously were separately billed services into a single budget neutrality equation.

> *To determine the budget neutrality adjustment, we use our most current estimate of incurred costs for home health expenditures in FY 2001 under the interim payment system (IPS). Under the President's FY 2001 Budget assumptions, we are projecting this amount to be $11,273 million. This amount includes the medical supplies which were billed separately under IPS but will be bundled under PPS. Our best estimate of what would be spent in FY 2001 on Part B therapies not currently included in the home health benefit but which will be covered by the benefit under the PPS is $109 million. We did not include this in the home health spending for the FY 2001 budget because we had not yet determined it needed to be added to the spending target. We are adding $109 million to the $11,273 million to determine the total spending target for home health PPS spending, $11,382 million.*[6]

This approach allowed the Secretary to take into account the budget effects of services migrating from one payment system to another in order to achieve the congressional objective of budget neutrality without setting payment levels artificially low for home health providers. The Secretary should adopt a similar approach in assessing the budget effects of proposed changes in the ASC payment system that are likely to encourage even greater migration of services across payment settings.

DEMONSTRATION PROJECTS

When it comes to congressionally-mandated or administratively-selected demonstration projects, CMS often makes greater conceptual leaps in applying budget neutrality than it does under statutory mandates for reforming specific payment systems. As an example, when considering the implementation of a congressionally-mandated demonstration program for rural community hospitals to "test the feasibility and advisability of establishing 'rural community hospitals' for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries," the statute mandated that such a program be budget neutral.

But in discussion of the issue in the context of the Final Rule, CMS noted that Section 410A of Public Law 108–173 requires that:

> *"In conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would*

[6] 65 *Fed. Reg.* 41,186 (July 3, 2000).

have paid if the demonstration program under this section was not implemented. Generally, when CMS implements a demonstration on a budget neutral basis, the demonstration is budget neutral in its own terms; in other words, aggregate payments to the participating providers do not exceed the amount that would be paid to those same providers in the absence of the demonstration. This form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration participants. These reduced expenditures offset increased payments elsewhere under the demonstration, thus ensuring that the demonstration as a whole is budget neutral or yields savings."[7] (Emphasis added.)

CMS goes on to state that it is well aware of the limitations inherent in such an approach.

"However, the small scale of this demonstration, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration could be viable under the usual form of budget neutrality. Specifically, cost-based payments to 15 small rural hospitals is likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these providers. In order to achieve budget neutrality, as we proposed, we are adjusting national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are applying budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. (Emphasis added). *We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. This is because the statutory language refers merely to ensuring that ''aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented,'' and does not identify the range across which aggregate payments must be held equal."*[8] (Emphasis added.)

Likewise, in reviewing the requirements for budget neutrality in the context of a Chiropractic Demonstration Project, CMS stated that:

"The statute requires the Secretary to ensure that the aggregate payments made under the Medicare program do not exceed the

[7] 69 *Fed. Reg.* 49,183 (August 11, 2004).
[8] *Id.*

> *amount that would have been paid under the Medicare program in the absence of this demonstration. Ensuring budget neutrality requires that the Secretary develop a strategy for recouping funds should the demonstration result in costs higher than would occur in the absence of the demonstration. We will first determine over the two-year demonstration whether the demonstration was budget neutral. If the demonstration is not budget neutral, we plan to meet the legislative requirements by making adjustments in the national chiropractor fee schedule to recover the costs of the demonstration in excess of the amount estimated to yield budget neutrality. We will assess budget neutrality by determining the change in costs based on a pre-post comparison of costs and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We will not limit our analysis to reviewing only chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs.*"[9] (Emphasis added.)

In this context, CMS appeared to recognize the effect of the demonstration on other Medicare costs and how those costs related specifically to chiropractic care.

Likewise, CMS should construct a revised ASC payment system that contemplates other Medicare cost changes, especially anticipated cost reductions associated with service migration from more costly HOPD settings to less costly ASCs.

CONCLUSION

Congress enacted the MMA to modernize Medicare, improve patient choice, and lower costs. Outpatient surgery is recognized as a valuable, high quality service for Medicare beneficiaries. Congress acted upon the opportunity to modernize and lower the cost of outpatient surgical services by encouraging competition between sites of services for such services, namely, ASCs and HOPDs. The Secretary should adhere to Congress' intent by designing a payment system that improves patient choice and lowers program costs, by improving and enhancing access to outpatient surgical services in ASCs, and by applying the budget neutrality provision in a broad and dynamic way – consistent with these policy goals and the language of the statute – that recognizes the new payment system's effects not just on payments to ASCs, but also its overall cost savings to the Medicare program.

[9] 70 *Fed. Reg.* 4,132 (January 28, 2005).

Migration Analysis 2008 Estimates: 65%
Based on CMS file with Estimated 2008 payments and volume

Attachment #3

Table 3: 84% and 62% @ 65% BN									
	2008 Current Payment (65% BN)	New Payment	Percent Change	Cost	% of 2008 OPPS pay for ASC Services	Total Cost of Proposed Leg per 100	Assumed Migration for BN	Total Cost of Migration	2006 pay equivilent
Gastroenterology	84.2	84	-0.4%	0	20.7	-8	0%	0	89
Pain/Neurology	80.5	62	-22.8%	-18	8.2	-151	-2%	6	66
Pulmonary	67.5	62	-7.9%	-5	0.1	0	-1%	0	66
Ophthalmology	66.4	62	-6.3%	-4	46.7	-196	-1%	18	66
Dermatology	63.8	62	-2.5%	-2	2.7	-4	-1%	1	66
Urology	51.9	62	19.7%	10	3.3	34	13%	-16	66
Otolaryngology	40.9	62	51.9%	21	1.7	35	18%	-11	66
General Surgery	40.1	62	55.2%	22	1.9	41	18%	-13	66
Vascular	37.4	62	66.3%	25	0.6	14	19%	-4	66
Orthopedics	36.2	62	71.6%	26	13.8	357	21%	-109	66
OB/GYN	35.9	62	73.1%	26	0.4	9	19%	-3	66
						131	3%	-131	

Migration Analysis 2008 Estimates: 65%
Based on CMS file with Estimated 2008 payments and volume

Attachment #3

Table 1: 84% and 65% @ 65% BN									
	2008 Current Payment (65% BN)	New Payment	Percent Change	Cost	% of 2008 OPPS pay for ASC Services	Total Cost of Proposed Leg per 100	Assumed Migration for BN	Total Cost of Migration	2006 pay equivlent
Gastroenterology	84.2	84	0.0%	0	20.7	0	0%	0	89
Pain/Neurology	80.5	65	-19.3%	-16	8.2	-128	-2%	6	69
Pulmonary	67.5	65	-3.7%	-3	0.1	0	-1%	0	69
Ophthalmology	66.4	65	-2.1%	-1	46.7	-64	-1%	16	69
Dermatology	63.8	65	1.9%	1	2.7	3	9%	-9	69
Urology	51.9	65	25.2%	13	3.3	44	33%	-39	69
Otolaryngology	40.9	65	58.8%	24	1.7	40	50%	-29	69
General Surgery	40.1	65	62.3%	25	1.9	47	50%	-33	69
Vascular	37.4	65	73.8%	28	0.6	15	50%	-10	69
Orthopedics	36.2	65	79.4%	29	13.8	395	54%	-260	69
OB/GYN	35.9	65	81.0%	29	0.4	10	50%	-6	69
						363	10%	-363	69

Migration and Cost Analysis at 65% Budget Neutrality:
CMS Presentation

Attachment #4

Table 2: 65% @ 65% BN; based on survey results									
	2008 Current Payment (65% BN)	**New Payment**	**Percent Change**	**Cost**	**% of 2008 OPPS pay for ASC Services**	**Total Cost of Proposed Leg per 100**	**Assumed Migration for BN**	**Total Cost of Migration**	**2006 pay equivilent**
Gastroenterology	84.2	65	-22.4%	-19	20.7	-391	**-15%**	108	86
Pain/Neurology	80.5	65	-18.8%	-15	8.2	-125	**-2%**	6	69
Pulmonary	67.5	65	-3.2%	-2	0.1	0	**-1%**	0	69
Ophthalmology	66.4	65	-1.5%	-1	46.7	-48	**-1%**	16	69
Dermatology	63.8	65	2.4%	2	2.7	4	**3%**	-3	69
Urology	51.9	65	25.8%	13	3.3	45	**9%**	-10	69
Otolaryngology	40.9	65	59.7%	24	1.7	40	**12%**	-7	69
General Surgery	40.1	65	63.2%	25	1.9	47	**12%**	-8	69
Vascular	37.4	65	74.7%	28	0.6	16	**17%**	-3	69
Orthopedics	36.2	65	80.3%	29	13.8	400	**20%**	-95	69
OB/GYN	35.9	65	81.9%	29	0.4	11	**20%**	-2	69

Attachment #5

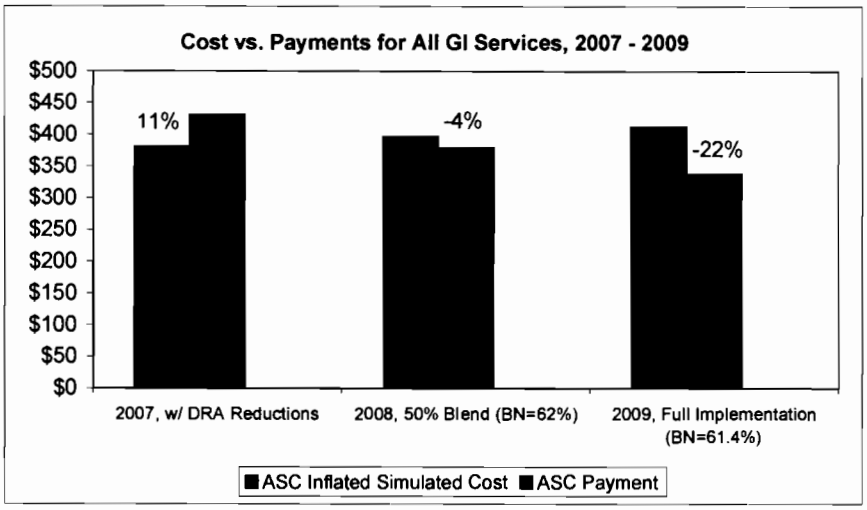
CMS
Hospital Median Costs vs. 2006 Q1 HOPPS Rates
10/16/2006

					35%	65%	
				20	7	13	
Specialty	**CPT4**	**2006 Q1 HOPD Rate (Unadjusted)**	**CMS Median Cost**	**Margin**	**Winner**	**Loser**	**Margin %**
GI	45378	$509.34	$452.02	$57.32	1	0	12.7%
GI	43239	$480.03	$475.02	$5.01	1	0	1.1%
GI	45385	$509.34	$553.54	($44.20)	0	1	-8.0%
GI	45380	$509.34	$527.62	($18.28)	0	1	-3.5%
GI	43235	$480.03	$395.24	$84.79	1	0	21.5%
GI	45384	$509.34	$577.63	($68.29)	0	1	-11.8%
GI	G0121	$449.56	$449.07	$0.49	1	0	0.1%
GI	G0105	$449.56	$448.88	$0.68	1	0	0.2%
GI	43249	$480.03	$659.50	($179.47)	0	1	-27.2%
GI	45383	$509.34	$578.11	($68.77)	0	1	-11.9%
GI	43248	$480.03	$484.31	($4.28)	0	1	-0.9%
GI	43450	$315.23	$278.16	$37.07	1	0	13.3%
GI	43246	$480.03	$594.78	($114.75)	0	1	-19.3%
GI	43760	$133.15	$149.63	($16.48)	0	1	-11.0%
GI	43262	$1,107.92	$1,357.46	($249.54)	0	1	-18.4%
GI	43259	$480.03	$616.75	($136.72)	0	1	-22.2%
GI	43247	$480.03	$465.41	$14.62	1	0	3.1%
GI	43264	$1,107.92	$1,278.69	($170.77)	0	1	-13.4%
GI	43251	$480.03	$546.56	($66.53)	0	1	-12.2%
GI	45331	$280.21	$336.52	($56.31)	0	1	-16.7%

Migration and Cost Analysis at 65% Budget Neutrality:
CMS Presentation

Attachment #6

	ASC Inflated Simulated Cost	ASC Payment	Margin
2007, w/ DRA Reductions	$380.89	$430.20	11%
2008, 50% Blend (BN=62%)	$396.13	$379.30	-4%
2009, Full Implementation (BN=61.4%)	$411.98	$338.12	-22%



Migration and Cost Analysis at 65% Budget Neutrality:
CMS Presentation

Attachment #7

Table 2: 81% and 65% @ 65% BN									
	2008 Current Payment (65% BN)	**New Payment**	**Percent Change**	**Cost**	**% of 2008 OPPS pay for ASC Services**	**Total Cost of Proposed Leg per 100**	**Assumed Migration for BN**	**Total Cost of Migration**	**2008 pay equivilent**
Gastroenterology	84.2	81	-4.1%	-3	20.7	-72	-2%	8	86
Pain/Neurology	80.5	65	-19.3%	-16	8.2	-128	-2%	6	69
Pulmonary	67.5	65	-3.7%	-3	0.1	0	-1%	0	69
Ophthalmology	66.4	65	-2.1%	-1	46.7	-64	-1%	16	69
Dermatology	63.8	65	1.9%	1	2.7	3	8%	-8	69
Urology	51.9	65	25.2%	13	3.3	44	36%	-42	69
Otolaryngology	40.9	65	58.8%	24	1.7	40	41%	-24	69
General Surgery	40.1	65	62.3%	25	1.9	47	41%	-27	69
Vascular	37.4	65	73.8%	28	0.6	15	41%	-8	69
Orthopedics	36.2	65	79.4%	29	13.8	395	43%	-207	69
OB/GYN	35.9	65	81.0%	29	0.4	10	43%	-5	69
						291		**-291**	

Attachment #8

Question 1: If Medicare drops payments by the indicated percnets, by what perent will your Medicare and commercial payment mix change?		
Payment Reduction	**Change in Medicare Patients**	**Change in Commercial Patients**
-5%	41% expect no change in quantity; 28% will reduce quantity between 1-5%; 20% will reduce quantity between 6-20%	44% expect no change in quantity; 28% will increase quantity between 1-5%; 24% will increase quantity 6-20%
-10%	42% will reduce quantity between 1-10%; 20% will reduce quantity between 11-20%; 4% will eliminate Medicare patients	17% expect no change in quantity; 30% will increase quantity between 1-10%; 41% will increase quantity 11-20%
-15%	14% will reduce quantity between 1-10%; 28% will reduce quantity between 11-20%; 25% will eliminated Medicare patients	12% expect no change in quantity; 36% will increase quantity between 11-30%; 32% will increase quantity over 30%
-20%	19% will reduce quantity between 40-50%; 15% will reduce quantity between 70-90%; 33% will eliminate Medicare patients	12% expect no change in quantity; 20% will increase quantity between 41-50%; 21% will increase quantity over 50%

Question 2: At what payment level will you stop accepting and treating Medicare patients?	
n=28	
Payment Level	Percent of Facilities
0-5%	3.6%
5-10%	3.6%
11-20%	10.7%
21-30%	10.7%
31-40%	3.6%
41-50%	3.6%
51-60%	3.6%
61-70%	7.1%
71-80%	21.4%
81-90%	25.0%
91-100%	7.1%
	100.0%

Question 3: Do you expect the waiting time for Medicare patients between the date it is determined they need a procedure to the date the procedure is performed will be longer, shorter, or about the same once the proposed payment changes take effect?	
n=29	
Response	Percent of Facilities
Longer wait	89.7%
Shorter wait	0.0%
About the same wait time	10.3%
	100.0%

Question 11: Assuming the changes proposed by CMS for Medicare ASC payments are implemented:				
	Yes	No	N=	
a. Do you expect that your ASC would close its business?	18%	82%	28	100.0%
c. Would you expect to increase the total number of hours per week that the ASC treats patients?	7%	93%	27	100.0%
f. Would you expect a reduction in the total number of employees at your ASC?	79%	21%	28	100.0%
h. Would you expect a reduction in the average compensation level (salary and benefits) for the ASC's employees?	68%	32%	28	100.0%

AMERICAN COLLEGE OF GASTROENTEROLOGY

4900 B South 31st Street, Arlington, Virginia 22206-1656, (703) 820-7400, FAX (703) 931-4520

September 3, 1998

Health Care Financing Administration
Department of Health and Human Services
Attention: BPD-1006-P
P. O. Box 26688
Baltimore, Maryland 21207-0488

Re: Comments on Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Other Part B Payment Policies, RIN 0938-AH94, 42 CFR Parts 400, 405, 410 and 414

The American College of Gastroenterology (ACG) is pleased to provide these comments with respect to HCFA's proposal to modify the practice expense component of the Medicare Part B Physician Fee Schedule and other related topics.

1. INTRODUCTION

The American College of Gastroenterology (ACG) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers nearly 7,000 physicians among its membership. While the majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology--the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be, educational.

The American College of Gastroenterology is very concerned with respect to the effort by the Health Care Financing Administration (HCFA) to implement a new methodology for computing the practice expense component of the Medicare physician fee schedule. We believe that HCFA's implementation of this policy, without the benefit of accurate, truly independent, verifiable data on actual physician practice expenses has the potential to wreak considerable havoc on the medical community, with adverse effects on patient care.

Acting under provisions of the Omnibus Budget Reconciliation Act of 1994 (OBRA 1994), updated via the Balanced Budget Act of 1997, HCFA's Notice of Proposed Rulemaking (NPRM) proposes to make major modifications to the existing Medicare Fee Schedule by changing the method for computing the practice expense component of the fee, which accounts for about 50% of the Medicare payment to providers. If implemented in its current form, this modification to the Fee Schedule would have an especially devastating and adverse impact on fees for endoscopic services as well as surgical services. Payments to gastroenterologists would drop by approximately 20% below what they are this year. Even with the new mandate from Congress for a one-year delay and four-year phase-in, the substantive issues remain unchanged in many respects. Regardless of when/if, a rule similar to this proposal is ultimately implemented, it will represent a fundamental setback for all stakeholders in health care. The plan HCFA is proposing is not a budget-cutting effort that will help to balance the budget or save federal dollars. HCFA's program is not about Medicare reform--but it would constitute a preemptive re-distribution of income in the medical community that would leave many physician practices financially devastated, with reductions in staffing and the concomitant negative impact on ability to deliver quality patient care.

Congress clarified its intent by specifying that the Secretary utilize, to the "maximum extent practicable" generally accepted cost accounting principles which (i) recognize all staff, equipment, supplies and expenses, not just those that can be tied to specific procedures, and (ii) use actual data on equipment utilization and other key assumptions. Congress also directed HCFA to consult with organizations representing physician specialties regarding the methodology and data to be used and to develop a refinement process to be used during each year of the four-year transition.

Because continuing refinement of the underlying data is necessary, and because real limitations are being placed on HCFA's resources as a consequence of the "Year Two Thousand" ("Y2K") problem, a four-year transition period is inadequate. HCFA should either seek additional time from Congress to implement the rule or otherwise extend the phase-in period.

HCFA did secure the services of an outside contractor to compile independent data and the agency had projected that the database would be completed by Spring, 1996. This deadline was not met. In 1996, HCFA canceled its contract with the outside contractor and assumed responsibility for completing the data collection and analysis--tasks which were not timely or appropriately completed. Despite the lack of reliable data, HCFA still published the initial proposal last year and has issued a second proposal on new premises published in this latest proposed rule. HCFA needs to document practice expenses using independent data and analyze the resulting data to test different ways for estimating practice costs for the different CPT codes/services in the fee schedule. Even after Congress mandated an additional year to permit collection of real data, HCFA has failed to do so, turning instead to the AMA's SMS database, compiled for a wholly different purpose and deficient in many respects for practice expense data. Through a series of gymnastic statistical adjustments, the agency arrived at what HCFA claims is a reliable source of data.

Although HCFA appears to have abondoned its efforts to collect such data through direct surveys, the legal requirement to base practice expense RVU on actual data has not changed. Indeed, the BBA actually affirms and reinforces those requirements.

HCFA has not gathered the necessary data but seems prepared to skip over that part of the job and simply announce a modification to Medicare fees that would drastically reduce what the government pays for most major diagnostic and surgical services.

It is difficult, if not impossible, to find anything that costs less today than it did ten years ago. Costs for food, electricity, and transportation have all risen. So have the rents, staff salaries, employee benefits, and costs for purchasing and maintaining new equipment in physician offices needed to serve their patients better. Health insurance costs have increased. *But what the Federal government pays for the services and procedures that gastroenterologists provide has gone down-Medicare payments for many services have already dropped by 50% or more since 1987.*

TABLE 1

HCFA's Proposed Fee Schedule Payment

	1987 Fee	1997 Fee	1998 Reimbursement		Proposed Reimbursement (With new Practice Expense Changes Per HCFA's June 1998 Proposal)		% Change in Rates for Outpatient Procedures From	
SERVICE			Outpatient (RVU)	Office (RVU)	Outpatient (RVU)	Office (RVU)	1998 rates	1987 Rates
EGD (43234)	$344.22	$165.17	$165.82 (4.52)	$179.03 (4.88)	$116.29 (3.17)	$170.96 (4.66)	-30%	-66%
EGD (43235)	N/A	$194.61	$194.80 (5.31)	$210.95 (5.75)	$134.27 (3.66)	$237.73 (6.48)	-31%	N/A
EGD w/biopsy (43239)	N/A	$218.64	$211.20 (5.98)	$228.81 (6.46)	$140.58 (4.11)	$241.66 (6.90)	-33%	N/A
ERCP (43260)	$532.32	$417.31	$452.35 (12.33)	N/A	$314.04 (8.56)	N/A	-31%	-41%
Flex Sig (45330)	$148.46	$78.18	$78.51 (2.14)	$84.74 (2.31)	$53.56 (1.46)	$165.09 (4.50)	-32%	-64%
Colonoscopy (45378)	$509.23	$267.82	$288.10 (8.16)	$290.30 (8.22)	$208.17 (6.06)	$292/34 (8.38)	-28%	-60%
Colonoscopy w/ w/lesion removal (45385)	$424.42	N/A	$414.17 (11.73)	$443.89 (12.54)	$277.71 (8.11)	$375.88 (10.82)	-33%	N/A

HCFA's announcement includes listings of the impact on a few CPT codes in an outpatient and office setting. HCFA's examples include its calculations on how fees for diagnostic colonoscopy would change under the new fee proposal. The current Medicare fee for diagnostic colonoscopy (45378) is stated by HCFA as being $288.10 if done in the hospital or ASC and $290.30 if done in the office.

Under the new proposal when it is fully implemented, HCFA would pay only $208.17 for outpatient procedures (including those in ambulatory surgery centers)--a cut of 28%; the HCFA fee if the procedure is done in the office would be $292.34 or an increase of 1%. However, the impact also includes EGD with biopsy (#43239) and colonoscopy with lesion removal (#45385) both of which are slated for 33% cuts--while less than the 40% cuts which had been slated in last year's rule for these procedures when performed at outpatient facilities, the prospect of 30% cuts in the three highest volume GI procedures both calls into question the fundamental accuracy of HCFA's statement on the magnitude of projected cuts and demonstrates the challenge we face to provide quality patient care in this setting of reimbursements which continue in a downward spiral.

2. HCFA is Correct in Selecting the Top-Down Methodology; The New, Top-Down Approach Is Preferable To Last Year's Bottom-Up Methodology

In this Notice of Proposed Rulemaking (NPRM), HCFA has proposed a new methodology to calculate practice expense relative value units. Commonly referred to as the "top-down" method, this new proposal is a substantial departure from the older, failed "bottom up" system that HCFA had proposed last year. Congress explicitly rejected that approach and directed HCFA to: (1) start with total practice expenses; and (2) use an accounting methodology. HCFA has made a good faith effort to comply with that mandate and has used data from the American Medical Association and an accounting based strategy for allocating those expenses to the CPT code level. While we recognize that much work still needs to be done, the framework is far better than any earlier proposals and will be more accurate when refined. Congress has provided time for an extensive refinement process of the "top-down" methodology, anticipating the need to address a number of complex questions.

There are many deficiencies in this proposal, and a great deal we disagree with, as is noted below. However, one positive improvement is the new "top-down" methodology adopted by HCFA. While this aspect of the proposal is an important improvement on the "bottom-up" approach used last year, it is still not good enough and would result in an unfair, devastating redistribution of income.

Unfortunately, the problem with the absence of accurate, independent data remains. The decision to use the AMA's SMS database as an attempted substitute, while perhaps well-intentioned, is still short of the mark in terms of what HCFA needs to produce to support a rulemaking of this magnitude and far-reaching importance. Specifically, in the case of gastroenterology, it is clear that the sample for AMA's SMS database is incredibly small, much too small to be relied upon for valid results. The proposal states at page 30825 that "...if any reliable data exist at all, they are only for a few scattered specialties." HCFA also states that as part of the refinement process, the agency hopes to address the situations where the AMA SMS database is inadequate or unreliable. We believe that HCFA must be held to a standard that requires the agency to develop accurate, independent data that is capable of being validated. We do not believe that the SMS data satisfies that obligation with respect to practice expenses. Even if HCFA is not going to meet that statutory standard, clearly gastroenterology is one of the specialties which would have to be included in review during the refinement process. Fortunately, we believe there are existing data which may, perhaps with updating, prove to be reliable sources. The AMA comments on SMS (pp. 30828-29) underscore the sample size problems: "Sample sizes from some specialties will be

:oo small to permit separate calculation of expense data from SMS, even some of the larger specialties, :he inherent variability of the expense data will mean that the average expense figures provided will be subject to significant sampling error."

By tying practice expense values to numbers that come closer to approximating actual costs incurred, the proposed "top-down" methodology accords more closely with the intent of the Medicare Act and more accurately accomplishes the goals of the shift to resource-based methodologies than the bottom-up methodology. While we will focus most of our comments pointing out many deficiencies with this proposed rule, we believe that in adopting the top-down methodology HCFA has made a significant first step in the right direction with this new NPRM.

3. The Problems For GI Codes Continue To Be Data-Related; The AMA SMS Data Is Not A Valid Substitute For Collecting Independent Data--The GI Sample Is Simply Too Small

Physician Time Data As Computed in the Harvard Studies Are Not Current and So Are Likely Inappropriate for Use in Step 2 of the "Top-Down" Computation

HCFA states that "primary sources for the physician time data are surveys submitted to the AMA's RUC and surveys done by Harvard for the initial establishment of the work RVUs." Much of this work is now nearly ten years old--much in physician practice has changed in the interim, and there is no assurance that this data, if it ever was accurate, remains so today.

HCFA Has Taken Data out of Context, with Resulting Distortions of Accuracy

AMA Socioeconomic Monitoring System data was used by HCFA despite the fact that SMS data were ever collected for the purpose of developing relative values. Practice expenses are only one of many sues addressed by the survey, so there is not much detail on practice expense categories or on how rsonnel, office space, supplies, and equipment are used.

HCFA's Data Is Not Sufficient to Support a Rulemaking of this Magnitude

ual practice expenses have not been documented to date. The use of validation panels, and resorting ie AMA SMS data and its use for purposes that were never contemplated or intended--**particularly istified reliance on exceedingly small samples such as those in gastroenterology**--is not in any e a reasonable alternative for actual data on practice expenses which HCFA has heretofore failed to oile. As was noted above, delays and problems in gathering data and complex data collection ys impeded progress on this project and precluded the Secretary of HHS from timely compliance.

Problems With AMA SMS Database As Developed to HCFA Specifications and As It Relates to Gastroenterology

tated above, the AMA's SMS database was not developed for the purpose of establishing practice es. For certain specialties, the SMS data is based on a very small sample. In such instances

HCFA should carefully consider other data. Moreover, HCFA has not used the entire SMS database, but has established a series of limitations and qualifications which have had the effect of eliminating approximately two-thirds of the respondents to the SMS survey from consideration for the segment of the database that HCFA is using.

Gastroenterology Has the Lowest Percentage Response Rate of Any Specialty

Attached is a Table developed by the AMA to reflect response rates and average weighting which need to be constructed by HCFA to compensate for low response rates. We have already underscored that the sample used by HCFA from SMS for gastroenterology is very small, stated variously as 75 respondents and 84 cases. **(Appendix - Table B1 - Number of Respondents-Response Rates)** Perhaps as important, or more important, is the fact that the response rate from gastroenterology, reported at 53.6%, is the lowest response rate among any specialty. This means that the numbers generated by HCFA from the SMS database as they relate to gastroenterology are more dependent upon weighting, a complex of statistical adjustments. The combination of the low sample size and the low response response rate make the gastroenterology number being used by HCFA particularly suspect.

Inconsistencies Are Apparent When SMS Data for Gastroenterology Is Compared to Two Other Specialties

We have noted for comparison the HCFA-generated compilations from the SMS database for two other specialties--general surgery and general/family practice--as well as the all physicians categories. Underlying our selection of these categories for review is the fact that the SMS data show that general surgeons generally spend somewhere close to 25% more time performing procedures outside the office than gastroenterologists (27.6% of gastroenterologists reported spending in the range of 51% to 100% of their time in the office, contrasted to just 8.2% of general surgeons; 14.6% of gastroenterologists reported spending 0-25% of their time in the office, compared to 40.8% of general surgeons), yet the mean practice expenses per hour spent in patient care activities is closely parallel--$56.6 for gastroenterology, compared to $54.1 for general surgery.

We have looked at equipment expense per hour, and note that these costs are listed at $1.8 for gastroenterology--lower than any of the other three categories referenced for comparison, i.e., general surgery equipment costs of $2.0 per hour, $3.2 per hour for all physicians and $3.6 per hour for general/family practice. These numbers seem to fail to meet a face validity standard. It can be assumed that virtually all gastroenterology practices own and maintain one or more flexible sigmoidoscopes, and many of them also own and maintain more expensive colonoscopes and upper GI endoscopes. Some gastroenterology practices maintain monitoring and resuscitation equipment. This is generally going to be in addition to the routine equipment which would be maintained in a typical internal medicine practice. This range of equipment exceeds significantly the equipment which is maintained in the general surgery office. Yet, the numbers HCFA is using to generate this rulemaking maintain that gastroenterology will have only one-half the equipment per hour costs of the typical general/family practice group, and that the equipment per hour expense in gastroenterology fall below those of both

general surgery, by a small margin, and behind the "all physicians" category by a factor which approaches two.

SMS Data in All Six Practice Expense Subcategories Appears to Grossly Understate Actual Practice Expenses

Data developed and made available by the **AMA** compiles by subspecialty mean and percentile statistics various subcategories of practice expenses. When we compared these with data from the ACG's Operating Ratios Report, it appears that all categories are understated by a large measure in HCFA's iteration of the SMS database. For example, mean expenses for non-physician payroll are stated at 63,464 for gastroenterology, comparable to the 61,992 recorded for general surgery, even though, as pointed above, this same SMS data points to general surgeons spending substantially less time in the office which should translate into significantly higher non-physician payroll needed by gastroenterologists to staff offices during the heavier loads of times when gastroenterologists are in the office seeing patients, as contrasted to general surgery.

A look at non-physician payroll in some other specialties also reveals anomalies--the mean non-physician payroll reported in allergy/immunology and ophthalmology is more than double the reported numbers for gastroenterology.

Gastroenterology Figures Derived from SMS Data Suffer from The Bias Relating to Mid-Level Physician Extenders

HCFA has underscored at page 30832 that because the "practice expenses per hour from the SMS survey are calculated in terms of hours spent in patient care activities by physicians in the practice," resulting in the methodology being "...potentially biased in favor of specialties who use more, relative to other specialties, mid-level providers as physician-extenders." Typically, GI practices do not make any significant use of such mid-level providers as physician extenders, so the gastroenterology numbers would be penalized by the bias, as well as being severely compromised and almost certainly invalidated by inadequate sample size.

Physician Reports of Number of Hours Are Much Less Reliable Than Reports of Practice Expense Dollars

Perhaps the most critical component in HCFA's computation is the practice expenses per hour. This is not a statistic which can be derived directly from the SMS database. Rather, HCFA developed a formula which involves a combination of the number of weeks reported worked, and the number of hours per week reported as worked by physician owners and physician employees. This same statistical extrapolation assumes that average annual hours worked among all employee physicians in a particular practice is equal to average annual hours worked among all employee physicians of that specialty, an assumption which we think is open to serious question.

HCFA is also assuming that the reports of number of hours worked and number of weeks worked are being reported with the same level of accuracy as actual dollars of practice expenses. Again, we think that this assumption is at best very questionable. The SMS database is used for purposes that do not rest upon the crucial "expense per hour of patient care," that is being used in this rulemaking. We believe that the reported hours are likely to be much more in the nature of a "guess," and will generally be prone to be overstated. One indication that this is the case is that 305 responses to SMS had to be excluded by HCFA because they stated that they spent 168 hours per week (7 days X 24 hours daily) or less than 26 weeks in the preceding year in patient care. While HCFA chose to exclude such reports, what assurance do we have that many other reports that were not excluded were not similarly prone to overly high statements?

4. Among All The Problems With This Proposal, Proposed Fees For Colonoscopy Codes (45378 to 45385) Represent The Most Egregious Error

a. The Proposed PE RVUs for CPT #45378 are inconsistent with, and markedly lower than they should be based on comparability to #45330

The direct costs for CPT #45378, diagnostic colonoscopy, are severely understated for both office and outpatient procedures. We have used as the basis for this comparison, the PE RVUs assigned to #45330, flexible sigmoidoscopy, diagnostic. Both are fiber optic procedures whereby the physician directly visualizes a portion of the GI tract. However, the most fundamental difference is that there are different bowel preps involved, and in diagnostic colonoscopy, the patient is sedated during the procedure, while any such sedation is less common with flexible sigmoidoscopy.

The physician work RVUs provide us with a good relative sense of the level of complexity and amount of physician time involved. The diagnostic colonoscopy (#45378) has been assigned 3.70 work RVUs, while flexible sigmoidoscopy (#45330) has been assigned .96 work RVUs. From this, one would assume that the diagnostic colonoscopy (45378) is about 4.0 times more complicated than flexible sigmoidoscopy, diagnosis (#45330), and that the former takes about 4 times longer than the latter.

In calculating direct expenses, staff time involved in the diagnostic colonoscopy (#45378) is always higher than in the flexible sigmoidoscopy, diagnosis (#45330). In part this is due to the sedation, as well as the likelihood that the patient's symptoms are more complicated, as is the procedure. As was noted above, the bowel prep is much more complicated than for flexible sigmoidoscopy (#45330) and even more complicated than another procedure that includes sedation, upper GI endoscopy diagnostic (#43235). Also, follow-up is complicated as the patient is sedated and information must be conveyed subsequently, in person, by telephone or in writing. Additionally, the patient needs to have transportation arranged so that there is likely to be family to interact with, or the physician's staff becomes involved in transportation arrangements for those patients who cannot be accompanied by a family member. *These factors arise, independent of whether the procedure is done in an outpatient or office setting.*

For these reasons, the comparative work RVUs ought to provide a rough estimate of the comparisons of direct practice expenses as between the two procedures. Yet, when we compare the two procedures, in terms of direct PE expenses and total PE expenses, this relationship is not borne out in any way. Here are the relative ratios between various components of these two procedures.

TABLE 2

COMPARING RATIOS OF WORK TO PE-COMPONENTS FOR 45330 (FLEX. SIG.) AND 45378 (DIAGNOSTIC COLONOSCOPY)

	45330 (flex sig.)			45378 (Diagn. Colonoscopy)		
WORK	.96	=	.281	3.70	=	.862
Non-facility PE (TOTAL)	3.42			4.29		

If the ratios of each factor for the #45378 (Diagn Colonoscopy) were the same as for the #45330 (flex. sig.) it would result in significantly higher PE RVUs for the #45378. Here are the components of the PE RVU for #45378 which would result if the ratios linked to the work RVUs were the same as between these two procedures:

TABLE 3

MODIFICATIONS REQUIRED TO 45378 (DIAGNOSTIC COLONOSCOPY) PE COMPONENT TO PARALLELWORK/PE COMPONENT RATIOS OF 45330 (FLEX. SIG.)

	45330 (flex sig.)			45378 (Diagn. Colonoscopy)		
WORK	.96	=	.281	3.70	=	.281
Non-facility PE (TOTAL)	3.42			13.17		

The resultant PE and total RVUs for #45378 from maintaining this relationship would be: 16.837

b. The Proposed PE RVUs for CPT #43235 are inconsistent with, and markedly lower than they should be based on comparability to #45330

The direct costs for CPT #43235, upper GI endoscopy, diagnosis, are understated for both office and outpatient procedures. We have used as the basis for this comparison, the PE RVUs assigned to #45330. flexible sigmoidoscopy, diagnostic. Both are fiber optic procedures whereby the physician directly visualizes a portion of the GI tract. However, the most fundamental difference is that there are different bowel preps involved, and in upper GI endoscopy, the patient is sedated during the procedure, while any such sedation is rare with flexible sigmoidoscopy.

The physician work RVUs provide us with a good relative sense of the level of complexity and amount of physician time involved. The upper GI endoscopy, diagnosis (#43235) has been assigned 2.39 work RVUs, while flexible sigmoidoscopy (#45330) has been assigned 0.96 work RVUs. From this, one would assume that the upper GI endoscopy, diagnosis (43235) is about 2.5 times more complicated than flexible sigmoidoscopy, diagnosis (#45330), and that the former takes about 2-1/2 times longer than the latter.

TABLE 4

COMPARING RATIOS OF WORK TO PE-COMPONENT FOR 45330 (FLEX. SIG.) AND 43235 (UPPER GI ENDOSCOPY, DIAGNOSIS)

	45330 (flex sig.)		43235 (Up. GI endosc., diag)
WORK	.96	= .281	2.39 = .629
Non-facility PE (TOTAL)	3.42		3.80

If the ratios of each factor for the #43235 (Up. GI endosc., diag) were the same as for the #45330 (flex. sig.) it would result in significantly higher PE RVUs for the #43235. Here are the components of the PE RVU for #43235 which would result if the ratios linked to the work RVUs were the same as between these two fiberoptic endoscopic procedures:

TABLE 5

MODIFICATIONS REQUIRED TO 43235 (UPPER GI ENDOSCOPY, DIAGNOSIS) PE COMPONENTS TO PARALLEL WORK/PE COMPONENT RATIOS OF 45330 (FLEX. SIG.)

	45330 (flex sig.)		43235 (Up. GI endosc.. diag)
WORK	.96	= .281	2.39 = .281
Non-facility PE (TOTAL)	3.42		8.51

The resultant PE and total RVUs for #43235 from maintaining this relationship would be: 10.90

In response to the June 18, 1997 NPRM, ACG's comments pointed out that to the extent physician work bears a relationship with practice expenses. PE-RVUs for diagnostic colonoscopy and upper GI endoscopy should be increased to maintain some parallel with flexible sigmoidoscopy. In this proposed rule, HCFA has appropriately increased the PE-RVU for flexible sigmoidoscopy, but has further decreased the PERVUs for both diagnostic colonoscopy and upper GI endoscopy, making the dichotomy disproportion worse when these are compared with flexible sigmoidoscopy . Last year, the PERVU for diagnostic colonoscopy was proposed at 4.56 (facility), and it should have been 6.79 to parallel the same ratio of physician work. Now, the PERVU for diagnostic colonoscopy is proposed at 4.29, whereas the values required to maintain consistent work/PE relationship would be 13.167.

Measuring the similar parallels for upper GI endoscopy, last year the PERVU for upper GI endoscopy was proposed at 4.34, and it should have been 4.39 (1.02 facility) to parallel the same ratio of physician work. Now, the PERVU for upper GI endoscopy is proposed at 3.80, whereas the values required to maintain consistent work/PE relationship should be 10.90 when compared with flexible sigmoidoscopy. HCFA cannot continue to ignore the relationship of physician work with procedure expense RVU.

5. Magnitude of Cuts Among Top 5 Gastroenterology Services Will Be Devastating to GI Practices

Today, five CPT codes account for approximately 50% of the Medicare income derived by gastroenterology practices. These are #43239 (upper GI endoscopy with biopsy), #45378 (diagnostic colonoscopy). #45385 (colonoscopy, lesion removal), #45380 (colonoscopy and biopsy), and #43235 (upper GI endoscopy, diagnosis). The attached Table generated by Compass Health Analytics, Inc. demonstrates that 44.03% of all practice expense payments to gastroenterologists are generated from these five procedures. It also demonstrates that the impact upon gastroenterology practices will be disproportionately large as to these five codes. All but one of these codes has a reduction in PE payments of nearly 60% after full implementation. Also, all but one of these has a total reduction in payments of 30% or more after full implementation.

Intended or not, it is unmistakable that the impact of adoption of this proposal would present a radical change in the way in which gastroenterology is practiced. This is inconsistent with HCFA's directives on the fee schedule generally, which is to avoid using payments to change health care practice patterns. The legislative history indicates that HCFA may not use RBRVS to discourage the provision of any type of service, such as surgical procedures. It is also essential to remember that these projected impacts do not take into account the impact of the troublesome site-of-service policy--in those practices where all or virtually all procedures are done in the hospital or ASC facility setting, the revenue impact arising because of even greater reductions in physician fees triggered by the site-of-service policy would be even more pronounced than is represented by the numbers reflected in the table. **(Appendix, Tab 4, Payment Impact--Top 50 Services, Gastroenterology)**

Referencing the same table **(Appendix, Tab 4, Payment Impact--Top 50 Services, Gastroenterology)**, the vast shifts that would be experienced in this specialty are underscored. HCFA claims that the net impact upon full implementation would be only -14%. This number simply cannot be substantiated either by HCFA or an outside independent examination. Again, this is a number which ignores the potential skewing effect of the dubious site-of-service policy, which would have an even larger impact in reducing payments. Moreover, 26 of the top 50 services in the field of gastroenterology have total fee swings upon full implementation of +/- 25% or more. Such wide swings are not consistent with a sound policy. We think that HCFA's claim that the total impact will be -14% is questionable for reasons articulated elsewhere in these comments. Such total impact which ignores both these wide swings, and ignores the site-of-service differential impact is a misleading number. Increasing one service by 50%, and decreasing another by 50% may tabulate to 0 change, but would have a remarkable impact on patient care. That is the type of practice change in gastroenterology that HCFA would create with this unsound proposed policy change.

6. <u>There Is No Explicit Statutory Requirement To Move To Separate Office-Based vs. Outpatient Practice Expenses</u>

In seeking to explain how it arrived at some procedures having both office and outpatient amounts while others had no practice expense levels specified for an office setting, HCFA stated in its June 18, 1998 proposal that: "(G)enerally, if a service was furnished both in an office setting and in an out-of-the-office setting less than 10% of the time in either of these settings, it was not profiled in that setting."

HCFA notes that they are proposing only one level of practice expense RVUs by code for the following categories of service:

-those that have only TC practice expense RVUs;
-those that have only PC practice expense RVUs;
-certain evaluation and management services, such as hospital or nursing facility sites, that are furnished exclusively in one setting/a major surgical center

As is noted above, we believe that HCFA's plan to provide two separate levels of practice expense RVUs/codes to correspond to services provided in the office or in an outpatient setting is not directly referenced in the statute and is inconsistent with the PPRC's expectation, and the legislative history that the practice expense change would be site neutral. The fact that HCFA's proposal includes these several categories retaining a single practice expense RVU serves to further demonstrate the discriminatory nature of this policy and to underscore its inappropriateness.

HCFA is Both Internally Inconsistent, and in Error, in Attempting to Establish Separate Office and Outpatient Reimbursement Levels for GI Endoscopy Codes (43234 through 45385)

The proposal states at page 30834 the premise for applicability of the new site-of-service differential and establishment of two separate fee levels (and two separate levels of practice expense RVUs), as being "...if a physician service of the type routinely furnished in physician offices is furnished in facility settings." In fact using either that criteria or the 10% threshold required above from HCFA June, 1997 proposal, there would not be justification to establish separate office and outpatient reimbursement levels for GI endoscopy codes (43234 through 45385). HCFA's own data demonstrates that in virtually all cases, 95% or more of these GI endoscopies are being done in the "facility" setting--so it can hardly be maintained that these cases are "routinely furnished in physician offices", and HCFA's 10% standard that the agency articulated last year would be violated. Rather, the data establishes that these GI endoscopies precisely parallel "surgical services...(that) are performed entirely or almost entirely in the hospital" (or comparable ASC) and as to which HCFA states that it is "..generally providing a practice expense RVU only for the out-of-office or facility setting." This is how GI endoscopy codes (43234 through 45385) should be treated, i.e., a return to a single fee and composite RVU (not simply a slightly increased version of the extraordinarily low facility total--but a return to the 1997 levels), derived from the 1997 fee schedule, with the appropriate update for down payment and 1998 MEI.

Finally, HCFA's proposal inaccurately states that "we are proposing to replace the current policy...with a policy that would generally identify two different levels." In fact, for many codes, including many GI endoscopies, HCFA has already implemented this policy which it now says it is proposing for comment. As ACG stated in its comments on the October 31, 1997 fee schedule announcement, we believe that implementation was premature and inappropriate.

7. **HCFA's Policy to Incentivize Office-Based Procedures Would Deviate from the Prevailing Standard of Care, and Would Frequently be Inconsistent with the Best Interests of Medicare Patients**

HCFA is wrong to maintain the system of separate fee structures implemented 1/1/98 that reduces physician fee payments if an endoscopy is performed in the hospital or ambulatory surgery center

compared to the fee if the same case is done in an office setting. We are extremely concerned that HCFA took the initial step toward differentiating physician fees for office-based procedures from those performed on an outpatient basis at either an Ambulatory Surgical Center ("ASC") or in a hospital outpatient facility when the agency published separate facility/non-facility fee reimbursement rates in its 1998 Medicare fee schedule.

In this proposal, HCFA attempts to legitimatize and perpetuate the unprecedented fundamental change in the Final 1998 Medicare Physician Fee Schedule Rule, published by HCFA in October 1997, which irrationally established different practice expense relative value units (RVUs) and, therefore, differing reimbursements for certain endoscopic procedures depending on whether such procedures are provided in a facility or non-facility setting.

The majority of diagnostic colonoscopies on Medicare patients are performed in the hospital or ASC for good reason that has nothing to do with economics--*to meet the quality of care standard for the safety of the patient.* While colonoscopy has an excellent record of safety, it cannot be regularly and safely performed in the ordinary office setting.

> *1. The patient is regularly sedated with Versed, demerol or similar medication and requires monitoring equipment and access to interventional devices in the event of an adverse reaction to these medications.*
>
> *2. A recovery area is required where the physician and other professional staff can assure that the patient has regained all normal functions before being released.*
>
> *3. While complications of bleeding or perforation are limited, the facility must be equipped to deal immediately with such complications when they occur.*
>
> *4. As mandated by OSHA, routine sterilization and infection control of equipment (generally) requires a separate room and equipment where cleansing can be accomplished completely distinct from patient treatment areas.*

The normal physician office setting does not provide these safeguards. HCFA knows this. HCFA has, for instance, helped mandate the criteria that must be met to qualify as a Medicare-approved ambulatory surgery center. Colonoscopies on the Medicare population cannot be performed safely in a routine physician office setting. There are a small number of gastroenterologists' offices across the country that have been outfitted with the types of facilities present in an ambulatory surgery center, but where the physician has not applied for Medicare certification. It is arguable that significant volumes of Medicare colonoscopies can be safely performed in such a "certifiable" setting. Such situations likely account for the modest percentage of Medicare colonoscopies that are billed as being performed in an office setting. *But this modest number of unique office settings cannot be cited as a criteria to change the medical standard of care.*

We believe that it is inappropriate to carry this bifurcation forward in the absence of a very explicit legislative directive to fundamentally change the Medicare physician fee schedule. The differential between non-facility vs. facility under both Practice Expense RVUs and Total RVUs is inappropriate and not supportable. The practical effect of this differential will motivate utilizing physician offices as

the site of services, and this may not be the safest place for all procedures. It is a breach of faith with ASCs which have met HCFA's criteria for Medicare certification to incentivize moving cases to uncertified office settings by paying a higher professional fee if a case is performed in an uncertified office setting and a lower fee if it is performed in a Medicare-certified ASC. The policy is flawed and incongruent.

HCFA should establish a high threshold of acceptance in the medical community before formally condoning the performance of particularly risky procedures in the office setting.

It can also create inappropriate incentives that jeopardize patient care. The establishment of separate payment levels can be seen as a judgement by HCFA that the procedures are safe and efficacious when performed in an office setting. However, many services pose an unacceptably high level of risk if not performed in a hospital or other appropriately equipped and staffed facility. HCFA should avoid creating this type of incentive.

Contrary to the PPRC recommendations that constitute an important piece of the legislative history on the Congressional mandate for resource-based practice expenses, and which envisioned a site-neutral practice expense policy, HCFA's proposal creates clear incentives for physicians to shift procedures from the outpatient setting into the office. In fact, HCFA now has created significant financial penalties for physicians who continue to provide Medicare procedure services in a hospital or ambulatory surgery center. Only by shifting these cases to the office would the physician be permitted to re-coup anything beyond the most marginal direct practice expense cost. For example, on diagnostic colonoscopies, HCFA's rule would pay the physician about 1.97 x conv. factor for all direct practice expense costs if the case is performed in the hospital or ASC, but would pay approximately 4.29 x conv. factor for practice costs. if the case is performed in the office.

If HCFA's proposal results in significant volumes of Medicare colonoscopies being done in the office, an impossible anomaly would result. Physicians performing office procedures would be subject to malpractice litigation in which they would undoubtedly be challenged for having violated the prevailing standard of care which would require the kind of special facilities found in the hospital or ASC. Medicare's own rules establishing the certification criteria would be cited. *Would HCFA's incongruous policy of providing economic incentives to have physicians shift these cases to the office be sufficient to protect these physicians from adverse judgements?--undoubtedly not!*

In fact, it has been reported to us that there are state regulations in some jurisdictions that ***require*** *that colonoscopies must be performed in hospitals or ambulatory surgery centers. Would HCFA's policy incentivizing the movement of these colonoscopies to office settings be a defense in claims of a violation of such state law?*

ACG previously stated in its December 30 comments on the October 31 Medicare Fee Schedule announcement relative to the site-of-service/bifurcated fee schedule changes:

> Finally, the ACG is concerned that the Final Rule irrationally establishes different practice expense relative value units (RVUs) for certain endoscopic procedures depending on whether such procedures are provided in a facility or non-facility setting. Congress' decision to delay implementation of resource-based practice expense RVUs

reflects its concern that HCFA could not generate reliable practice expense data prior to the original January 1, 1998 implementation deadline. ACG believes that HCFA should use the additional one-year period granted by Congress to further develop practice expense data so that practice expense RVUs, once implemented, will accurately reflect actual practice expenses for all providers. No bifurcation of the fee schedule into facility and non-facility categories could legitimately be implemented unless and until a complete practice expense methodology is implemented in accordance with the rules established under BBA '97.

The Differentiation of Non-Facility vs. Facility Under Both Practice Expense RVUs and Total RVUs is Inappropriate. Congress Did Not Intend That BBA '97 Was Authorizing/Establishing A Permanent Bifurcated Fee Schedule With Its Inherent Incentives To "Steer" Patients To A Specific Site For Services

HCFA has inappropriately and prematurely re-structured the Medicare physician fee schedule in establishing differing levels of physician Part B reimbursement depending upon where the procedure was performed. From the beginning of the Medicare physician fee schedule through the 1997 Fee Schedule that was announced on November 22, 1996, HCFA has observed a policy of a single fee for each CPT code, regardless of the site of service. On June 18, 1997, HCFA published in the Federal Register its proposal to establish a new means for computing practice expenses, and as part of the proposal first articulated in this publication for the practice expenses, HCFA added separate computations for practice expenses for in-office and out-of-office services, increasing the number of columns for each CPT code from 4 (in the 11/22/96 rulemaking) to 8 (in the June 18, 1997 practice expenses proposal). This, for the first time, resulted in two distinct composite RVUs per code--one labeled, "Total in office" and the second labeled, "Total out of office (headings have now been shifted to non-facility and facility)." In summary, this bifurcation represents a modification that first appeared in the 6/18/97 HCFA practice expense proposal.

In examining the statute, Congress did not explicitly direct HCFA to pay differing Part B physician reimbursements for the identical physician service, depending upon where that service was performed. What HCFA has published in its October 31, 1997 fee schedule announcement is to implement this same bifurcated structure with the only modification being in name only. We believe adoption of a permanent bifurcated fee schedule is not what Congress intended by the BBA 97 transitional provisions, particularly in light of the explicit Congressional decision, after reviewing the June 18, 1997 Federal Register notice, to delay implementation of any new methodology for practice expenses until January 1, 1999.

The format for the 1998 Medicare physician fee schedule should have been exactly the same as for the 1997 Medicare physician fee schedule, i.e., a single value for the practice expense RVUs for each code, and a single total RVUs for each code. The 1999 fee schedule for endoscopic services should return to that format. *The differentiation of non-facility vs. facility under both practice expense RVUs and total RVUs is inappropriate, does not have a specific, permanent legislative mandate, and is inconsistent with the intent of the BBA '97 provision to delay implementation of the practice expense rule until January 1, 1998, after a new rule (different from the June 18, 1997 proposal which is the basis for the facility/non-facility differentiation) has been promulgated subject to the additional controls mandated by Congress.* HCFA needs to drop the facility/non-facility differentiation now rather than place the entire fee schedule

subject to legal challenge as to its validity. **We are attaching ACG's substantive critique of the comparable in-office/out-of-office differentiation that we had submitted in our comments on the June 18, 1997 proposed rule, with the request that it be incorporated by reference into these comments.**

The incongruity of this process is apparent when we examine what HCFA has promulgated, which simply lacks validity. Some codes are unchanged from 1997-with identical facility and non-facility values. Codes that have smaller reimbursement levels have differentials/reductions between facility/non-facility payments that are twice as large as for other services that have double the level of reimbursement. As published, this bifurcated approach is clearly inequitable, and it is obvious that it is not sufficiently coherent to form the basis for reimbursement under the Medicare program.

Obviously, the correct answer here is that HCFA's incentives toward office-based colonoscopies are out of sync with the prevailing standard of care, physician malpractice obligations, and state law. The answer is NOT to simply drop the practice expense payment for office procedures to the same unfairly low level as this proposal would prescribe for outpatient services. That would compound the inequity. **HCFA needs to scrap the office/outpatient differential in practice expense payment, and return to the current policy of a single, fair unified fee--at a minimum at the level which had prevailed in the 1997 Medicare Fee Schedule (MFS), prior to the June, 1997 NPRM--reinstating a single level--to fairly compensate physician practice expenses**, whether in the outpatient or office setting (the type of site-neutral policy that PPRC espoused to Congress), and continue to use the tray fee **(See comments under Paragraph 9 below)** and site of service differential to address the differences between costs/payments for office and outpatient site of service. We believe that the plans to change the site-of-service policy across the board are ill-conceived. We know there is a compelling reason not to adopt the policy as to GI services, and that reason is patient protection in these procedures which require conscious sedation.

In conclusion. HCFA's decision to increase payment for office-based endoscopic procedures (and decrease outpatient fees) will lead to major problems. Gastroenterologists may not be able to provide the same assurance of safety in many cases when Esophagogastroduodenoscopies (EGD) and colonoscopies are performed in an office. These procedures require conscious sedation and are often associated with additional therapeutic modalities. such as polypectomy and control of bleeding. They should be performed in an outpatient or inpatient endoscopic center. Among other things, such units have monitoring and resuscitation equipment, specific safety and building codes, appropriately trained personnel, credentialing of provider qualifications, sterilization equipment, backup generators, and the list goes on. But in short, they are constructed, maintained, and managed for the safety of the sedated patient undergoing upper and lower endoscopic procedures.

The practical effect of this differential will motivate utilizing physician offices as the site of services. and this may not be the safest place for all procedures. By establishing a higher RBRVS for "office procedures", you will be using a financial incentive for some physicians to develop a false sense of security and inappropriately begin performing EGDs and colonoscopies in their offices. There has been no clinical evidence, to our knowledge, to support a change from the standard of care of performing such procedures in an ASC or hospital-based endoscopic center. This proposal, if enacted. can lead to placing Medicare patients, who are already at a higher risk from endoscopic complications because of their age and co-morbidity problems, at an even higher risk for serious complications and potentially delivery of

suboptimal care. Liability issues could potentially be expected to arise from such a HCFA-inspired change in practice standards.

8. ACG Opposes Plans To Eliminate the Existing Site-Of-Service Differential (as maintained at least through 1997) and to Replace It With a New Policy

HCFA's proposal to replace the site-of-service differential with two levels of practice expense RVUs by code is premised on its contention that practice expenses for hospital-based and ambulatory surgery center procedures are covered under the facility fees. In fact, a facility fee is paid to the institution and the physician does not receive that payment nor does it cover the physician's expenses. Therefore, the policy HCFA proposes is too short sighted and, as HCFA should clearly understand, is inequitable.

As noted above, we therefore oppose the proposed revisions to policy Section 414.32 modifying the site-of-service differential.

9. ACG Opposes Plans To Scrap Separate Tray Fee (Section 414.34)

HCFA has also proposed to discontinue separate payment for supply codes, i.e., A4263, A4300 and A4550. Previously HCFA established RVUs which included practice expense payments to physicians for all procedures. The agency recognized that there were additional costs involved for supplies when services were provided in the physician's office and provided these tray fees to cover those costs. This policy was acknowledged favorably by PPRC in its background documentation incorporated into the legislative history which persuaded Congress to enact a resource-based practice expense policy. HCFA, through this rulemaking, is initiating steps to cut significantly the practice expense RVUs for all procedures including those done in the office. Therefore, HCFA is already ratcheting office supply fees lower. Maintaining a separate tray fee is the preferred, proven way of increasing the reimbursement to cover practice expenses associated with procedures performed in the office, without the many problems that would be encountered by the adopting of the proposed bifurcated "Facility Fee Schedule." To remove the tray fee which had been instituted to recognize higher in-office costs is unwise and unwarranted.

As noted above, we therefore oppose the proposed revisions to policy Section 414.34 relating to separate payments/tray fees for medical supplies.

10. Budget Neutrality Provision Is Being Used To Unfairly Dictate Gross Underpayment of Practice Expenses for Procedure Services

The Pending Proposal Is Not Truly Budget Neutral, and Thereby Violates the Intent of Congress When it Mandated Placing Practice Expenses on a Resource-based Methodology

Dating back to 1993 when Congress had discussed and legislated on the topic of Medicare practice expenses, up through the 1997 Balanced Budget Act amendments, the premise of re-computation of the Medicare fee schedule's practice expense component has been that it would be budget neutral. However, we believe that the current proposal is not truly budget neutral, because the addition of the bifurcated fee schedule (first initiated in HCFA's June 18, 1997 practice expense proposal) will generate significant net reductions in the amount HCFA pays out to the extent that physicians are incentivized to

perform their procedures in the office instead of at the hospital outpatient facility or at the ambulatory surgery center. HCFA has consistently accounted for, and attempted to estimate the impact of behavioral change where the agency believes a change in the rules may create incentives for additional services to be used and federal expenses incurred. In this instance, the net effect of the behavioral change that HCFA seems to be incentivizing will be to reduce HCFA costs by eliminating facility fee payments to hospital outpatient departments and Medicare-certified ambulatory surgery centers. This tends to generate positive revenue benefits to the Medicare program, but HCFA does not appear to have incorporated this potential savings into its computations on budgetary impact--the rule would generate savings that should be factored back in to permit lesser cuts than are contemplated. Since facility fees that are averted will come at the expense of providers, the proposal also significantly understates the financial impact. While most gastroenterologists do not have an ownership interest in an ambulatory surgery center, some do, and the impact of this rule on them will be remarkably greater than has been calculated. Moreover, it is not even clear whether HCFA's calculations of specialty impact take into account the split between facility and non-facility cases. For example, in gastroenterology, about 95% of cases are done in a facility setting, so these specialists will be hit extremely hard with much lower reimbursement (unless HCFA's action forces a behavior change to undertake procedures in uncertified office settings)--the magnitude of HCFA's estimate of projected cuts does not appear to take this into account.

The departure of this rulemaking from true budget neutrality is both contrary to Congressional intent, and we believe threatens the legitimacy of the entire rulemaking.

The plan does not do anything to reduce the cost of government; it simply re-distributes resources among winners and losers.

Additionally, we would like to examine both the accuracy of HCFA's interpretation of Section 1848(c)(2)(B)(ii)(II) of the Act as well as specific interpretations HCFA has drawn in terms of projected payments had adjustments not been made.

In drafting the bill which originally ushered in the RBRVS, the House Budget Committee emphasized that the Secretary should make changes in relative values only to reflect changes in the practice of medicine, in the delivery of services, or in technological innovation--not simply to reduce expenditures.

We believe that HCFA seriously misinterprets the Congressional intent with respect to the parameters established for budget neutrality. The premise of the proposed rule seems to be that, "Section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs because of changes resulting from a review of those RVUs may not cause total physician fee schedule payments to differ by more than $20 million from what they would have been had the adjustment not been made. If this tolerance is exceeded, we must make adjustments to the conversion factors (CFs) to preserve budget neutrality"(from June, 1997 NPRM). It seems clear to us that Congress intended HCFA to, in essence, take a "freeze frame" of the "average payment per beneficiary" based on the laws and payment practices as they existed on the date of enactment, and incorporate volume increases triggered by increases in the number of beneficiaries and any inflation updates, and to calculate the budget neutrality on this basis. Subsequent measures which hastened certain cuts should not have a multiplier effect of reducing payments quicker and also reducing the conversion factor as they appear to under HCFA's interpretation.

HCFA's interpretation misunderstands the use of "current"--this clearly means current rules applicable as of the date of enactment of the RBRVS fee schedule, not the rules which prevail at a later time. Clearly, HCFA's misinterpretation in this area has caused tremendous problems, converting the original intent of the law from providing equity in physician payments to a series of virtually universal and draconian cuts in payments to physicians. For instance, the continual shifts required to remedy flaws in the original work RVUs have taken the RBRVS fee schedule from being a parsimonious payment plan to a completely unrealistic one through consistent attrition in the work values.

In conclusion, we believe HCFA's interpretation of the budget neutrality provision serves to exacerbate an already serious problem. HCFA's concern to reduce the payment per service to account for volume increases is misplaced. HCFA is simply wrong in interpreting the Congressional directive as meaning that the 1998 pie needs to be virtually exactly the same size as the 1997 pie; Congress recognized that there would be increases in volume primarily based on an increase in the number of beneficiaries. Hence, as was noted above, HCFA's job is limited to computing what the total 1998 payments on a per beneficiary basis would have been, using the rules as they existed on the date of enactment of OBRA '89. Volume increases triggered by larger number of beneficiaries/technology advances/inflation increases could be added to arrive at the enlarged 1998 pie that Congress contemplated. HCFA would then set about to apply the new rules which will result in dividing the pie differently than has been done in the past.

11. HCFA's Decision to Use 1998 As The Base Year is Incorrect; 1997, Not 1998 Should Be The Base Year

ACG noted previously in our December 30, 1997 comments on the October 31, 1997 regulation establishing the 1998 Medicare fee schedule:

> ACG also is concerned that both the Final Rule and the Notice of Intent to Regulate assume that the 1998 adjusted practice expense relative value units (RVUs) are to be used in the transition formula for phasing in resource-based practice expense RVUs. This contradicts the plain language of the BBA '97 by using adjustments that were intended to accomplish a one-time redistribution from specialty codes to primary care codes to perpetuate the redistribution for three more years at a cost of an additional $490 million to specialists.
>
> We therefore strongly urge HCFA not to use the 1998 adjusted practice expense work values in the phase-in period. Instead, HCFA should follow Congressional intent by using the practice expense RVUs that would ordinarily have been derived from the pre-amendment formula and revise the language of the Final Rule accordingly.

HCFA states that they have selected 1998 as the base year for the transitional provisions that were referenced for BBA '97. HCFA also notes that several commentors have argued in favor of 1997 as the appropriate base year. Had this rulemaking proceeded on the original timetable, it is clear that 1997 would serve as the base year for a transition to full and immediate implementation of the rule in 1998. The legislative history makes clear the House initiated legislative provisions to delay the effective date by one year, and to establish a four-year phase-in period. Only AFTER it became clear that there would almost certainly be a legislative mandate for this delay/phase-in, was the so-called down-payment

provision proferred, essentially to placate with a one-time boost, the reimbursements for primary care, cognitive services that would have benefitted from the immediate 1998 full implementation. Congress set a specific numerical maximum on the down-payment provision, i.e., a $390 million limit, since the impact of HCFA's using 1998 as the base year pushes this figure up by a factor of between 2 and 3. *HCFA's interpretation and use of 1998 as the base year is incorrect and contrary to Congressional intent. HCFA must modify the final rule to recognize 1997 as the proper base year.*

To proceed under HCFA's current interpretation would be to violate the BBA and unjustifiably re-allocate value units from physicians who practice primarily in hospitals to those who practice primarily in offices.

By statute, the total aggregate reallocation cannot exceed $390,000,000. This is not a per-year limitation. Making the re-allocation for each year of the transition will certainly exceed the aggregate limit.

12. Failure To Survey/Need For Actual Data

In HCFA's September 20, 1995 submission to the Office of Management and Budget (OMB) [required by law to justify the study] entitled, *Data Collection and Analysis for Generating Procedure-Specific Cost Estimates*, states the following:

> "In order to develop service specific (e.g., CPT-4) estimates of medical practice expenses, it is necessary for HCFA to collect detailed costs and practice characteristic data (e.g., service-mix) at the practice level for different practice types representing the range of medical specialties. Such data are currently unavailable from existing HCFA administrative files or other research data sets." [Emphasis added] HCFA's own statements established that collection of actual objective data on practice expenses was critical to developing a fair and accurate rulemaking.
>
> HCFA recounts that under its contract, ABT "originally intended to use two processes, the 'Clinical Practice Expert Panels' [CPEPs] and 'Survey and Practice Costs' to collect data that could be used to generate practice expense RVUs for each service."

Through a HCFA contract to ABT Associates, Inc., data on the direct expenses involved in each service were collected from 15 clinical practice expert panels.

HCFA's national survey was abandoned in September, 1996, due to low response rates. This left HCFA without a major source of data on practice expenses, and how PEs are distributed across specialties. In reporting on the failure to complete ABT's "Survey of Practice Costs" or some similarly objective survey instrument, HCFA notes that "the survey would have yielded data to assist in the development of methodologies to allocate indirect costs to specific services, the survey itself would not have determined the indirect costs for specific procedures."

No alternative approach to gather this necessary actual data was formulated by the agency. This development left HCFA without its intended major source of actual relevant data from physician practices. Thus, instead of using actual practice expense data, HCFA has relied on hypothetical assumptions, and formulaic approaches.

ACG stated in previous comments that ...

> The College recognizes some of the problems with time constraints in collecting new data, as well as problems with the concept of "refinements" to the ill-defined process of developing a new practice expense methodology, that are mentioned in the comments of the Practice Expense Coalition. The College concurs with the Coalition's recommendation, "...that HCFA publish interim values in May that cause the least disruption to current payments. The agency has no information to do otherwise. The NPRM should then lay out in explicit terms how HCFA plans to accomplish the balance of the work, including data collection. A specific timetable should be announced. For example, HCFA could indicate that data collection will be completed by a time certain in the year 2000 or some other achievable point in time within the transition period."

AMA Socioeconomic Monitoring System (SMS) data were used by HCFA *despite the fact that SMS data were never collected for the purpose of developing relative values.* Practice expenses are only one of many issues addressed by the AMA SMS survey, so it lacks sufficient detail on practice expense categories or on how personnel, office space, supplies, and equipment are used.

Actual practice expenses across specialties have not been documented by the agency or independently to date. Delays and problems in gathering data and complex data collection surveys impeded progress on this project and precluded the Secretary of HHS from timely compliance. In 1996, HCFA canceled its contract with the outside contractor and assumed responsibility for completing the data collection and analysis -- tasks which were not timely or appropriately completed. Despite the lack of reliable data, HCFA proceeded to publish this proposed rule.

13. Direct vs. Indirect Split

Last year, HCFA detailed at some length the steps in the development of its methodology and noted that the agency adopted a major distribution of direct and indirect expense RVUs from Medicare data at 55% direct and 45% indirect. This represented one of the more serious flaws in the 1997 rulemaking in continuing to substantially understate indirect costs. A variety of other sources have found direct costs well below 50% and indirect costs well in excess of 50%. This ratio varies widely by specialty.

Procedure practice expenses can be divided into direct expenses, which are the specific staff, equipment, and supplies utilized in the procedure, and indirect expenses, which include office rent, furniture, utilities, and other costs which cannot be attributed to specific procedures. At one point, HCFA's proposals assumed that all physicians have the same indirect costs. AMA data finds, however, that indirect costs (using HCFA's definition of the costs included in indirect costs) range from $35,000 to $200,000 for different specialties.

In the June, 1997 NPRM, HCFA made an assumption that all medical equipment is in use 70% of the time that an office is open; subsequently, the agency amended this estimate to 50%. This assumption was essentially a guess; in reality, it greatly overstated actual utilization. The result is that the cost of each piece of equipment that was attributed to each service for which the equipment is used was much too low. HCFA also lacked data about the actual prices paid by physician practices for their equipment. After universal purchasing of the equipment, the price drops. However, HCFA's methods used data on

current equipment prices, not actual purchase prices. The result of HCFA's approach in 1997 was the determination that 55 percent of practice costs would be classified as direct and 45 percent as indirect. These results are wholly inconsistent with those of other researchers. The Lewin Group ACS survey found direct expenses in the **25 percent to 45 percent range**. Similarly, Pope and Burge found direct expenses to be approximately **36 percent** of the total, while Dunn and Latimer found direct expenses to be about **32 percent** of the total. HCFA substantially underestimates the indirect costs.

In the end, HCFA's system of practice cost allocation must accurately reflect the fact that certain specialties do indeed have relatively high practice costs per physician. One way to do this is to allow for surgical and other high practice cost specialties' higher proportion of indirect procedure expenses. Another way would be to use physician work or current Medicare PE payment as the basis for allocating indirect practice costs back to individual codes. The method HCFA used last year in its bottom-up calculations were not only inaccurate but also unfair to procedure-oriented specialties.

14. ACG Operating Ratios Report - Data on GI Practice Expenses Derived from ACG Operating Ratios Report Demonstrates That HCFA NPRM Grossly Understates GI Practice Expenses

Since 1994, the American College of Gastroenterology has conducted an annual GI practice operating ratios report. This project was initiated to offer gastroenterologists a vehicle that would enhance their practice efficiency and permit them to have a valid basis for comparing their own performance by expense category with that of other similar practices.

There are a total of 17 different expense categories recorded in the annual report. Practices report their total revenue from patient services, as well as expenses in each of these seventeen categories. Practices submit their information in raw dollar amounts to an independent accounting firm which maintains a key that links the alphanumeric ID codes on the forms submitted, so that the practice may be assured of complete confidentiality. The various expense categories are therefore presented in a ratio format, measuring each expense category as a percentage of total patient practice revenue.

Data has been recorded on GI practices for four separate years, 1994-1997. The number of responding practices has ranged from a low of 100 practices, to a high of 156 practices. *It is important to note that this database covers more gastroenterology practices than those represented in the AMA SMS database, and, to our knowledge, represents the largest database anywhere on the expenses of operating a GI practice.* Like the SMS, the ACG Operating Ratios Report was established to collect data for a purpose which encompasses practice expenses but has a more general purpose, and, data for three of the four years referenced were collected data prior to the development and publication of HCFA's first practice expense proposal last year.

We have provided the annual average summaries for all practices for all three years. The data from the ACG Operating Ratios Report demonstrates two things conclusively:

(1) HCFA's NPRM Understates GI Practice Expenses

According to HCFA's data from the AMA's Physician Marketplace Statistics, 1996, practice expenses consume $181,177 per physician (updated for inflation) of the revenue of the average

practice. This information is drawn from the AMA SMS and similar databases, as well as on the expert experience represented in the CPEP. By contrast, the larger database consisting of the ACG Operating Ratios Database demonstrates that practice expenses consume $269,397 per physician of the total revenues derived from patient care services. In accessing comparable data for GI practices from the 1994 Abt Study of GI practices, the reported number of $183,883 from its survey, when adjusted for inflation, would amount to about $200,000 in 1998's dollars.

(2) ACG Data Demonstrates that HCFA Overstates Percentage of Direct Expenses

HCFA's 1997 conclusion that direct expenses constitute 55% of total practice expenses for medical practices, regardless of specialty was inaccurate. HCFA therefore also concluded the correlate that indirect expenses constitute 45% of total practice expenses for all medical practices, regardless of specialty also an error. Data from the ACG Operating Ratios Reports reveal that even under HCFA's old definition, in which all labor costs are direct, below 50 per cent of the total practice expenses are direct costs.

(3) GI Practice Costs Compiled Directly from GI Practices Demonstrate That AMA SMS Data Understates GI Practice Expenses

We underscore the problems and biases with the SMS database as to gastroenterology; these include a very small sample, the lowest expense level of any specialty, and a bias relating to minimal numbers of mid-level physician extenders.

15. Commentary from/on the Abt Associates Inc. Study of "Practice Costs in Gastroenterology, February, 1995"

In 1993, multiple gastroenterology associations, including the American College of Gastroenterology, the American Society for Gastrointestinal Endoscopy, and the American Gastroenterological Association engaged Abt Associates to conduct a study on practice expenses. The study included a survey of a sample of GI practices. The conceptual premise for this study was the approach to practice expenses articulated by the PPRC in its recommendations to Congress, which ultimately formed a major component of the legislative history for Congressional action on practice expenses. As noted above, HCFA has departed in major proportions from that conceptual framework-- e.g., failure to collect independent data on physician practice costs, the decision not to track the different proportions of direct/indirect expenses across specialties, HCFA's departure from having PE RVU results which approximate actual practice expenses in various specialties, and abandoning an incentive-neutral approach as between office and outpatient locations.

While the results of the GI Practice Expenses Study are therefore probably not directly applicable for purposes of the specific PE RVU values recommended by HCFA in this NPRM, the final study report is incisive in terms of how to go about the process of determining practice expense RVUs under the PPRC concept, and also provides some important information about practice expenses in gastroenterology. We have, therefore, detailed below some key excerpts from the study report which we believe are directly relevant, and which present information or methodologies which run directly counter to what HCFA proposed in the NPRM.

Findings

(1) The median gastroenterology practice nearly breaks even under the current Medicare reimbursement for practice expenses (as of 1994 when data was collected)

(2) Reimbursement under the PPRC "resource-based" proposal would be less than two-thirds of the current fee schedule level and would imply that *less than 60 percent of the average gastroenterology practice's current practice costs would be reimbursed.*

(3) Only about 10 percent of practices would be adequately reimbursed under the PPRC proposal. Given possible errors in the data and/or unusual practice situations, this finding suggests that few practices would survive under that reimbursement scenario, given their then current cost configurations.

(4) The PPRC proposal reduces the included gastroenterology practices' reimbursement for practice expenses by a median of 39 percent.

The median practice would receive only about 50 percent of its costs.

The expressed goal of the PPRC in the determination of practice expense reimbursement was to make it incentive neutral. Incentive neutrality is defined here to mean that the physician has no financial incentive to provide one type of service over another, or in some setting over another. (Approach suggested in Pauly, M.V., and Wedig, G.J., Allocating Practice Costs, HHS Agreement No. 99-C-99169/5-02, 1991.)

It is also true that the hospital-oriented practices are likely to have more indirect costs relative to each dollar of their direct costs than the office-oriented practices. Thus, their required mark-ups are different.

The problem this presents in allocating indirect costs to determine appropriate fee levels is that the mark-up levels required for each "pure" practice will be different than those for the hybrid practices, and the hybrid practice mark-ups will be appropriate only on average.

Data indicate that office staff devote "almost one third of their time in activities related to either surgical or other non-office patients". In addition, clinical office staff spend almost 5 percent of their time on hospitalized patients. This type of information serves to discredit the notion that physician office staff only provide services related to activities that occur in the office. Approximately 5 percent of patients are 'no-shows' and 10 percent cancel their appointments and must be re-scheduled. The physicians surveyed tend to practice at two or three hospitals, and to spend less than half their time seeing patients in their offices. [Tables 5, 6, 7]

TABLE 5

GASTROENTEROLOGY PRACTICE ALLOCATION OF STAFF TIME (REPORTED DATA REPRESENT THE MEAN FOR EACH CATEGORY)

Staff Time	Independent	Affiliated	Overall (non-center)	Endoscopy Center
% of non-clinical office staff's time devoted to office patients	61%	56%	57%	49%
% of non-clinical office staff's time devoted to endoscopic procedures or surgery	22%	9%	23%	34%
% of non-clinical office staff's time devoted to patients seen outside office or operating room (OR)	8%	6%	6%	9%
% of non-clinical office staff's time devoted to activities not related to support of patient care	6%	6%	6%	9%
% of non-physician clinical office staff's time devoted to inpatients currently hospitalized	4%	6%	5%	5%

-ABT Associates, Inc., "Practice Costs in Gastroenterology," February 1995

TABLE 6

GASTROENTEROLOGY PRACTICE PATIENT VISIT CANCELLATIONS (REPORTED DATA REPRESENT THE MEAN FOR EACH CATEGORY)

Visit Cancellations	Independent	Affiliated	Overall (non-center)	Endoscopy Center
% of "no-shows" each week	4%	7%	4%	3%
% of patients who cancel and are rescheduled	12%	8%	10%	8%

-ABT Associates. Inc., "Practice Costs in Gastroenterology," February 1995

TABLE 7

Descriptive Information of Sampled Practices

Characteristics of Practice Physicians

	Mean	**Median**
number of hospitals where physician practices	2.6	2
weeks providing patient services per year	47	48

Caseload of Sampled Physician

Weekly Hours:	Mean	**Median**
in the office (or other setting) seeing patients	20	20
performing GI procedures in any setting	17	17
on hospital rounds (excluding on-call time)	10	10
in the emergency room	2	1
in discussions with patient/family or communicating	6	5
providing other patient services, e.g. interpreting	3	2
travel for professional services	3	2
performing administrative duties	5	4
Total	66	61
Weekly Call Time:		

on call for a hospital	17	1
on call for practice	53	41
Total	**70**	**42**
Weekly Visits:		
E&M (CPT 99201-99499 in the office)	36	34
E&M (CPT 99201-99499) hospital (medical admissions/consultations)	17	10
E&M (CPT 99201-99499) hospital (post-operative patients)	13	10
Total	**66**	**54**
Weekly GI Procedures	22	20
Teaching	**Yes**	**No**
Clinical work involves teaching medical trainees	54	42

-ABT Associates, Inc., "Practice Costs in Gastroenterology," February 1995

The above data demonstrate that the degree of underpayment is substantial even if the reported expenses substantially overestimate the costs of operating an efficient gastroenterology practice.

16. <u>Another Better Data Source Available for GI Practice Expenses</u>

Since 1994, well before the practice expense rule was initiated, the American College of Gastroenterology has compiled a comprehensive annual report on the costs of operating a GI practice, in the form of the ACG's Annual Operating Ratios Report. ACG member practices receive a survey form and detailed instructions as to what is included in the various cost categories. To assure confidentiality, practices who participate in this annual study submit their completed survey forms to an independent CPA firm. Forms are inscribed with random alphanumeric codes. Only the accounting firm has the key to link the alphanumeric codes back to a specific practice, and this is used solely to alert each of the participating practices to where its data appears in the final report. The use of the independent CPA firm adds credibility to the data submitted in that any fear that the information may become known to either the College's staff or another GI practice is alleviated. The actual data submitted by members is in real dollars, but under the rules for the publication, it is published only in a ratio form, so that each expense item appears as a ratio in which the numerator is the cost attributable to that item, and the denominator is the total gross revenue of that practice. In each of the four years in which ACG has conducted this study, 100 or more practices have participated. The data is practice-based, so that presenting this information in a per physician format requires dividing the average nationwide cost in each category by the median number of physicians in the practices surveyed.

For purposes of the Table below and its comparison of practice expenses by category and practice expenses per physician, we have identified the average or mean total gross practice revenue for each of

the four years, as well as the average ratio for each of the survey categories. We arrived at categories similar to those expressed by HCFA by consolidating the 17 subcategories of expenses reported in the ACG Operating Ratios Report into 7 categories comparable to the data categories HCFA derived from the AMA SMS files. We are aware that HCFA has used median expenses per category instead of means--however, we have used means for two significant reasons: (1) the only rationale for selecting medians over means would be if there were a wide range of values reported. Since the Operating Ratios Report excludes from its averages data on practices that reported operating profits that were either below -20% or more than +33%, the most significant outliers have already been excluded; and (2) national average ratios in each of the 17 practice expense categories appear in the Operating Ratios Report, whereas medians have not been reported.

The following is an overview of the data derived from the ACG Operating Ratios Report. This report has a significantly higher sample than the AMA SMS data, and therefore is more representative of the typical GI practice. The results derived from four years of data from the ACG Operating Ratios Report serve to confirm and substantiate that the values derived from the AMA SMS database significantly understate the actual costs of GI practice. Given the small AMA SMS sample size, and the fact that gastroenterology had the lowest percentage response rate of any specialty in the SMS database, it is clear that HCFA needs to look at and rely on other data sources. The College would be pleased to work with HCFA to derive additional information from the ACG Operating Ratios Report.

Table 8

ACG OPERATING RATIOS DATA

		1994 n=100 practices average patients per physician per week=48.34		1995 n=154 practices average patients per physician per week=57.32		1996 n=136 practices average patients per physician per week=50.90		1997 n=110 practices average patients per physician per week=43.62		
	SMS Data Mean	Mean per physician	Mean per practice	Mean per physician	Mean per practice	Mean per physician	Mean per practice	Mean per physician	Mean per practice	% ACG oper. ratios >AMA/SMS
Non-Physician Payroll	63,464.0	64,296	192,889	62,305	186,914	70,584	211,752	70,213	280,850	10.63%
Clerical Payroll	41,573.7	65,647	196,940	51,758	155,275	72,385	217,155	70,710	282,842	70.08%
Office Expenses	48,693.7	74,631	223,892	71,533	214,599	81,458	244,374	86,022	344,091	65.63%
Medical Equipment	5,052.2									
Medical Supplies	7,003.3	8,514	25,542	9,228	27,685	10,007	30,021	11,267	45,065	60.88%
Other Expenses	30,833.7	32,060	96,180	37,371	112,114	41,963	125,890	31,185	124,739	1.14%
TOTAL EXPENSES excluding PLI & M.D. Payroll	155,046.8	245,148	735,443	232,196	696,587	276,397	829,192	269,397	1,077,587	73.75%
Average Revenue (Mean)			1,761,540		1,719,543		2,001,429		2,489,807	

Commentary on Differences Between the AMA SMS Practice Expense Category Totals and the ACG Operating Ratios Report

Since the Operating Ratios Report is a practice-based survey instrument, it is important to recognize that the actual number of GI physicians represented in the ACG Operating Ratios database ranges from 372 in 1994, on up to 537 in 1996, with 515 physicians covered by the 1997 data, tabulation of which has just been completed. So this represents nearly 7 times the number of physicians as were measured in the AMA SMS database.

When the various categories of practice costs per physician are compared, the expenses compiled by the AMA SMS database are lower in every category on an average basis. The spread between the two databases are very substantial. **In the total expenses, excluding PLI and M.D. payroll category, AMA/SMS states these at $155,046, whereas the Operating Ratios database references per physician expenses of $269,397 for 1997--73.75% higher than the AMA/SMS database.** There are very large differences in three subcategories--**Operating Ratios 1997 numbers for clerical payroll are 70.08% higher than AMA/SMS, and 65.63% higher in office expenses** (because the Operating Ratios Report does not separately measure Medical Equipment Costs but includes these in office expenses, AMA/SMS data have been consolidated to create a combined category of Office Expenses + Medical Equipment to achieve comparability), and are **60.88% higher for medical supplies**. There are more modest spreads on **non-physician payroll**, where **Operating Ratios exceeds the AMA/SMS numbers by 10.63%**, and a close parallel on Other Expenses where Operating Ratios numbers are just 1.14% higher than AMA/SMS. It is important to note that in this latter category however, the ACG Operating Ratios report value for 1997 is lower than in any of the three preceding years and, in that respect, represents a data outlier.

In summary, the fact that the Operating Ratios Report represents a database of physician reporters 7 times larger than AMA/SMS, spanning a period of 4 years, and consistently demonstrates much higher values in all categories of practice expenses than those reflected in the AMA/SMS data, another strong challenge to the credibility of the data HCFA has used in this NPRM as the basis for GI practice costs has been added. This data, taken together with the exceedingly small sample size of the AMA/SMS GI data, the fact that the response rate in GI was the lowest of any specialty, the inherent bias relating to physician extenders, and some of the face validity problems noted when the AMA/SMS data subset for gastroenterology is compared with general surgery, general/family practice and all physicians, makes the conclusion that HCFA has significantly understated the proposed PERVUs for gastroenterology virtually inescapable.

Other Data Sources Also Tend to Confirm That AMA SMS Data on GI Practice Expenses Are Inaccurate

The Operating Ratios Report is not alone in pointing to significant undervaluation of GI practice costs in the data used by HCFA. We recently had the opportunity to review the report prepared by Gary Siegel and Associates, which was commissioned by three GI organizations. While some of the eighteen practices which provided data for that report may well be members of the College, ACG was not a participant or funder of this study. However, we do note that the Siegel report likewise concludes that the AMA SMS data significantly understates actual practice costs for a typical GI practice.

Given the findings that HCFA's AMA SMS data is at variance with data collected through two completely independent data sources, at least one of which (ACG Operating Ratios) has a larger number of physician practices submitting data than the AMA SMS database, and the other which seems to have recorded larger amounts of data on specific services and procedures (Siegel) than the AMA SMS data, we believe that HCFA is compelled to look to these sources to provide a more reliable picture, both in generating a final rule and throughout the transition and refinement/implementation period. HCFA must immediately correct and compensate for the readily evident deficiencies and undervaluations within the AMA SMS data. But, more than anything else, the presence of multiple data sources, all indicating that figures derived from the decidedly small and suspect sample of gastroenterologists from the AMA/SMS report are skewed substantially lower than any of the other sources points to the compelling need for HCFA to look to sources other than AMA/SMS if HCFA is to develop fair and accurate PERVUs for gastroenterology.

ACG Membership Survey -- 1994

In the summer of 1994, the American College of Gastroenterology conducted an extensive membership survey. The survey was forwarded to every member of the ACG, and a total of 3,177 responses were received for a response rate of 62.0%. The survey is a physician level survey, with responses from individual doctors rather than responses per practice. This survey did not attempt to measure practice costs, but it did cover a significant number of demographic factors. Some of the key results from this survey are summarized below.

Key Conclusions from ACG's 1994 Membership Survey, Including Responses of 3,177 Physicians With Respect to Issues Relevant to Practice Expenses

- Medicare, 36.3% - practice source income.
- The median age of the membership was 47 years in 1986 compared to 43.2 years in 1994.
- In 1994, 69.3% of the total ACG membership were Board-Certified in Gastroenterology. Among members with a primary specialty of Gastroenterology, the rate was 77.6%.
- In 1994, ACG members reported an average of 3.9 full-time GI specialists in their practice, including themselves. The median number was 3.0 specialists. Over half of the members practiced in a group with 2-5 specialists (57.4%).
- In 1994, 21.3% indicated only one specialist, suggesting a solo practice.
- On average, 74.1% of their time was spent on patient care at that time.
- On average, 31.9% of their practice time involves endoscopic procedures. Some 24.1% of members devote half or more of their practice time to endoscopic procedures. However, 6.5% devote less than 10% of their practice time to these procedures.
- Members reported an average of approximately 60 patient visits per week.

- On average, ACG members saw 41.7 outpatients per week, compared to 19.7 inpatients per week--a number which may include many endoscopic patients (some 95% of these cases were not performed in the office setting). Almost half of the members saw 26-50 outpatients per week (48.5%). Most saw less than 26 inpatients per week (77.1%).

There are some very notable and significant distinctions between the profile of gastroenterology derived from this sample, and the profile of the small number of participants in the AMA SMS database for gastroenterology. Among the noteworthy distinctions between the AMA SMS profile of 75-84 responses, and the ACG national membership survey covering 3,177 gastroenterologists are:

-- there is a good match on age--AMA/SMS said 45.7 years and the ACG membership database found 43.2 years

--there was a reasonable match on level of Medicare--AMA/SMS said 41.7% of revenues, while ACG membership database says 36.3%

--there was a discrepancy on percentage of Board-certified--AMA/SMS said 91% were Board certified; whereas ACG membership database said 77.6% (Note: since gastroenterology is a subspecialty board, it may be that the AMA/SMS data is capturing individuals who may be Board-certified in Internal Medicine, but not all of whom may have achieved the gastroenterology subspecialty boards)

--the size of group had a significant spread--the limited AMA/SMS pool shows 50.8% solo practice compared to just 21.3% solo in the ACG membership database, and 57.4% of the 3,000+ providing data for the ACG membership survey reported being members of a practice with 2-5 specialists.

--ACG members reported spending 74.1% of their time spent on patient care, with approximately 60 patients visits per week (which is higher than the consistent totals reported over a four year period in the ACG Operating Ratios Report), with two-thirds devoted to outpatients. HCFA has used a complicated formula to develop its practice expenses per patient hour, which does not appear to include specific data collected on the number of patients seen per week. Moreover, HCFA has made assumptions using the average annual hours worked by physicians in various specialties as applicable to all employee physicians in that field. We do not believe that these hours were reduced to account for the fact that in gastroenterology, for example, 26% of the physician time is spent in non-patient care areas. In summary, the practice expenses per patient hour computation is too important not to include a direct input on the number of patients seen per week in each specialty; moreover, it would be a remarkably low number if the roughly one-quarter of time spent in non-patient care areas were not accurately discounted.

17. Inequity of HCFA Policies Relating to Ambulatory Surgery Centers

Unfair Treatment for Ambulatory Surgery Centers

We are particularly troubled by HCFA's recurrent failure to address ambulatory surgery centers (ASCs) as well as the unfair treatment accorded to ambulatory surgery centers by HCFA's grouping them in

terms of the greatly reduced outpatient physician fee rates. Generally, ambulatory surgery centers provide greater convenience to beneficiaries. HCFA generally pays less for their services than the comparable services in a hospital setting. HCFA's discriminatory treatment of ambulatory surgery centers, which have consistently supplied a cost effective means of delivering important patient care service; the agency's approach is unfair and irresponsible.

The proposal indicates that costs for clinical staff, medical supplies, and medical equipment furnished to hospital patients are included in the DRG payment made to the hospital as required by Section 1862(a)(14). The proposal fails to articulate a comparable rationale for including ambulatory surgery centers in the outpatient subcategory for purposes of practice expenses. The assumption that a physician's practice expenses are being covered by the facility fee paid to the ASC (generally less than the hospital & outpatient fee) is flawed, particularly where the physician performing the procedure has no proprietary interest in, and no income flowing from, the ASC. It is irresponsible and inequitable for HCFA to renege on its responsibility for fairness in payments to physicians by simply suggesting that physicians may seek payment from hospitals for a portion of the practice expense provided to the hospital under the DRG.

18. While Modestly Enhanced for Some Codes, RVU For GI Out-Of-Office/Billing, Scheduling, Records Remains Inadequate

In the June, 1997 NPRM, HCFA grossly understated costs for services in scheduling, patient preparation, records and billing provided by the gastroenterologist's office, as reflected by assigning the most token practice expense RVU for almost all major endoscopic codes performed in the outpatient setting. HCFA had proposed to allow approximately $5 for all costs associated with the office scheduling a procedure at an outpatient setting, providing and instructing the patient on the preparation for that procedure, other communications (e.g. follow-up questions initiated by patients), office follow-up of lab and pathology reports, communication of the results of the procedure to the patient (both verbal, and usually follow-up in writing), explanation of prescriptions, follow up medications and billing costs. In this NPRM, the PE-RVUs have been consolidated and there have been some modest enhancements. Conservative estimates from GI practitioners place the above office services steps at 1 ½ hours of staff time, at the very minimum--applicable to each procedure, regardless of whether provided as outpatient or in office. The PERVUs for the physician's cost on these facility-based procedures continues, nonetheless, to be significantly understated.

19. Implementing the Rule in a Format Similar to This Proposal Would Depart from Sound Health Care Policy

Since HCFA's practice expense rulemaking initiative, if implemented, will affect both access to care and quality of care, our Medicare patients are major stakeholders in this matter. Medicare patients deserve the highest quality of care available and to have choices, i.e., access to the physician of their choice.

The overall result of this proposed dramatic change in the Medicare fee schedule for gastroenterologists will be to make seeing Medicare patients, in many instances, a losing proposition. For example, the amount reimbursed may not be enough to cover the costs of keeping the office open during the time the patient was seen. We expect that some physicians may respond to these cuts by terminating their affiliation as participating physicians in the Medicare program; economic pressures could force those physicians who are not affiliated with Medicare as participating physicians to reduce or eliminate Medicare patients from their practice.

Patients and physicians alike are concerned that HCFA's proposal would unfairly and arbitrarily shift fees, with little regard for either collecting objective data on practice costs or the impact of the proposed changes in terms of quality of care. HCFA's proposal to substantially change the fee schedule is placing too great a burden on physicians. It is hard to disagree with the concept of compensation being tied to the work performed and resources used. However, this is incompatible with simply trying to reduce health care costs by unfairly and arbitrarily shifting fees with little regard for either collecting objective data on practice costs or the impact of the proposed changes in terms of quality of care. If this HCFA rule results in changes to the fee schedule that mean the government would reimburse the doctor less than the cost of keeping the office open during the time patients are seen, some physicians will almost certainly significantly reduce (or even eliminate) Medicare patients from their practice. The government cannot cut fees by 20% or more in certain specialties without seeing the results in reduced quality of patient care. We are strongly opposed to the development of a two-tiered system, with one level of care for those with private insurance and the second for government-reimbursed patient services. Such a system would reduce patients' ability to choose their own physician. Physicians may not be able to afford to spend as much time with or provide sufficient attention to those Medicare patients whom they are able to see.

Lower Fees Will Reduce Patient Access

Under HCFA's methodology, Medicare payments for many major surgical and other procedures would drop below Medicaid. The extreme practice expense changes proposed by HCFA would make Medicare the lowest payer for many important services, which could seriously hamper patient access to them.

Adverse Effect on Patients

This proposal will adversely affect patients--one likely result is fewer participating Medicare providers to choose from, and physicians could easily be "incentivized" to office-based procedures to the detriment of quality care.

Our nation's most at-risk populations--minorities and the disabled--could see their access to specialty care put at risk; rural areas and inner cities across the country could lose their access to life-saving

medical treatment. Medicaid patients are already widely perceived as charity cases. Medicare patients could be perceived the same way if HCFA's proposal is approved. Such a system would lead to reduced ability to choose one's own physician, as Medicare patients would be perceived as another form of charity care.

The proposed reimbursement cuts will severely compromise access to high quality, cost-effective specialty care. Physicians who cannot secure fair reimbursement for practice expenses cannot absorb these drastic reductions and continue to offer access to world-standard medicine. Adoption of HCFA's reimbursement plan will render near moot widely supported legislation to guarantee patient access to specialty care. Moreover, this problem will not be limited to Medicare beneficiaries. The problems of access to care in Medicaid are already well documented. If private insurers follow Medicare's lead, as often they do, payment inequities will mushroom, and other patients will find the quality of medical care similarly diminished.

HCFA's Proposal Will Unfairly Cut Fees, Devastate Practices, and Adversely Impact Both Patient Access and Quality of Care

The Medicare program already has undergone significant belt-tightening in order to assure the long-term financial stability of the program, and providers already have done their fair share. *In 1997, for the first time since the Medicare fee schedule was implemented, HCFA defied inflation and paid less for services in 1997 than it did in 1996.* Now, we face another proposal of massive cuts--but HCFA's program is not about Medicare reform--it is a preemptive strike at gastroenterologists, surgeons and others that would leave practices financially devastated. Just as importantly, cuts of this magnitude will almost certainly lead to serious cuts in both access to care and quality of care.

Until now, the practice expense discussion has been debated as an isolated issue. Serious disruptions and access problems may occur if policymakers impose drastic payment cuts. With Congress recently enacting new or additional physician payment cuts as part of the budget process, it is imperative that HCFA policies accurately reflect physicians' actual practice costs.

Because of its inaccuracies and data flaws, this proposal is grossly unfair and ill-conceived economically. If HCFA actually implements these drastic cutbacks, physicians will have to reduce their office staff dramatically. Patient satisfaction will go down, the quality of care they can deliver may deteriorate; physicians will have no choice. In no other sector of the economy would government consider mandating that employers cut their income by 20-25%! Yet that is exactly the kind of income re-distribution policy that HCFA is proposing.

Implementation of HCFA's Policy Would Endanger Medical Education and Research

The dramatic decrease in Medicare payments proposed by HCFA will have a devastating impact on our nation's academic medical centers. We risk undercutting these centers' ability to provide high-quality, specialized education for physicians. Moreover, the proposed HCFA reductions could result in fewer dollars for academic medical centers to distribute to their research facilities. Such cuts would have disastrous impacts on the kind of superb academic medical centers that attract our best and brightest young physician talent. If we send the message that we no longer consider education and research a

national priority, we will sacrifice one of our nation's greatest assets, our world-class teachers and researchers, and a generation of students. We cannot afford to do this.

Implications of This Rulemaking Extend Far Beyond Medicare

A large number of public and private payers follow HCFA physician payment policies. We have received reports that some private insurance plans are preparing to implement huge physician payment cuts correlating to HCFA's announcement of a re-structured fee schedule based on its new practice expenses methodology.

HCFA should also consider the degree to which dislocations would occur in pursuit of this goal as it develops its final policy. HCFA might pay special attention to possible access issues--for example, specialties that treat a high proportion of Medicare patients would see their per physician practice expense payments reduced by substantially larger amounts than specialties that serve primarily other ages. Substantial efforts to moderate the impact of this policy, beyond delay and phase-in, should be a major priority--but HCFA has virtually ignored this economic imperative.

Major discrepancies between current HCFA payment levels and the new levels proposed by HCFA should be carefully scrutinized. To guard against undue impact on patient service, for instance, limits might be set on how much a given specialty could lose or gain in either absolute or percentage dollar terms. HCFA should also place limits on the swing of RVUs upward or downward. (as was noted above, 26 of the 50 top GI procedures would have swings of +/- 25% or more). Given this overall lack of precision, HCFA might place limits on the percentage loss or gain any code or specialty group could receive under HCFA's proposed payment rules.

HCFA should suspend its plans to implement the proposed changes to the practice expense aspect of the Medicare fee schedule until HCFA has secured solid independent evidence of actual practice expenses and has evaluated the impact of the rule on Medicare participation.

Agreement should be reached on the basic methodology and the data base before the design of a transition and refinement process. Transitions and refinements cannot address fundamental flaws.

20. Problems with CPEP

HCFA Validation Panels Met--GI Panel Recommended Significant Increases in Staff Time Allocations

One of the most important steps in HCFA's process for revising its practice expense proposal was securing input from meetings of so-called 'validation panels.' The validation panels consist of expert groups, including a gastroenterology panel, which met on October 6, 1997, to see if the HCFA proposal accurately covered all key issues/costs. The GI panel consisted of gastroenterologists, internists, surgeons, and government personnel--it should be noted that gastroenterologists, while well-represented, constituted a minority of the panel. This was consistent with the overall objective for these panels of assuring that no single specialty had a majority on a validation panel.

The GI panel reviewed evidence, documentation and recommendations with respect to 14 GI CPT codes that were examined. The first code examined by the group was flexible sigmoidoscopy--this code falls within the purview of the GI group, even though over half of the Medicare flexible sigmoidoscopies are performed by non-gastroenterologists. Much of the rationale as it relates to amounts of staff time expended in scheduling, patient counseling, insurance pre-certification and billing used on flexible sigmoidoscopy carried over to the other procedures that are mostly done by gastroenterologists. After a great deal of discussion, deliberation and, in some cases debate, the GI validation panel recommended to HCFA significant increases in the time allocated for administrative staff work, and more modest increases in clinical staff time, for the GI procedures. The gastroenterology panel also expressed serious concern with respect to HCFA's efforts to take differing reimbursement approaches to the practice expenses allocated for endoscopic services, depending upon whether the procedure is performed in the physician's office, as compared to either the hospital or the ambulatory surgery center. They pointed to the rules that Medicare itself has established as the minimal criteria for certification as an ambulatory surgery center, as well as quality of care issues that very often gravitate toward doing these procedures in the hospital or ASC setting.

HCFA Errs in Not Incorporating the Revisions to CPEP Inputs from October, 1997 Validation Panel

In summarizing the basis for this rulemaking, HCFA states the October, 1997 validation panels continued to review, revise and validate the work of the CPEPs. Yet, at page 30836, HCFA announced

> "we have not incorporated any of those revisions (October, 1997 validation panels) to the data primarily because our methodology for developing RVUs has been revised, and we were not convinced that all the revisions that occurred during the validation panels were correct."

We think it is patently unfair and disingenuous for HCFA on the one hand to cite the work of the validation panels as one of the inputs to justify this rule, and then simply and arbitrarily to choose to disregard the results. We believe the work of the GI validation panel did make significant improvements in addressing several important CPEP deficiencies. We believe that the data revisions that occurred during the validation panels are indeed still appropriate and should be incorporated into the final rule.

21. Expansion of Multiple Surgery Rules; Deferral of Action on Any Reductions in Practice Expense Value Units for Multiple Procedures

We agree with the agency's decision not to propose any further reductions as to multiple procedures. As ACG commented in previous rulemakings, reductions to endoscopic procedures which involve a separate instrument being introduced into a separate body orifice and at a separate, subsequent time, is not appropriate, resulting in little, if any, reduction in physician work, and no reduction on practice expense in such instances. This makes multiple endoscopies very different from multiple surgeries performed through a single incision. No comparable reductions therefore should be taken as to multiple endoscopic procedures.

We believe that HCFA's proposal last year to reduce practice expense RVUs for multiple procedures was unjustified and inappropriate. The policy called for a reduction in the physician fee schedule amount for the second through the fifth procedure. This would have involved a reduction in work

practice expense and malpractice RVUs for multiple procedures. Since the fee being paid for the second and additional procedures would already be reduced under the current proposal, further reductions in the practice expense RVUs would create an exponential regression in physician fee payments. We oppose any modifications that create a multiplier effect to further reductions in physician fee payments.

A special problem has arisen with respect to upper and lower endoscopies performed on the same day. HCFA has articulated previously a unique policy for multiple endoscopies. We believe that HCFA's current policy results in underpayment for multiple endoscopies; nevertheless, we absolutely oppose any modification that might result in still further reductions. In fact, as noted below, there are very good reasons why HCFA should make full payment when an upper and lower endoscopy are performed on the same day.

Currently, where two or more surgical procedures are performed, HCFA reimburses 100% for the most expensive procedure and 50% for the second. RBRVS researchers at Harvard who developed the original fee schedule methodology considered multiple surgical services through a common incision, and found when more than one procedure is performed on the same day, that the level of work the physician does is about 50% less than what it would be if such traditional "open" procedures were performed on different days. This rationale falls apart when applied to endoscopic services.

GI endoscopic services are not major surgical or abdominal procedures that use a single abdominal incision, so applying this policy is inappropriate.

(1) For GI endoscopic services, the physician time expenditure, risk and overhead are identical for each procedure, whether they are performed on the same or different days. There are no "savings" or economies realized by the gastroenterologist when these procedures are performed on the same day.

(2) The two (upper and lower) procedures are performed via different body entry points, with different equipment; the patient is, by necessity, positioned differently for the procedures.

(3) When a patient has GI bleeding and other symptoms and it is unclear whether the patient problem emanates from the upper or lower GI tract, it is normal for an inconclusive lower GI exam to prompt an upper GI exam, and vice versa.

(4) It is preferable frequently for the patient to undergo same day procedures so that the patient does not have to undergo multiple preparations, fastings, risk, sedations, and trips, and miss more than one day of work.

To remove the existing financial disincentives, HCFA rules should be revised as they apply to GI endoscopic services, to reimburse 100% of each procedure, provided procedures use separate entry points and different instruments. To encourage performance of these procedures in the less expensive outpatient setting, HCFA should not deny reimbursement for separate facility fees for both services to the same extent that such fee would be payable for either of the services if performed on separate days.

22. Behavioral Offset, Budget Neutral Conversion Factor and Baseline for Measuring Magnitude of Cuts

There are two basic grounds where HCFA's unfairness is especially evident--the behavioral offset, (where fees are cut more than necessary to offset HCFA's assumption that some physicians will cheat the system to try to make up for reduced Medicare fee income), the concept of budget neutral conversion factor and the baseline against which the magnitude of these proposed fee cuts is being measured.

For gastroenterologists, this rulemaking would be the latest in a series of drastic fee cuts sustained over the past ten years--HCFA's practice expense/fee schedule proposal indicates that when this rule is implemented, we can expect to lose 14% off of today's fees. But the rulemaking uses the wrong baseline! If we look at 1998 fees (under this proposal) compared to fees on December 1, 1987, or even GI Medicare fees as of the time when the Medicare fee schedule was enacted, gastroenterologists are looking at cumulative cuts on outpatient procedures of about 65%!

HCFA's proposal includes a justification for the so-called behavioral offset. In addition to having triggered universal opposition for this additional uncalled for financial hit, the most obvious question for HCFA's discussion on this is, "where did Congress express any intent for a behavioral offset?" Neither explicit nor implied intent are found in our reading of the legislation--in fact, we find no reference to the concept. *Quite simply, Congress did not intend or authorize HCFA to incorporate any behavioral offset into the conversion factor. Congress never explicitly authorized it, and, therefore, we believe that HCFA is completely unjustified in its attempt to implement this concept.*

HCFA presumes that physicians will provide more services or bill at higher levels to offset a portion of every dollar that they lose because of reductions in the practice expense component of payments under the Medicare Fee Schedule. This presumption makes no common sense: will neurosurgeons do more brain surgeries, because they are paid less for each one? How do physicians "invent" more coronary bypasses? It is insulting to a profession that has ethical standards and is focusing ever more closely on what is the most appropriate and cost-effective way of treating every specific medical problem. Results of the efforts are evident in a flattening of the Medicare Fee Schedule payments.

23. Issues Relating to Specific Codes & Values

We reiterate our concerns with several GI codes, most pointedly--the obvious error relating to PERVU for diagnostic colonoscopy (45378) and other colonoscopy codes.

Other refinements include HCFA's request that commenters identify problems in relative terms to the associated family procedure codes--therefore, we provided above detailed comparisons of upper and lower GI endoscopies to flexible sigmoidoscopy.

Parallels to Conscious Sedation Codes Demonstrate GI Codes Seriously Undervalued

To better understand the work involved in most endoscopies, it is helpful to see it in two components--administration of conscious sedation and the diagnostic/therapeutic procedure itself.

We are concerned with the under-valuation of endoscopic procedures, payments which would be further reduced by virtue of the NPRM. It must be understood that with each endoscopic procedure utilizing conscious sedation (Upper GI Endoscopy, Colonoscopy, ERCP, etc.), including established patients, there is an initial assessment by the physician to ascertain several things, including seeing that the preparation was complete, that no drug allergies are present, that no new drugs are being taken, that a physical examination to include auscultation of chest and heart is performed, and that an explanation of the procedure to obtain informed consent has been provided. Then the patient is given intravenous medication to produce conscious sedation. The endoscopic examination is performed. Then the record is completed, usually written, and a dictated account of the procedure is performed. Often additional letters to the other physicians caring for the patient are dictated as well. Finally, the physician meets with the patient and family member prior to discharge from the endoscopy area, and makes a final assessment of the patient's response to the examination. The physician also gives a full explanation of the findings of the study as well as how this will affect the patient's management, often with dietary instructions and a prescription for medications.

When one considers the RVU for conscious sedation, (HCPC's 00810AA), and if one subtracts the RVU for conscious sedation from upper GI Endoscopy codes (43235 and related codes), Colonoscopy codes (45378-45385), the RVUs for the conscious sedation plus the endoscopic procedures is often close to the RVUs that would be available for the conscious sedation alone. Anyone who has performed both will tell you that they would rather give conscious sedation to three or four patients than handle the work of total colonoscopy.

24. Medicare Reimbursement For GI Services Since 1987

The American College of Gastroenterology, working in conjunction with the American Gastroenterological Association and the American Society for Gastrointestinal Endoscopy, commissioned a study of gastroenterology which was conducted by the Battelle Institute in 1989-90. The methodology used to measure pre- and post-service activities was to ask respondents to estimate the percentage additional effort required for pre and post service activities. In fact, this is the same methodology that had originally been used in the Hsiao research; subsequently Hsiao determined that substantially lower overall pre- and post-values could be obtained by direct work ratings and extrapolation in some cases. The final Hsiao numbers were derived by asking for a combined estimate of pre-and post, which yielded lower values than if each component were asked separately.

Perhaps the most striking finding is that nationally, five different procedure codes (diagnostic UGI endoscopy--CPT 43235, diagnostic colonoscopy--CPT 45378, colonoscopy for polypectomy--CPT 45385, UGI endoscopy for collection of specimen--CPT 43239, and colonoscopy for collection of specimen--CPT 45380) accounted then for 50.9% of the total Medicare payments to gastroenterologists.

The RVUs for these five services (which are also referred to above under subsection 5) already were substantially undervalued. This is clearly one reason why the economic impact on gastroenterology is so much more serious than what HCFA originally projected. The evolution of 13 key GI codes is outlined below. We are providing comments with respect to specific families of codes. However, the overall perspective of what HCFA's past policies have done to reimbursement to the specialty demonstrates why, gastroenterology objects to yet another unjustified ratcheting down.

Here's a quick summary of the probable impact on GI reimbursements if HCFA succeeds in this attempt to revamp the RBRVS fee schedule:

TABLE 9

Medicare Reimbursements for GI Services Since 1987

CPT CODE	PROCEDURE/ SRVC	RVUs PER ORIG. FEE SCH.	NAT'L AVG TOTAL ALLOWED 1987	NAT'L AVG TOTAL ALLOWED 1989	ACTUAL AMOUNT REIM-BURSED (1/1/91) (AVG)	ACTUAL AMOUNT REIM-BURSED (1/1/92) (AVG)	TOTAL CUTS 87/89 THRU '92	ACG RECOM-MENDED RVU PER BATTELLE DATA	1997 MFS***	1998 MFS*** Office Rates	1998 MFS*** Outpatient Rates	2002 MFS Per '98 NPRM Office Rates)(At full implement ation using 1998 Conversion Factor	2002 MFS*** Per '98 N(RM Outpatient Rates (At full implement ation using 1998 Conversion Factor
43200	Esophag	4.76	$300.61		$234.12	$179.06	-41%	6.82**	3.89 / $131.68	3.89 / $142.71	3.60 / $132.07	5.78/ $212.05	2.85/ $104.55
43234	Upper GI	5.63	$344.22		$242.67	$193.26	-44%	8.07**	4.88 / $165.18	4.88/ $179.03	4.52 . $165 83	4.66/ $170.96	3.17/ $116.30
*43235	EGD	6.68		$307.00	$269.66	$228.16	-26%	9.58	5.75 / $194.64	5.75 / $210.95	5.31 $194 81	6.48/ $237.73	3.66/ $134 28
*43239	Upper GI/biop	7.62		$350.00	$308.47	$262.15	-25%	12.67	6.46 / $218.67	6.46 / $228.81	5.98 / $211 20	6.90/ $241.66	4.11/ $140.58
*43246	Place Gas tmy tube	11.43		$522.00	$461.56	$406.02	-23%	16.40	10.39 / $351.70	NA	9.60 $352 20	N/A	6.49/ $238.10
*43255	Operative Upper GI	10.97		$462.00	$380.73	$339.09	-27%	15.74**	10.41 / $352.33	NA	9.62 $352.93	N/A	6.40/ $234.80
*43260	ERCP	13.01	$532.52	$506.00	$440.34	$395.92	-26%	17.44	12.33 / $417.37	NA	12.33 $452.35	N/A	8.56/ $314.04
*43262	Sphinct.	17.89		$745.00	$773.24	$620.73	-17%	25.90	16.97 / $574.43	NA	16.10 $590 67	N/A	10.69/ $392.19
*45330	Sigmoid.	2.52	$148.46	$106.00	$84.77	$73.39	-50%	5.96	2.31 / $78.19	2.31 / $84.75	2.14 . $78 51	4.50/ $165.09	1.46/ $53.56
45331	Sigmoid/biop	3.31		$142.00	$140.69	$117.49	-18%	7.83**	3.02 / $102.22	3.02 / $110.80	2.80 $102.72	4.85/ $177.93	1.90/ $69.70
*45378	Diag. Col.	8.48	$509.23	$452.00	$310.44	$262.42	-49%	13.21	8.22 / $267.82	8.22 / $290.30	8.16 $266.10	8.38/ $292.34	6.06/ $208.17
*45380	Col./biop.	9.49		$503.00	$346.35	$294.89	-42%	15.97	9.20 / $311.42	9.20 / $337.52	8.82 $323 59	8.78/ $322.11	6.15/ $225.63
*45385	Col./polyp	12.46		$704.00	$486.95	$420.04	-41%	17.13	12.54 / $424.48	12.54 / $443.89	11.73 $414 17	10.82/ $375.88	8.11/ $277.71

* Discrepancies in these categories are of heightened importance because these are among the top twenty gastroenterology services, in terms of overall financial impact on the GI practice, per 1989 Battelle Institute study.

** These RVUs were extrapolated from ACG recommended RVUs on closely related services which had been derived from Battelle data.

*** Amounts are calculated simply by published total RVUs x $33.85 (1997 conversion factor), and $36.6873 (1998 conversion factor, respectively); total dollar amounts vary slightly from HCFA NPRM tables and text, which were computed differently.

25. Economic Impact and Other Technical/Regulatory Deficiencies

The economic impact of the proposed regulation will be devastating.

We do not believe that HCFA can, in candor or fairness, maintain that there is only negligible economic impact since its objective is to make payments more equitable--with major proposed increases in cognitive services and commensurate decreases in procedural ones. Moreover, HCFA again has unfairly changed the baseline--looking only at short increments and ignoring the longer term picture that tends to reduce the apparent magnitude of the cuts. HCFA's figures do not reflect the cumulative tremendous adverse impact on certain specialties like gastroenterology where, with this latest proposal, reimbursements will have dropped in the range of 65%.

The Endoscopy and Gastroenterology field has made major technological and practice strides in recent years. It is generally agreed amongst physicians that this field has provided a significant positive impact on health care. Our investigative efforts have greatly decreased the need for surgery in treatment of peptic ulcer disease. Surgery for gallbladder disease has diminished greatly in recent years, in part because of endoscopic removal of gallstones. Endoscopic treatment of gastrointestinal bleeding has diminished greatly the need for emergency surgeries. Our ability to remove colonic polyps should lead to elimination of colon cancer, the second leading cause of cancer in this country today. Rapid advances in cost-effective therapy will be undermined by HCFA's proposed cut in support for this type of work. This is penny-wise and pound foolish.

While the volume of endoscopic services has increased significantly, it should be noted that these procedures are not regarded as necessarily pleasant and therefore there is virtually no risk of volume abuse. ACG and other gastroenterology groups work hard at patient education and prevention. There is significant evidence that these procedures, unlike most others, ultimately result in savings of federal funds, with malignancies being diagnosed earlier, and patients spared many later surgeries and other expensive hospitalizations and treatments.

Endoscopy has made a great impact in improving quality of care. It has gone a great distance in sparing medical costs. It is incongruous on the one hand that the federal government has recently recognized the critical role of colorectal cancer screening by implementation of the Congressional enacted Medicare benefit, and then imposition of such a major reduction in outpatient colonoscopy, a 28% decrease can easily translate in reduced interest by some physicians in encouraging screening.

26. The Current Rulemaking Is Deficient in Not Incorporating and Responding to All of the Comments Received from the June 18, 1997 Proposal

HCFA initiated a Notice of Proposed Rulemaking on Medicare Practice Expenses on June 18, 1997, and solicited comments on the proposed rulemaking. Comments were encouraged for receipt in advance of an August 18, 1997 deadline date, and thousands of comments were submitted. The June 5, 1998 proposed rule addresses the same issue, and refers in several areas to the June 18, 1997 Notice of Proposed Rulemaking. HCFA should have reviewed and responded to the comments it received on the June 18, 1997 proposal as background and preface for the June 5 new proposal. We do not see such a comprehensive review of comments in the pending proposal. We believe that the quality, integrity and legal legitimacy of the rulemaking is compromised by HCFA's failure to catalog and respond to the comments submitted on the similar predecessor rulemaking that the agency published last year.

Who Commented, and What Do The Comments Say?

Looking back at the comments on the June 18 NPRM, it appears HCFA received as many as 9,000 comments. We believe that a significant percentage of those comments came from gastroenterologists and others with interest in the GI field. Of copies of comments that ACG has catalogued and reviewed thus far, two-thirds came from gastroenterologists. With two-thirds of the comments coming from gastroenterologists, it is clear that this rulemaking is unique in terms of the magnitude of the potential financial impact on the GI community. We hope that HCFA will bear the magnitude of the concerns from the GI community in mind as the agency reviews the comments and re-writes the proposal.

Physicians Need Greater Opportunity to Validate Data and Assumptions

With the work values, physicians had four years to evaluate the methods and data before the initial implementation date. The practice expense changes involve far greater potential reductions in payment than occurred with the work values. HCFA ignored a Congressional mandate to issue a report in June, 1996 on the methodology and potential impact of practice expense changes. Congress wanted physicians and policymakers to have 18 months to determine if HCFA was on the right track. HCFA used one set of assumptions for the 1997 proposed rule, and physicians then attempted to generate new data based on those assumptions. Now the premise for the policy has changed significantly and we are again asked to perform high speed analysis on a new conceptual framework. Under best case scenarios, physicians will have no more than eight weeks to prepare for the initial stage of changes affecting Medicare, cutting physician payments to our practice a minimum of 14%!

27. Regulatory Impact/Flexibility/Record Keeping Statements Were Not Prepared for the Rule

a. Regulatory Impact Analysis Under Executive Order 12291

HCFA does not cite any evidence in either of its proposals, to support its contention that no Regulatory Impact Statement is required. If no policy were being changed, it might be possible to avoid the Regulatory Impact Statement. However, this proposal includes not only the new practice expense methodology, but also a bifurcation in office and outpatient payment policies. In this rulemaking, HCFA moves to abolish existing policies on site-of-service differential and tray fees. Therefore, we believe a Regulatory Impact Statement is imperative.

We think that it is clear this practice expense rulemaking, with all it entails, would undoubtedly result in expectations that physicians provide the same or greater services as compared to those which they currently provide, but for reduced reimbursement. Undoubtedly, the adoption of this proposal would result in significant economic detriment to physicians. HCFA notes, if this Fee Schedule were implemented, it will result in a 20% reduction in the Medicare income of gastroenterologists prospectively. As we have demonstrated using HCFA's own numbers, in actuality, this translates to cumulative cuts of 65% when compared to 1987.

b. Regulatory Flexibility Act and Paperwork Reduction Act of 1980 (44 U.S.C. 3501)

We contend that implementation of this proposal, as it stands, would violate the Regulatory Flexibility Act and the Paperwork Reduction Act of 1980 because adequate filings required in both of these Acts did not accompany the proposal.

28. Request for A Public Hearing

We believe that the issues discussed in this proposal are of very broad interest, with a lasting significance to physicians, other providers, third party carriers and beneficiaries. For this reason, we request that the agency schedule and conduct public hearings to receive a broad range of viewpoints on this important question.

29. Conclusion

Doctors will support an equitable Medicare reimbursement system. What HCFA has proposed here, however, while improved somewhat from last year's NPRM, remains fundamentally unfair, is based on questionable methodology, and has a large number of obvious flaws. It utilizes as a substitute for gathering current data, an existing database not designed for the practice expense purpose, which grossly understates gastroenterology practice expenses, traceable in at least some measure to a very small sample size and the lowest of all response ratios. The proposal also misstates the likely economic impact on gastroenterologists. HCFA's rulemaking is wholly unacceptable, and requires major additional revisions before it could form an acceptable basis for reform of existing policies on Medicare practice expenses.

HCFA's proposal is unilateral in the sense that it is not backed by sound actual data on physician practice expenses from an independent source. The proposal, if implemented in anything close to its current form, will have grievous implications not only for physicians--gastroenterologists and other procedural specialties--but for patient care as well. These actions fly in apparent total disregard for the Congressional mandate for accurate collection of data before such an implementation could be effected. We re-emphasize that there is virtually no other industry that has such actions forced upon them by a government agency without accurate collection of data, assessing the impact on not only the providers but on recipients of the providers' services.

We welcome the opportunity to meet with you and to respond to any questions you may have regarding our comments.

Sincerely,

Sarkis J. Chobanian, MD, FACG
President

John W. Popp, Jr., MD, FACG
Chairman, National Affairs Committee

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Appendix #1

Table B1. Number of Respondents, Response Rates, and Average Weights for the 1997 AMA Socioeconomic Monitoring System Survey of Nonfederal Physicians

	Number of Respondents	Response Rate	Average Weight
All Physicians	3955	61.1%	1.00
General/Family Practice	519	58.5	0.99
Internal Medicine	909	55.6	1.03
General Internal Medicine	626	55.8	1.03
Cardiovascular Diseases	127	53.6	1.04
Gastroenterology	75	53.6	1.02
Other	81	59.1	1.03
Surgery	638	64.0	0.90
General Surgery	233	65.8	0.93
Otolaryngology	75	61.5	0.86
Orthopedic Surgery	162	56.3	0.88
Ophthalmology	164	77.0	0.88
Urological Surgery	78	61.4	0.93
Other	126	61.2	0.89
Pediatrics	318	67.8	1.02
Obstetrics/Gynecology	265	65.0	1.01
Radiology	212	63.1	1.01
Diagnostic Radiology	117	60.6	1.00
Other Radiology	95	66.4	1.01
Psychiatry	247	62.9	1.04
Anesthesiology	206	61.7	1.11
Pathology	107	71.8	0.84
Other Specialty	334	61.1	1.10
Emergency Medicine	120	58.5	1.17
Neurology	66	60.5	1.09
Dermatology	73	67.0	1.01
Other	75	60.5	1.06
New England	258	60.4	1.05
Massachusetts	111	52.6	1.08
Other	147	68.1	1.04
Middle Atlantic	627	58.9	1.03
New Jersey	113	54.1	1.04
New York	302	54.3	1.05
Pennsylvania	212	62.9	0.99
East North Central	658	63.5	0.95
Illinois	182	61.3	0.91
Michigan	143	65.1	0.94
Ohio	163	66.3	0.97
Other	170	61.6	0.99
West North Central	259	67.3	0.99
South Atlantic	743	60.3	1.01
Florida	202	52.9	1.01
Other	541	63.6	1.00
East South Central	241	66.6	0.95
West South Central	376	62.7	0.99
Texas	229	61.4	1.00
Other	147	64.5	0.98
Mountain	225	66.0	1.00
Pacific	568	58.0	1.02
California	400	55.4	1.02
Other	168	65.4	1.01
Self-Employed*	2291	N.A.	0.98
Solo Practice	1029	N.A.	1.00
Two Physician Practice	236	N.A.	0.98
Three Physician Practice	201	N.A.	0.96
Four-Eight Physician Practice	432	N.A.	0.95
Over Eight Physician Practice	372	N.A.	0.96
Employee	1486	N.A.	1.03
Independent Contractor	176	N.A.	1.05

*Includes one respondent who did not indicate practice size.
N.A.—Not available.

Table 1. Mean practice expenses per hour spent in patient care activities, hours and expenses adjusted for practice size (in dollars)

SPECIALTY	# OF CASES	NON-PHYS PAYROLL PER HOUR	CLERICAL PAYROLL PER HOUR*	OFFICE EXPENSE PER HOUR	SUPPLIES EXPENSE PER HOUR	EQUIPMENT EXPENSE PER HOUR	OTHER EXPENSE PER HOUR	TOTAL EXPENSE PER HOUR**
ALL PHYSICIANS	3910	27.0	15.0	19.1	7.2	3.2	11.0	67.5
GENERAL/FAMILY PRACTICE	409	30.2	15.1	18.2	8.1	3.6	8.6	68.6
GENERAL INTERNAL MEDICINE	430	22.4	13.3	17.0	6.4	2.1	6.2	54.2
CARDIOVASCULAR DISEASE	94	30.2	14.9	19.9	5.8	6.4	20.7	82.9
GASTROENTEROLOGY	84	23.2	15.4	17.9	2.7	1.8	11.0	56.6
ALLERGY/IMMUNOLOGY	31	66.2	27.0	33.3	17.5	3.3	16.4	136.6
PULMONARY DISEASE	49	20.0	12.2	15.0	2.8	1.6	6.4	45.8
ONCOLOGY	27	44.7	22.7	25.7	87.2	5.5	10.3	173.4
GENERAL SURGERY	257	22.5	15.7	17.2	3.1	2.0	9.4	54.1
OTOLARYNGOLOGY	103	44.8	27.3	33.4	7.7	5.8	18.3	110.1
ORTHOPEDIC SURGERY	203	42.9	26.0	30.8	10.3	3.6	18.1	105.6
OPHTHALMOLOGY	210	52.9	27.8	35.9	11.3	9.0	22.7	131.8
UROLOGICAL SURGERY	118	29.6	18.6	22.8	24.5	6.0	11.6	94.6
PLASTIC SURGERY	85	28.6	18.3	30.2	16.3	4.6	23.3	103.0
NEUROLOGICAL SURGERY	42	33.5	24.3	31.7	1.8	1.1	15.7	83.9
CARD/THOR/VASC SURGERY	44	30.1	16.2	18.3	1.4	3.1	11.0	63.8
PEDIATRICS	249	26.1	13.3	20.0	10.8	1.6	8.4	66.9
OBSTETRICS/GYNECOLOGY	266	32.3	16.9	21.2	7.3	3.4	11.7	75.9
RADIOLOGY	214	19.0	9.6	12.5	4.8	0.3	13.6	50.2
PSYCHIATRY	351	7.3	5.3	10.1	0.4	0.3	7.5	25.6
ANESTHESIOLOGY	232	14.4	3.7	5.9	0.3	0.4	5.7	26.7
PATHOLOGY	82	16.7	8.4	6.7	4.0	1.6	17.7	46.7
DERMATOLOGY	96	49.5	26.7	33.1	12.5	4.8	15.2	115.0
EMERGENCY MEDICINE	61	5.3	1.9	1.6	0.5	0.1	5.5	13.0
NEUROLOGY	61	26.2	21.6	15.8	5.0	4.2	7.7	58.8
PHYS MED/RHEUMATOLOGY	75	38.6	23.2	28.5	4.9	3.9	12.0	88.0
OTHER SPECIALTY	37	21.1	12.4	19.7	3.6	1.3	9.7	55.4

Source: American Medical Association, 1995-1997 Socioeconomic Monitoring System (SMS) surveys.

*Clerical payroll is included in total non-physician payroll.
**Total expenses exclude professional liability insurance premiums and employee physician payroll.

Notes:
(1) Only self-employed non-federal non-resident patient care physicians who responded to all relevant expense questions are included. Self-employed physician respondents with no practice expenses for the year are excluded.
(2) Physicians whose typical number of hours worked in patient care activities per week is missing, less than 20, or equal to 168 (3 cases) are excluded. Physicians whose number of weeks worked the previous year is missing or less than 26 are excluded.
(3) For each respondent, total practice expense and expense components per hour are calculated as (4) / (5) below.
(4) Expenses adjusted for practice size = self-employed respondent expenses * # physician owners
(5) Hours adjusted for practice size = (respondent hours * # physician owners) + (employee physician hours (see (6) below) * # employee physicians)
(6) The typical number of hours worked in patient care activities for the employee physician(s) of a self-employed physician's practice is not known. Mean hours worked in patient care activities for employee physicians of each specialty are used as an estimate of employee physician hours.

Table 2. Standard errors of mean practice expenses per hour spent in patient care activities, hours and expenses adjusted for practice size (in dollars)

SPECIALTY	# OF CASES	NON-PHYS PAYROLL PER HOUR	CLERICAL PAYROLL PER HOUR*	OFFICE EXPENSE PER HOUR	SUPPLIES EXPENSE PER HOUR	EQUIPMENT EXPENSE PER HOUR	OTHER EXPENSE PER HOUR	TOTAL EXPENSE PER HOUR**
ALL PHYSICIANS	3910	0.5	0.3	0.4	0.3	0.2	0.3	1.1
GENERAL/FAMILY PRACTICE	409	1.3	0.6	1.2	0.5	0.7	0.6	3.0
GENERAL INTERNAL MEDICINE	430	1.2	0.6	1.0	0.6	0.3	0.6	2.6
CARDIOVASCULAR DISEASE	94	2.9	1.4	1.9	0.8	1.3	5.2	8.0
GASTROENTEROLOGY	84	1.6	1.1	1.9	0.3	0.3	2.2	4.1
ALLERGY/IMMUNOLOGY	31	7.9	3.8	3.8	4.2	1.5	2.9	11.2
PULMONARY DISEASE	49	1.6	1.4	2.2	0.6	0.5	0.9	3.5
ONCOLOGY	27	7.5	3.8	5.7	16.4	1.4	3.8	23.2
GENERAL SURGERY	257	1.4	0.9	0.9	0.3	0.3	0.8	2.5
OTOLARYNGOLOGY	103	3.0	2.3	3.5	0.9	1.1	2.1	6.8
ORTHOPEDIC SURGERY	203	1.7	1.2	2.1	0.8	0.4	2.0	4.7
OPHTHALMOLOGY	210	2.9	1.4	2.6	1.3	1.1	2.1	6.3
UROLOGICAL SURGERY	118	1.4	1.0	2.1	1.8	1.0	1.4	4.4
PLASTIC SURGERY	85	2.3	1.4	3.5	2.8	1.0	3.4	8.1
NEUROLOGICAL SURGERY	42	4.0	2.5	5.7	0.7	0.4	2.1	9.4
CARD/THOR/VASC SURGERY	44	4.2	2.0	2.9	0.3	1.7	2.2	8.0
PEDIATRICS	249	1.6	0.7	1.7	1.0	0.3	1.2	3.8
OBSTETRICS/GYNECOLOGY	266	1.7	0.9	1.3	0.7	0.3	1.0	3.3
RADIOLOGY	214	2.0	0.9	2.0	0.8	1.9	1.3	5.7
PSYCHIATRY	351	0.7	0.5	0.6	0.2	0.1	0.6	1.5
ANESTHESIOLOGY	232	1.8	0.6	0.8	0.1	0.1	0.7	2.4
PATHOLOGY	82	2.7	1.8	1.7	0.8	0.5	2.9	6.4
DERMATOLOGY	96	4.8	2.0	5.2	2.0	1.2	1.8	10.4
EMERGENCY MEDICINE	61	1.4	0.6	0.5	0.3	0.1	0.9	2.1
NEUROLOGY	61	3.1	3.1	1.4	1.5	1.1	2.2	6.4
PHYS MED/RHEUMATOLOGY	75	5.1	2.5	6.1	0.7	1.4	2.9	12.1
OTHER SPECIALTY	37	4.4	2.4	5.1	1.1	0.6	2.1	9.5

Source: American Medical Association, 1995-1997 Socioeconomic Monitoring System (SMS) surveys.

*Clerical payroll is included in total non-physician payroll.
**Total expenses exclude professional liability insurance premiums and employee physician payroll.

Notes:
(1) Only self-employed non-federal non-resident patient care physicians who responded to all relevant expense questions are included. Self-employed physician respondents with no practice expenses for the year are excluded.
(2) Physicians whose typical number of hours worked in patient care activities per week is missing, less than 20, or equal to 168 (3 cases) are excluded. Physicians whose number of weeks worked the previous year is missing or less than 26 are excluded.
(3) For each respondent, total practice expense and expense components per hour are calculated as (4) / (5) below.
(4) Expenses adjusted for practice size = self-employed respondent expenses * # physician owners
(5) Hours adjusted for practice size = (respondent hours * # physician owners) + (employee physician hours (see (6) below) * # employee physicians)
(6) The typical number of hours worked in patient care activities for the employee physician(s) of a self-employed physician's practice is not known. Mean hours worked in patient care activities for employee physicians of each specialty are used as an estimate of employee physician hours.

TABLE 2-1
SMS TABULATIONS FOR RUC/SPECIALTY SOCIETIES
DETAILED STATISTICS ON PRACTICE EXPENSES, HOURS WORKED, AND PRACTICE SIZE
ANALYSIS VARIABLE = NON-PHYSICIAN PAYROLL

SPECIALTY	SAMPLE SIZE	MEAN	STANDARD ERROR	25TH PERCENTILE	MEDIAN	75TH PERCENTILE	MINIMUM	MAXIMUM	# OF ZERO RESPONSES	ITEM RESPONSE RATE (%)
ALL PHYSICIANS	3910	72811.1	1268.0	23000.0	56000.0	100000.0	0.0	996000.0	434	68.4
GENERAL/FAMILY PRACTICE	409	80557.5	3423.5	41000.0	69000.0	100000.0	0.0	828000.0	15	65.0
GENERAL INTERNAL MEDICINE	430	63142.4	2937.8	30000.0	54000.0	81000.0	0.0	450000.0	22	64.9
CARDIOVASCULAR DISEASE	94	90920.7	9337.4	35000.0	65000.0	124000.0	0.0	450000.0	1	54.4
GASTROENTEROLOGY	84	63464.0	4550.6	38000.0	61500.0	95000.0	0.0	203000.0	1	62.4
ALLERGY/IMMUNOLOGY	31	127888.6	17449.2	68000.0	98000.0	154000.0	13000.0	460000.0	0	61.0
PULMONARY DISEASE	49	57257.3	4191.5	40000.0	58000.0	80000.0	0.0	120000.0	2	60.0
ONCOLOGY	27	111576.4	19992.8	55000.0	110000.0	178000.0	5000.0	466000.0	0	60.4
GENERAL SURGERY	257	61992.5	3763.4	30000.0	50000.0	79000.0	0.0	620000.0	9	68.3
OTOLARYNGOLOGY	103	109595.1	6403.4	67000.0	95000.0	135000.0	18000.0	500000.0	0	69.4
ORTHOPEDIC SURGERY	203	127984.7	5657.8	67000.0	105000.0	169000.0	0.0	500000.0	2	64.4
OPHTHALMOLOGY	210	129242.8	7387.3	60000.0	102500.0	165000.0	0.0	996000.0	3	69.8
UROLOGICAL SURGERY	118	82350.5	3897.9	54000.0	77000.0	110000.0	4000.0	250000.0	0	67.3
PLASTIC SURGERY	85	70454.4	5672.9	35000.0	65000.0	102000.0	0.0	270000.0	3	71.7
NEUROLOGICAL SURGERY	42	99712.8	11701.3	41000.0	80500.0	138000.0	0.0	425000.0	2	76.2
CARD/THOR/VASC SURGERY	44	105635.6	22241.2	38000.0	73000.0	132500.0	0.0	800000.0	1	57.3
PEDIATRICS	249	73693.7	4457.8	35000.0	60000.0	100000.0	0.0	632000.0	16	63.8
OBSTETRICS/GYNECOLOGY	266	91828.4	4884.0	50000.0	75000.0	120000.0	0.0	500000.0	12	66.5
RADIOLOGY	214	49148.6	5488.8	0.0	20000.0	60000.0	0.0	800000.0	54	70.1
PSYCHIATRY	351	17302.7	1607.7	0.0	6000.0	22000.0	0.0	329000.0	135	90.7
ANESTHESIOLOGY	232	41749.6	5087.4	0.0	8500.0	41500.0	0.0	450000.0	84	75.7
PATHOLOGY	82	44255.9	7235.4	0.0	8000.0	41000.0	0.0	300000.0	38	81.5
DERMATOLOGY	96	111412.6	11827.4	50000.0	80000.0	134000.0	0.0	900000.0	2	72.3
EMERGENCY MEDICINE	61	27405.2	9116.9	0.0	5000.0	20000.0	0.0	400000.0	23	79.2
NEUROLOGY	61	80356.6	12606.5	30000.0	47000.0	66000.0	0.0	450000.0	1	59.8
PHYS MED/RHEUMATOLOGY	75	86809.6	10954.0	38000.0	68000.0	100000.0	0.0	699000.0	3	72.2
OTHER SPECIALTY	37	66670.9	15254.9	20000.0	39000.0	81000.0	0.0	300000.0	5	67.2
Crosswalked Specialties										
GENERAL PRACTICE	90	54537.1	5679.2	15000.0	40500.0	75000.0	0.0	250000.0	7	71.6
FAMILY PRACTICE	319	88372.2	3991.7	50000.0	75000.0	106000.0	0.0	828000.0	8	63.1
NEPHROLOGY	30	65016.9	17655.6	21000.0	35000.0	100000.0	10000.0	450000.0	0	59.3
GEN INT MED EXCL NEPHROLOGY	400	62996.7	2876.7	30000.0	55000.0	80500.0	0.0	400000.0	22	65.3
RADIATION ONCOLOGY	40	63638.7	12907.4	7000.0	21500.0	60000.0	0.0	400000.0	7	82.7
RADIOLOGY EXCL RAD ONCOLOGY	174	45792.2	6057.6	0.0	20000.0	60000.0	0.0	800000.0	47	68.0
PHYS MEDICINE & REHAB	37	81146.1	20052.5	30000.0	43000.0	84000.0	0.0	699000.0	3	71.4
RHEUMATOLOGY	38	91942.2	9544.3	50000.0	71500.0	112000.0	18000.0	212000.0	0	73.0

Source: Center for Health Policy Research, American Medical Association, 1995-1997 SMS Surveys.

Appendix #4

TABLE 2-2
SMS TABULATIONS FOR RUC/SPECIALTY SOCIETIES
DETAILED STATISTICS ON PRACTICE EXPENSES, HOURS WORKED, AND PRACTICE SIZE
ANALYSIS VARIABLE = CLERICAL PAYROLL

SPECIALTY	SAMPLE SIZE	MEAN	STANDARD ERROR	25TH PERCENTILE	MEDIAN	75TH PERCENTILE	MINIMUM	MAXIMUM	# OF ZERO RESPONSES	ITEM RESPONSE RATE (%)
ALL PHYSICIANS	3910	39849.6	696.0	12000.0	30000.0	55000.0	0.0	850000.0	611	65.0
GENERAL/FAMILY PRACTICE	409	39462.2	1502.6	20000.0	35000.0	50000.0	0.0	300000.0	30	60.7
GENERAL INTERNAL MEDICINE	430	36647.3	1495.3	18000.0	30500.0	50000.0	0.0	200000.0	33	61.2
CARDIOVASCULAR DISEASE	94	43321.6	4466.4	20000.0	35000.0	55000.0	0.0	225000.0	7	47.8
GASTROENTEROLOGY	84	41573.7	2772.9	26500.0	41000.0	60000.0	0.0	100000.0	1	57.0
ALLERGY/IMMUNOLOGY	31	50384.2	7324.7	28000.0	41000.0	60000.0	10000.0	230000.0	0	55.9
PULMONARY DISEASE	49	33637.5	3185.5	20000.0	30000.0	47000.0	0.0	86000.0	2	55.8
ONCOLOGY	27	57939.8	12447.9	30000.0	45000.0	75000.0	5000.0	348000.0	0	52.8
GENERAL SURGERY	257	42130.6	2262.4	20000.0	35000.0	55000.0	0.0	296000.0	15	64.5
OTOLARYNGOLOGY	103	63778.2	4065.4	32000.0	50000.0	85000.0	0.0	300000.0	2	65.6
ORTHOPEDIC SURGERY	203	76112.9	3886.0	38000.0	60000.0	100000.0	0.0	400000.0	5	59.5
OPHTHALMOLOGY	210	69344.1	4531.0	35000.0	55000.0	80000.0	0.0	850000.0	3	67.8
UROLOGICAL SURGERY	118	50706.0	2819.8	30000.0	48000.0	63000.0	0.0	250000.0	1	63.6
PLASTIC SURGERY	85	44374.2	3143.1	25000.0	40000.0	63000.0	0.0	143000.0	4	71.7
NEUROLOGICAL SURGERY	42	72624.5	7439.4	39000.0	60000.0	81000.0	0.0	250000.0	3	73.0
CARD/THOR/VASC SURGERY	44	53054.1	8771.8	22000.0	35000.0	55000.0	0.0	300000.0	2	50.5
PEDIATRICS	249	36524.0	2045.3	16000.0	30000.0	50000.0	0.0	200000.0	22	60.1
OBSTETRICS/GYNECOLOGY	266	48056.3	2876.4	22000.0	38000.0	60000.0	0.0	404000.0	15	62.7
RADIOLOGY	214	24816.9	2358.8	0.0	12000.0	34000.0	0.0	259000.0	75	65.5
PSYCHIATRY	351	11839.0	1060.7	0.0	1000.0	19000.0	0.0	214000.0	173	90.2
ANESTHESIOLOGY	232	10199.2	1624.9	0.0	0.0	12000.0	0.0	200000.0	123	76.8
PATHOLOGY	82	19920.5	4231.7	0.0	0.0	15000.0	0.0	270000.0	48	79.0
DERMATOLOGY	96	59033.1	4851.0	26000.0	50000.0	81000.0	0.0	300000.0	2	70.3
EMERGENCY MEDICINE	61	9546.8	3568.7	0.0	0.0	10000.0	0.0	200000.0	32	78.2
NEUROLOGY	61	67761.8	12787.7	20000.0	40000.0	60000.0	0.0	450000.0	2	58.1
PHYS MED/RHEUMATOLOGY	75	51525.0	4399.4	25000.0	42000.0	68000.0	0.0	280000.0	4	67.5
OTHER SPECIALTY	37	35724.6	7914.7	10000.0	25000.0	40000.0	0.0	250000.0	7	64.2
Crosswalked Specialties										
GENERAL PRACTICE	90	31125.1	3313.9	10000.0	25000.0	40000.0	0.0	150000.0	12	64.5
FAMILY PRACTICE	319	41966.1	1662.7	23000.0	40000.0	52000.0	0.0	300000.0	18	59.7
NEPHROLOGY	30	32897.7	5844.2	13000.0	31000.0	52000.0	0.0	125000.0	2	58.8
GEN INT MED EXCL NEPHROLOGY	400	36938.7	1547.6	19500.0	30500.0	50000.0	0.0	200000.0	31	61.7
RADIATION ONCOLOGY	40	26930.9	5550.6	0.0	13000.0	30000.0	0.0	150000.0	14	78.8
RADIOLOGY EXCL RAD ONCOLOGY	174	24327.3	2612.0	0.0	12000.0	34000.0	0.0	259000.0	61	63.3
PHYS MEDICINE & REHAB	37	50070.1	7958.9	13000.0	40000.0	70000.0	0.0	280000.0	4	68.3
RHEUMATOLOGY	38	52843.6	4035.3	35000.0	45000.0	63000.0	18000.0	100000.0	0	66.7

Source: Center for Health Policy Research, American Medical Association, 1995-1997 S

TABLE 2-3
SMS TABULATIONS FOR RUC/SPECIALTY SOCIETIES
DETAILED STATISTICS ON PRACTICE EXPENSES, HOURS WORKED, AND PRACTICE SIZE
ANALYSIS VARIABLE = OFFICE EXPENSES

SPECIALTY	SAMPLE SIZE	MEAN	STANDARD ERROR	25TH PERCENTILE	MEDIAN	75TH PERCENTILE	MINIMUM	MAXIMUM	# OF ZERO RESPONSES	ITEM RESPONSE RATE (%)
ALL PHYSICIANS	3910	50698.2	1142.6	15000.0	30000.0	60000.0	0.0	996000.0	176	67.3
GENERAL/FAMILY PRACTICE	409	49913.0	3376.1	14000.0	28000.0	52000.0	0.0	600000.0	5	64.2
GENERAL INTERNAL MEDICINE	430	47576.5	2707.8	19000.0	30000.0	50000.0	0.0	600000.0	5	64.6
CARDIOVASCULAR DISEASE	94	54522.4	5215.6	26000.0	40000.0	74000.0	10000.0	320000.0	0	52.6
GASTROENTEROLOGY	84	48693.7	4965.0	22000.0	38500.0	54500.0	0.0	200000.0	1	62.4
ALLERGY/IMMUNOLOGY	31	63935.4	8558.0	35000.0	43000.0	85000.0	2000.0	200000.0	0	61.0
PULMONARY DISEASE	49	41317.3	5065.1	19000.0	34000.0	59000.0	0.0	138000.0	2	57.9
ONCOLOGY	27	67119.9	14946.0	28000.0	53000.0	80000.0	3000.0	367000.0	0	60.4
GENERAL SURGERY	257	47374.9	2969.5	20000.0	32000.0	52000.0	0.0	411000.0	1	68.5
OTOLARYNGOLOGY	103	80982.7	9197.2	31000.0	50000.0	83000.0	10000.0	996000.0	0	68.9
ORTHOPEDIC SURGERY	203	92180.2	7415.7	32000.0	60000.0	100000.0	3000.0	860000.0	0	65.6
OPHTHALMOLOGY	210	84674.1	5888.7	34000.0	60000.0	100000.0	1000.0	800000.0	0	68.1
UROLOGICAL SURGERY	118	64319.1	7055.8	30000.0	40000.0	75000.0	5000.0	650000.0	0	69.6
PLASTIC SURGERY	85	74207.0	8695.1	32000.0	50000.0	100000.0	12000.0	480000.0	0	71.0
NEUROLOGICAL SURGERY	42	87015.9	14587.7	30000.0	57000.0	100000.0	0.0	623000.0	1	73.0
CARD/THOR/VASC SURGERY	44	60266.9	13281.5	15000.0	26500.0	54000.0	3000.0	400000.0	0	58.3
PEDIATRICS	249	55775.5	5114.1	17000.0	30000.0	60000.0	0.0	800000.0	4	64.2
OBSTETRICS/GYNECOLOGY	266	60938.7	3696.8	27000.0	47000.0	80000.0	0.0	500000.0	3	65.7
RADIOLOGY	214	33976.5	5214.3	1000.0	9000.0	35000.0	0.0	800000.0	51	67.1
PSYCHIATRY	351	20852.9	1244.7	9000.0	15000.0	25000.0	0.0	350000.0	4	84.5
ANESTHESIOLOGY	232	16106.4	2486.1	1000.0	6000.0	18000.0	0.0	324000.0	49	71.5
PATHOLOGY	82	17122.6	3710.3	0.0	5000.0	15000.0	0.0	250000.0	22	77.4
DERMATOLOGY	96	75412.7	12526.2	21500.0	38000.0	70000.0	0.0	800000.0	2	73.5
EMERGENCY MEDICINE	61	6470.3	2123.4	0.0	1000.0	5000.0	0.0	96000.0	26	73.3
NEUROLOGY	61	44762.9	3676.2	20000.0	36000.0	60000.0	4000.0	110000.0	0	60.7
PHYS MED/RHEUMATOLOGY	75	59405.3	10546.5	20000.0	35000.0	50000.0	1000.0	630000.0	0	72.2
OTHER SPECIALTY	37	62821.6	22151.6	21000.0	30000.0	60000.0	1000.0	600000.0	0	67.2
Crosswalked Specialties										
GENERAL PRACTICE	90	44263.2	8246.2	9000.0	18000.0	40000.0	0.0	480000.0	1	69.2
FAMILY PRACTICE	319	51609.8	3652.8	17000.0	31000.0	55000.0	0.0	600000.0	4	62.8
NEPHROLOGY	30	37087.6	5946.3	18000.0	38000.0	50000.0	3000.0	149000.0	0	61.0
GEN INT MED EXCL NEPHROLOGY	400	48391.6	2873.4	19000.0	30000.0	50000.0	0.0	600000.0	5	64.9
RADIATION ONCOLOGY	40	31951.8	7551.1	1000.0	7500.0	33500.0	0.0	234000.0	8	82.7
RADIOLOGY EXCL RAD ONCOLOGY	174	34445.5	6181.5	1000.0	9000.0	37000.0	0.0	800000.0	43	64.6
PHYS MEDICINE & REHAB	37	50578.7	11171.7	15000.0	25000.0	50000.0	1000.0	300000.0	0	71.4
RHEUMATOLOGY	38	67404.5	17801.9	28000.0	36500.0	47000.0	7000.0	630000.0	0	73.0

Source: Center for Health Policy Research, American Medical Association, 1995-1997 SMS Surveys.

TABLE 2-4
SMS TABULATIONS FOR RUC/SPECIALTY SOCIETIES
DETAILED STATISTICS ON PRACTICE EXPENSES, HOURS WORKED, AND PRACTICE SIZE
ANALYSIS VARIABLE = MEDICAL SUPPLIES EXPENSES

SPECIALTY	SAMPLE SIZE	MEAN	STANDARD ERROR	25TH PERCENTILE	MEDIAN	75TH PERCENTILE	MINIMUM	MAXIMUM	# OF ZERO RESPONSES	ITEM RESPONSE RATE (%)
ALL PHYSICIANS	3910	19053.1	626.8	1000.0	7000.0	20000.0	0.0	948000.0	853	65.6
GENERAL/FAMILY PRACTICE	409	21049.8	1255.8	7000.0	14000.0	25000.0	0.0	282000.0	8	62.5
GENERAL INTERNAL MEDICINE	430	17825.0	1639.7	3000.0	9000.0	20000.0	0.0	500000.0	30	63.0
CARDIOVASCULAR DISEASE	94	16472.1	2184.6	3000.0	10000.0	25000.0	0.0	120000.0	8	51.3
GASTROENTEROLOGY	84	7003.3	892.4	2000.0	5000.0	10000.0	0.0	40000.0	9	60.0
ALLERGY/IMMUNOLOGY	31	30707.6	6049.5	12000.0	18000.0	36000.0	0.0	150000.0	1	61.0
PULMONARY DISEASE	49	7807.1	1484.8	2000.0	5000.0	10000.0	0.0	45000.0	6	56.8
ONCOLOGY	27	209410.6	35937.8	96000.0	160000.0	350000.0	13000.0	948000.0	0	58.5
GENERAL SURGERY	257	8525.4	900.4	2000.0	5000.0	10000.0	0.0	137000.0	14	67.4
OTOLARYNGOLOGY	103	19827.7	2296.9	6000.0	11000.0	20000.0	0.0	150000.0	2	66.1
ORTHOPEDIC SURGERY	203	29513.5	2196.4	12000.0	20000.0	33000.0	0.0	285000.0	2	61.6
OPHTHALMOLOGY	210	27830.7	3231.1	5000.0	10000.0	24000.0	0.0	390000.0	2	66.4
UROLOGICAL SURGERY	118	69017.7	4814.8	23000.0	60500.0	100000.0	0.0	250000.0	3	65.0
PLASTIC SURGERY	85	35842.9	5418.3	8000.0	20000.0	45000.0	0.0	350000.0	3	68.8
NEUROLOGICAL SURGERY	42	5864.7	2761.9	1000.0	2000.0	5000.0	0.0	136000.0	10	74.6
CARD/THOR/VASC SURGERY	44	4855.2	1444.4	1000.0	2000.0	6000.0	0.0	53000.0	9	56.3
PEDIATRICS	249	29864.5	2401.1	7000.0	20000.0	40000.0	0.0	360000.0	22	60.9
OBSTETRICS/GYNECOLOGY	266	19367.9	1575.5	5000.0	12000.0	26000.0	0.0	180000.0	11	61.9
RADIOLOGY	214	13332.4	2503.3	0.0	0.0	8000.0	0.0	330000.0	139	67.4
PSYCHIATRY	351	921.5	339.4	0.0	0.0	1000.0	0.0	150000.0	258	84.5
ANESTHESIOLOGY	232	825.4	269.4	0.0	0.0	0.0	0.0	50000.0	192	72.4
PATHOLOGY	82	10227.5	2148.4	0.0	0.0	6000.0	0.0	115000.0	45	76.6
DERMATOLOGY	96	28130.9	4815.4	6000.0	15000.0	29500.0	0.0	400000.0	2	72.3
EMERGENCY MEDICINE	61	2672.7	1670.4	0.0	0.0	0.0	0.0	100000.0	53	73.3
NEUROLOGY	61	18120.3	6078.2	1000.0	2000.0	6000.0	0.0	200000.0	10	60.7
PHYS MED/RHEUMATOLOGY	75	11092.2	1615.8	2000.0	6000.0	11000.0	0.0	70000.0	6	68.3
OTHER SPECIALTY	37	11826.7	3848.4	1000.0	4000.0	10000.0	0.0	85000.0	8	67.2
Crosswalked Specialties										
GENERAL PRACTICE	90	14679.5	1653.9	4000.0	10000.0	20000.0	0.0	100000.0	2	65.7
FAMILY PRACTICE	319	22963.0	1526.6	8000.0	16000.0	27000.0	0.0	282000.0	6	61.7
NEPHROLOGY	30	23965.3	15399.4	1000.0	6000.0	15000.0	0.0	500000.0	4	62.7
GEN INT MED EXCL NEPHROLOGY	400	17347.9	1343.9	3000.0	9000.0	20000.0	0.0	250000.0	26	63.0
RADIATION ONCOLOGY	40	13153.7	4770.7	0.0	0.0	3500.0	0.0	133000.0	28	80.8
RADIOLOGY EXCL RAD ONCOLOGY	174	13373.8	2882.6	0.0	0.0	8000.0	0.0	330000.0	111	65.2
PHYS MEDICINE & REHAB	37	6561.8	1973.1	1000.0	2000.0	5000.0	0.0	60000.0	6	65.1
RHEUMATOLOGY	38	15197.9	2363.9	6000.0	8000.0	20000.0	2000.0	70000.0	0	71.4

Source: Center for Health Policy Research, American Medical Association, 1995-1997 SMS Surveys.

TABLE 2-5
SMS TABULATIONS FOR RUC/SPECIALTY SOCIETIES
DETAILED STATISTICS ON PRACTICE EXPENSES, HOURS WORKED, AND PRACTICE SIZE
ANALYSIS VARIABLE = MEDICAL EQUIPMENT EXPENSES

SPECIALTY	SAMPLE SIZE	MEAN	STANDARD ERROR	25TH PERCENTILE	MEDIAN	75TH PERCENTILE	MINIMUM	MAXIMUM	# OF ZERO RESPONSES	ITEM RESPONSE RATE (%)
ALL PHYSICIANS	3910	8705.2	454.9	0.0	1000.0	8000.0	0.0	850000.0	1748	64.2
GENERAL/FAMILY PRACTICE	409	8738.0	1123.3	0.0	3000.0	9000.0	0.0	250000.0	129	60.7
GENERAL INTERNAL MEDICINE	430	6239.6	821.9	0.0	2000.0	6000.0	0.0	166000.0	183	60.9
CARDIOVASCULAR DISEASE	94	18861.1	3523.1	1000.0	8000.0	22000.0	0.0	221000.0	22	49.1
GASTROENTEROLOGY	84	5052.2	761.5	0.0	2000.0	9000.0	0.0	25000.0	31	59.4
ALLERGY/IMMUNOLOGY	31	5889.7	3255.5	0.0	2000.0	7000.0	0.0	107000.0	12	57.6
PULMONARY DISEASE	49	5055.1	1520.4	0.0	2000.0	5000.0	0.0	60000.0	17	57.9
ONCOLOGY	27	14240.7	3601.1	0.0	5000.0	20000.0	0.0	75000.0	7	56.6
GENERAL SURGERY	257	5308.8	760.4	0.0	1000.0	6000.0	0.0	92000.0	123	65.9
OTOLARYNGOLOGY	103	15617.7	2988.7	0.0	7000.0	20000.0	0.0	267000.0	27	63.3
ORTHOPEDIC SURGERY	203	10256.3	1063.0	0.0	5000.0	12000.0	0.0	120000.0	54	61.3
OPHTHALMOLOGY	210	22200.2	2822.3	5000.0	11000.0	27000.0	0.0	500000.0	26	64.1
UROLOGICAL SURGERY	118	17210.5	2717.6	2000.0	7500.0	17000.0	0.0	200000.0	23	62.7
PLASTIC SURGERY	85	13529.8	2884.8	0.0	5000.0	15000.0	0.0	180000.0	27	66.7
NEUROLOGICAL SURGERY	42	2969.4	1025.1	0.0	0.0	1000.0	0.0	48000.0	30	74.6
CARD/THOR/VASC SURGERY	44	13409.5	9255.8	0.0	0.0	3500.0	0.0	400000.0	26	51.5
PEDIATRICS	249	5006.5	766.9	0.0	1000.0	5000.0	0.0	128000.0	104	59.5
OBSTETRICS/GYNECOLOGY	266	10019.8	1102.0	0.0	5000.0	12000.0	0.0	200000.0	73	60.6
RADIOLOGY	214	22568.9	5332.6	0.0	0.0	10000.0	0.0	850000.0	128	67.9
PSYCHIATRY	351	670.6	138.9	0.0	0.0	0.0	0.0	27000.0	301	84.5
ANESTHESIOLOGY	232	804.0	287.4	0.0	0.0	0.0	0.0	60000.0	199	71.5
PATHOLOGY	82	3999.1	1061.3	0.0	0.0	2000.0	0.0	75000.0	54	76.6
DERMATOLOGY	96	10739.2	2614.0	0.0	3000.0	10000.0	0.0	209000.0	32	69.0
EMERGENCY MEDICINE	61	534.8	303.6	0.0	0.0	0.0	0.0	16000.0	54	73.3
NEUROLOGY	61	15108.4	4740.5	0.0	3000.0	8000.0	0.0	160000.0	18	59.0
PHYS MED/RHEUMATOLOGY	75	9886.0	4405.8	0.0	2000.0	5000.0	0.0	323000.0	27	66.7
OTHER SPECIALTY	37	3239.0	1023.9	0.0	0.0	6000.0	0.0	20000.0	21	65.7
Crosswalked Specialties										
GENERAL PRACTICE	90	5441.6	1432.6	0.0	1000.0	6000.0	0.0	132000.0	39	64.5
FAMILY PRACTICE	319	9728.0	1378.7	0.0	4000.0	10000.0	0.0	250000.0	90	59.7
NEPHROLOGY	30	3462.9	1636.7	0.0	0.0	4000.0	0.0	40000.0	17	59.3
GEN INT MED EXCL NEPHROLOGY	400	6455.4	874.3	0.0	2000.0	6500.0	0.0	166000.0	166	61.0
RADIATION ONCOLOGY	40	26814.3	10933.8	0.0	0.0	12500.0	0.0	500000.0	26	80.8
RADIOLOGY EXCL RAD ONCOLOGY	174	21585.5	6069.5	0.0	0.0	9000.0	0.0	850000.0	102	65.8
PHYS MEDICINE & REHAB	37	15729.2	8776.0	0.0	2000.0	5000.0	0.0	323000.0	13	63.5
RHEUMATOLOGY	38	4590.6	1394.5	0.0	1000.0	5000.0	0.0	36000.0	14	69.8

Source: Center for Health Policy Research, American Medical Association, 1995-1997 SMS Surveys.

TABLE 2-6
SMS TABULATIONS FOR RUC/SPECIALTY SOCIETIES
DETAILED STATISTICS ON PRACTICE EXPENSES, HOURS WORKED, AND PRACTICE SIZE
ANALYSIS VARIABLE = OTHER EXPENSES

SPECIALTY	SAMPLE SIZE	MEAN	STANDARD ERROR	25TH PERCENTILE	MEDIAN	75TH PERCENTILE	MINIMUM	MAXIMUM	# OF ZERO RESPONSES	ITEM RESPONSE RATE (%)
ALL PHYSICIANS	3910	29066.4	922.8	6000.0	14000.0	30000.0	0.0	900000.0	107	65.0
GENERAL/FAMILY PRACTICE	409	22718.7	1669.2	5000.0	12000.0	30000.0	0.0	347000.0	12	61.6
GENERAL INTERNAL MEDICINE	430	17642.2	1915.4	5000.0	10000.0	20000.0	0.0	566000.0	17	61.4
CARDIOVASCULAR DISEASE	94	69295.3	18131.5	9000.0	15000.0	40000.0	0.0	900000.0	2	50.0
GASTROENTEROLOGY	84	30833.7	5920.3	5500.0	14500.0	24500.0	0.0	261000.0	1	61.8
ALLERGY/IMMUNOLOGY	31	33185.0	9061.2	12000.0	24000.0	51000.0	0.0	300000.0	1	61.0
PULMONARY DISEASE	49	19019.8	2871.3	8000.0	13000.0	25000.0	1000.0	76000.0	0	57.9
ONCOLOGY	27	26789.6	11112.6	10000.0	16000.0	23000.0	0.0	340000.0	1	58.5
GENERAL SURGERY	257	25807.2	2180.2	6000.0	13000.0	32000.0	0.0	289000.0	11	65.9
OTOLARYNGOLOGY	103	43889.1	5058.4	11000.0	25000.0	50000.0	0.0	447000.0	2	65.6
ORTHOPEDIC SURGERY	203	54862.9	6496.5	10000.0	24000.0	50000.0	0.0	785000.0	5	62.3
OPHTHALMOLOGY	210	58265.3	6276.1	10000.0	28500.0	60000.0	0.0	836000.0	4	65.8
UROLOGICAL SURGERY	118	32382.3	4299.8	8000.0	16000.0	40000.0	0.0	347000.0	2	65.4
PLASTIC SURGERY	85	52004.5	8266.3	10000.0	20000.0	54000.0	0.0	673000.0	1	68.8
NEUROLOGICAL SURGERY	42	44370.7	5823.6	14000.0	30000.0	63000.0	0.0	158000.0	1	74.6
CARD/THOR/VASC SURGERY	44	30776.0	5779.1	6500.0	20000.0	35000.0	2000.0	245000.0	0	56.3
PEDIATRICS	249	22071.9	2963.9	5000.0	10000.0	25000.0	0.0	604000.0	6	60.3
OBSTETRICS/GYNECOLOGY	266	30672.3	2539.6	7000.0	20000.0	40000.0	0.0	301000.0	10	62.7
RADIOLOGY	214	34088.1	3355.5	7000.0	15000.0	40000.0	0.0	482000.0	2	67.1
PSYCHIATRY	351	15022.1	1074.7	5000.0	10000.0	18000.0	0.0	294000.0	10	83.6
ANESTHESIOLOGY	232	15567.3	1980.5	4000.0	8000.0	20000.0	0.0	395000.0	7	70.2
PATHOLOGY	82	46772.5	6430.5	9000.0	24500.0	55000.0	0.0	432000.0	1	75.8
DERMATOLOGY	96	33806.0	6023.8	10000.0	20000.0	39500.0	0.0	553000.0	3	71.0
EMERGENCY MEDICINE	61	15351.7	2718.4	3000.0	8000.0	20000.0	0.0	120000.0	2	70.3
NEUROLOGY	61	19373.7	4678.3	5000.0	10000.0	20000.0	0.0	285000.0	2	59.0
PHYS MED/RHEUMATOLOGY	75	28226.9	7153.5	5000.0	12000.0	29000.0	0.0	469000.0	3	70.6
OTHER SPECIALTY	37	27682.9	6948.7	9000.0	13000.0	30000.0	0.0	170000.0	1	68.7
Crosswalked Specialties										
GENERAL PRACTICE	90	16132.3	2677.7	4000.0	7500.0	18000.0	0.0	160000.0	2	64.5
FAMILY PRACTICE	319	24696.8	1991.5	5000.0	14000.0	33000.0	0.0	347000.0	10	60.8
NEPHROLOGY	30	31465.5	17261.0	5000.0	10000.0	25000.0	0.0	566000.0	2	57.6
GEN INT MED EXCL NEPHROLOGY	400	16568.0	1603.7	5000.0	10000.0	20000.0	0.0	464000.0	15	61.7
RADIATION ONCOLOGY	40	37590.4	5425.9	10000.0	28000.0	49000.0	0.0	185000.0	1	80.8
RADIOLOGY EXCL RAD ONCOLOGY	174	33276.8	3937.9	7000.0	15000.0	35000.0	0.0	482000.0	1	64.9
PHYS MEDICINE & REHAB	37	39513.0	14032.9	5000.0	10000.0	26000.0	0.0	469000.0	1	68.3
RHEUMATOLOGY	38	17998.8	3007.9	6000.0	13500.0	31000.0	0.0	79000.0	2	73.0

TABLE 2-7
SMS TABULATIONS FOR RUC/SPECIALTY SOCIETIES
DETAILED STATISTICS ON PRACTICE EXPENSES, HOURS WORKED, AND PRACTICE SIZE
ANALYSIS VARIABLE = TOTAL EXPENSES EXCL. PLI AND MD PAYROLL

SPECIALTY	SAMPLE SIZE	MEAN	STANDARD ERROR	25TH PERCENTILE	MEDIAN	75TH PERCENTILE	MINIMUM	MAXIMUM	# OF ZERO RESPONSES	ITEM RESPONSE RATE (%)
ALL PHYSICIANS	3910	180334.1	2957.2	66000.0	135000.0	238000.0	1000.0	2172000	.	.
GENERAL/FAMILY PRACTICE	409	182977.0	7473.5	95000.0	145000.0	233000.0	1000.0	1736000	.	.
GENERAL INTERNAL MEDICINE	430	152425.9	6870.8	73000.0	121500.0	189000.0	1000.0	1055000	.	.
CARDIOVASCULAR DISEASE	94	250071.6	27022.8	106000.0	193500.0	275000.0	22000.0	1161000	.	.
GASTROENTEROLOGY	84	155046.8	11130.0	99000.0	133500.0	205500.0	22000.0	501000.0	.	.
ALLERGY/IMMUNOLOGY	31	261606.3	25589.5	166000.0	220000.0	362000.0	50000.0	735000.0	.	.
PULMONARY DISEASE	49	130456.5	8548.0	89000.0	137000.0	179000.0	10000.0	252000.0	.	.
ONCOLOGY	27	429137.2	59165.8	261000.0	444000.0	595000.0	122000.0	1651000	.	.
GENERAL SURGERY	257	149008.7	7292.4	81000.0	128000.0	186000.0	11000.0	1206000	.	.
OTOLARYNGOLOGY	103	269912.3	17264.3	172000.0	231000.0	325000.0	62000.0	1671000	.	.
ORTHOPEDIC SURGERY	203	314797.5	15792.7	165000.0	261000.0	385000.0	18000.0	1525000	.	.
OPHTHALMOLOGY	210	322213.1	16852.7	161000.0	257500.0	430000.0	26000.0	2172000	.	.
UROLOGICAL SURGERY	118	265280.0	13961.6	175000.0	244500.0	338000.0	21000.0	1068000	.	.
PLASTIC SURGERY	85	246038.6	19056.5	113000.0	191000.0	343000.0	44000.0	978000.0	.	.
NEUROLOGICAL SURGERY	42	239933.4	24414.2	155000.0	198000.0	297000.0	30000.0	807000.0	.	.
CARD/THOR/VASC SURGERY	44	214943.3	42690.7	88000.0	126000.0	222000.0	23000.0	1650000	.	.
PEDIATRICS	249	186412.1	10972.8	88000.0	142000.0	237000.0	1000.0	1604000	.	.
OBSTETRICS/GYNECOLOGY	266	212827.1	9097.7	130000.0	185500.0	279000.0	5000.0	1095000	.	.
RADIOLOGY	214	153114.4	15522.7	30000.0	65500.0	165000.0	1000.0	1821000	.	.
PSYCHIATRY	351	54769.8	3070.8	22000.0	38000.0	65000.0	2000.0	679000.0	.	.
ANESTHESIOLOGY	232	75052.9	7014.0	19500.0	34000.0	79500.0	1000.0	762000.0	.	.
PATHOLOGY	82	122377.7	14725.9	21000.0	55000.0	190000.0	1000.0	749000.0	.	.
DERMATOLOGY	96	259501.4	26469.0	107500.0	189500.0	287500.0	24000.0	1550000	.	.
EMERGENCY MEDICINE	61	52434.7	12221.7	10000.0	20000.0	51000.0	1000.0	640000.0	.	.
NEUROLOGY	61	177722.0	25172.3	79000.0	112000.0	156000.0	22000.0	910000.0	.	.
PHYS MED/RHEUMATOLOGY	75	195420.0	24888.6	91000.0	133000.0	200000.0	9000.0	1554000	.	.
OTHER SPECIALTY	37	172241.1	37956.4	70000.0	95000.0	229000.0	18000.0	935000.0	.	.
Crosswalked Specialties										
GENERAL PRACTICE	90	135053.7	14944.1	56000.0	95000.0	162000.0	8000.0	804000.0	.	.
FAMILY PRACTICE	319	197369.9	8457.6	109000.0	162000.0	243000.0	1000.0	1736000	.	.
NEPHROLOGY	30	160998.2	43207.2	59000.0	111000.0	182000.0	22000.0	1055000	.	.
GEN INT MED EXCL NEPHROLOGY	400	151759.7	6661.1	74500.0	122500.0	190000.0	1000.0	1044000	.	.
RADIATION ONCOLOGY	40	173148.8	29716.4	45500.0	69000.0	190000.0	2000.0	1046000	.	.
RADIOLOGY EXCL RAD ONCOLOGY	174	148473.7	17847.8	29000.0	64500.0	159000.0	1000.0	1821000	.	.
PHYS MEDICINE & REHAB	37	193528.7	44141.2	67000.0	107000.0	179000.0	9000.0	1554000	.	.
RHEUMATOLOGY	38	197134.0	24476.3	110000.0	149500.0	204000.0	53000.0	793000.0	.	.

Source: Center for Health Policy Research, American Medical Association, 1995-1997 SMS Surveys.

Table 4

Payment Impact of the June 5, 1998 NPRM

Percent Change in Relative Value Units from MFS 1998

Top 50 Services, Ranked by 1998 Practice Expense Payments

Gastroenterology

ESCRIPTION	1998 PE Payments Rank*	% of Total 1998 PE Payments*	1996 Allowed Services	% Change in PERVU First Year	% Change in PERVU Fully Phased-In	% Change in Total RVU First Year	% Change in Total RVU Fully Phased-In
pper GI endoscopy, biopsy	1	12.00%	584,611	-15%	-69%	-8%	-30%
agnostic colonoscopy	2	10.49%	381,042	-12%	-48%	-6%	-25%
olonoscopy, lesion removal	3	9.64%	242,116	-15%	-60%	-8%	-31%
olonoscopy and biopsy	4	6.87%	228,582	-15%	-68%	-8%	-30%
pper gi endoscopy,diagnosis	5	5.09%	281,228	-15%	-69%	-8%	-30%
ffice/outpatient visit, est	6	4.20%	1,461,196	7%	29%	3%	12%
bsequent hospital care	7	3.96%	1,303,120	-1%	-5%	0%	-2%
olonoscopy	8	3.81%	109,106	-15%	-69%	-8%	-31%
ace gastrostomy tube	9	2.98%	92,569	-16%	-65%	-8%	-34%
bsequent hospital care	10	2.96%	1,152,332	-7%	-27%	-3%	-10%
itial inpatient consult	11	2.78%	343,900	1%	5%	0%	2%
ffice/outpatient visit, est	12	2.69%	704,987	12%	48%	4%	17%
ffice consultation	13	1.82%	227,206	12%	48%	4%	16%
ndoscopy,bile duct/pancreas	14	1.56%	28,340	-17%	-66%	-9%	-35%
ndoscopy,bile duct/pancreas	15	1.47%	56,430	-16%	-63%	-8%	-32%
itial inpatient consult	16	1.35%	127,148	1%	6%	0%	2%
igmoidoscopy, diagnostic	17	1.34%	212,413	32%	128%	15%	62%
bsequent hospital care	18	1.32%	325,166	0%	0%	0%	0%
itial inpatient consult	19	1.31%	204,484	0%	-1%	0%	0%
pensive upper GI endoscopy	20	1.14%	54,924	-17%	-66%	-9%	-35%
ffice consultation	21	1.12%	180,378	12%	48%	4%	17%
ndoscopy,bile duct/pancreas	22	1.07%	17,722	-16%	-63%	-8%	-32%
pper GI endoscopy/guidewire	23	1.07%	45,420	-16%	-64%	-8%	-33%
ffice/outpatient visit, est	24	0.96%	454,594	11%	43%	4%	18%
olonoscopy, lesion removal	25	0.79%	19,855	-14%	-57%	-7%	-28%
ffice consultation	26	0.79%	72,298	7%	28%	2%	9%
ndoscopy,bile duct/pancreas	27	0.77%	14,013	-17%	-66%	-9%	-35%
itial hospital care	28	0.76%	98,979	3%	12%	1%	3%
ffice/outpatient visit, est	29	0.70%	123,034	8%	31%	3%	10%
igmoidoscopy and biopsy	30	0.48%	49,519	2%	6%	1%	3%
pensive upper GI endoscopy	31	0.46%	18,171	-16%	-64%	-8%	-33%
sophagus endoscopy,dilation	32	0.45%	20,854	-16%	-64%	-8%	-33%
itial hospital care	33	0.43%	61,003	-3%	-10%	-1%	-3%
olonoscopy,control bleeding	34	0.42%	10,612	-15%	-59%	-8%	-30%
ffice consultation	35	0.37%	77,673	12%	48%	4%	17%
itial inpatient consult	36	0.36%	70,548	-2%	-6%	-1%	-2%
pper GI endoscopy & inject	37	0.36%	10,429	-16%	-66%	-9%	-34%
ecroendiogram, complete	38	0.34%	86,483	-15%	-59%	-11%	-44%
gital exam	39	0.34%	52,740	-25%	-100%	-25%	-100%
llow-up inpatient consult	40	0.33%	106,698	1%	4%	0%	2%
ace gastrostomy tube	41	0.31%	10,687	-12%	-47%	-6%	-22%
ffice/outpatient visit, new	42	0.31%	52,954	32%	128%	10%	40%
lon esophagus	43	0.29%	62,085	-3%	-14%	-1%	-5%
spital discharge day .	44	0.27%	78,294	3%	11%	1%	3%
nsive upper GI endoscopy	45	0.25%	10,081	-16%	-64%	-8%	-33%
doscopy,bile duct/pancreas	46	0.24%	5,415	-17%	-68%	-9%	-35%
itial exam, first hour	47	0.24%	24,913	1%	5%	0%	1%
nsive upper GI endoscopy	48	0.22%	8,166	-16%	-65%	-8%	-33%
ffice/outpatient visit, new	49	0.21%	33,047	34%	135%	9%	36%
he exam of abdomen	50	0.19%	13,364	-6%	-26%	-8%	-18%
mary of Top 50 Codes		94%	9,980,461	-8%	-32%	-4%	-14%
Other Codes		6%	1,038,915	-5%	-20%	-3%	-8%
Codes		100%	11,019,676	-8%	-31%	-3%	-14%

timated from 1998 RVUs and 1996 Medicare billing volumes crosswalked to 1998.

EXCERPT ON SITE-OF-SERVICE INCENTIVES FROM ACG COMMENTS ON JUNE 18, 1997 PROPOSAL

4. **HCFA's Policy to Incentivize Office-Based Procedures Would Deviate from the Prevailing Standard of Care, and Would Frequently be Inconsistent with the Best Interests of Medicare Patients**

Contrary to the PPRC recommendations that constitute an important component of the legislative history on the Congressional mandate for resource-based practice expenses, and which envisioned a site-neutral practice expense policy, HCFA's proposal creates clear incentives for physicians to shift procedures from the outpatient setting into the office. In fact, it is better to characterize it that HCFA has created penalties for physicians who continue to provide Medicare procedure services

in a hospital or ambulatory surgery center. Only by shifting these cases to the office would the physician be permitted to re-coup anything beyond the most marginal direct practice expense cost. For example, on diagnostic colonoscopies, HCFA's rule would pay the physician about $5 for all direct practice expense costs if the case is performed in the hospital or ASC, but would pay approximately $120.17 for direct practice costs, if the case is performed in the office.

The majority of diagnostic colonoscopies on Medicare patients are performed in the hospital or ASC for good reason that has nothing to do with economics--to meet the quality of care standard for the safety of the patient. While colonoscopy has an excellent record of safety, it cannot be regularly and safely performed in the ordinary office setting.

1. The patient is regularly sedated with valium, demerol or similarly medication and requires monitoring equipment and access to interventional devices in the event of an adverse reaction to these medications.

2. A recovery area is required where the physician and other professional staff can assure that the patient has regained all normal functions before being released.

3. While complications of bleeding or perforation are limited, the facility must be equipped to deal immediately with such complications when they occur.

4. Routine sterilization and infection control of equipment generally requires a separate room where cleansing can be accomplished completely distinct from patient treatment areas.

The normal physician office setting does not provide these safeguards. HCFA knows this. HCFA has, for instance, helped prescribe the criteria that must be met to qualify as a Medicare-approved ambulatory surgery center. Colonoscopies on the Medicare population cannot be safely be performed in a routine physician office setting. There are a small number of gastroenterologists' offices across the country that have been outfitted with the types of facilities present in an ambulatory surgery center, but where the physician has not applied for Medicare certification. It is arguable that significant volumes of Medicare colonoscopies can be safely performed in such a "certifiable" setting. Such situations likely account for the modest percentage of Medicare colonoscopies that are billed as being performed in an office setting. But this modest number of unique office settings cannot be cited as a criteria to change the standard of care.

If HCFA's proposal resulted in significant volumes of Medicare colonoscopies being done in the office, an impossible anomaly would result. Physicians performing office procedures would be subject to malpractice litigation in which they would undoubtedly be challenged for having violated the prevailing standard of care which would require the kind of special facilities found in the hospital or ASC. Medicare's own rules establishing the certification criteria would be cited. Would HCFA's incongruous policy of providing economic incentives to have physicians shift these cases to the office be sufficient to protect these physicians from adverse judgements?--undoubtedly not!

In fact, it has been reported to us that there are state regulations in some jurisdictions that **require** that colonoscopies must be performed in hospitals or ambulatory surgery centers. Would HCFA's policy incentivizing the movement of these colonoscopies to office settings be a defense in claims of a violation of such state law?

Obviously, the correct answer here is that HCFA's incentives toward office-based colonoscopies is out of sync with the prevailing standard of care, physician malpractice obligations, and state law. The answer is NOT to simply drop the practice expense payment for office procedures to the same unfairly low level as this proposal would prescribe for outpatient services. That would compound the inequity. HCFA needs to scrap the office/outpatient differential in practice expense payment, and return to the current policy of a single, fair unified fee--at a minimum at the level which the NPRM would set for office procedures--fairly compensate physician practice expenses, whether in the outpatient or office setting (the type of site-neutral policy that PPRC espoused to Congress), and continue to use the tray fee and site of service differential to address the differences between costs/payments for office and outpatient site of service.

5. ACG Opposes Plans To Scrap Site-Of-Service Differential (Section 414.32)

In addressing the site-of-service differential, HCFA acknowledges "that some office practice cost is incurred when physicians perform procedures outside the office setting." We agree with this statement but must underscore that HCFA has ignored the maxim in assigning the most token practice expense RVU of 0.14 relative value units to almost all major outpatient endoscopic codes. This means HCFA proposes to allow approximately $5 for all costs associated with the office scheduling a procedure at an out-patient setting, providing and instructing the patient on the preparation for that procedure, communication of the results of the procedure to the patient, explanation of prescriptions, follow up medications and billing costs. In short, with respect to the endoscopic codes, HCFA's policy essentially ignores the agency's own conclusion that some office expenses are incurred.

HCFA's proposal on replacing the site-of-service differential with two levels of practice expense RVUs by code is premised on its contention that practice expenses for hospital-based and ambulatory surgery center procedures are covered under the facility fees. In fact, a facility fee is paid to the institution and the physician does not receive that payment nor does it cover the physician's expenses. Therefore, the policy HCFA proposes is too short sighted and, as HCFA should clearly understand, is inequitable.

As noted above, we therefore oppose the proposed revisions to policy Section 414.32 modifying the site-of-service differential.

6. ACG Opposes Plans To Scrap Separate Tray Fee (Section 414.34)

HCFA also proposes to discontinue separate payment for supply codes, i.e., A4263, A4300 and A4550. Previously HCFA established RVUs which included practice expense payments to physicians for all procedures. They recognized that there were additional costs involved for supplies when services were provided in the physician's office and provided these tray fees to

TABLE 1-4
SMS TABULATIONS FOR RUC\SPECIALTY SOCIETIES
SPECIALTY PROFILES
GASTROENTEROLOGY

	ALL SMS	SMS-OWNERS	HCFA SAMPLE
# RESPONDENTS	231.0	165.0	84.0
MEAN AGE	44.8	45.5	45.7
LOCATION			
% RURAL	8.0	9.7	10.4
% SMALL METRO (< 1 MILLION)	35.4	33.2	34.7
% LARGE METRO (1 MILLION+)	56.6	57.0	54.9
CENSUS DIVISION			
% NEW ENGLAND	8.9	6.6	6.3
% MIDDLE ATLANTIC	12.2	13.7	7.7
% EAST NORTH CENTRAL	10.6	9.7	9.7
% WEST NORTH CENTRAL	3.0	0.9	1.0
% SOUTH ATLANTIC	23.3	25.8	22.9
% EAST SOUTH CENTRAL	9.1	10.7	16.2
% WEST SOUTH CENTRAL	11.8	10.6	8.5
% MOUNTAIN	2.1	1.7	3.2
% PACIFIC	18.9	20.3	24.5
% BOARD CERTIFIED	92.9	90.9	91.0
% TIME SPENT IN OFFICE			
% 0-25% OF HOURS IN OFFICE	21.6	19.0	14.6
% 26-50% OF HOURS IN OFFICE	51.8	53.4	57.8
% 51-75% OF HOURS IN OFFICE	23.4	24.5	24.0
% 76-100% OF HOURS IN OFFICE	3.2	3.0	3.6
% TIME SPENT IN SURGERY			
% 0-25% OF HOURS IN SURGERY	64.8	64.0	62.0
% 26-50% OF HOURS IN SURGERY	32.4	32.8	34.5
% 51-75% OF HOURS IN SURGERY	2.8	3.2	3.5
% 76-100% OF HOURS IN SURGERY	0.0	0.0	0.0
% OF REVENUES FROM MEDICARE	41.9	44.0	41.7
% PATIENTS COVERED BY MEDICARE	44.9	47.0	45.7
% USING PROXY FOR EXPENSES		26.2	18.2
TYPE OF PRACTICE			
% SOLO		47.1	50.8
% SINGLE SPECIALTY GROUP		39.4	41.4
% MULTIPLE SPECIALTY GROUP		13.5	7.8
PRACTICE SIZE			
% 2-4 MD PRACTICE		32.2	29.2
% 5-9 MD PRACTICE		13.3	16.5
% 10-25 MD PRACTICE		3.2	2.1
% 26+ MD PRACTICE		4.2	1.3
EQUIPMENT EXPENSES			
% WITH < $5K		58.3	57.3
% WITH < $6-14K		28.4	30.8
% WITH < $15-24K		9.2	10.6
% WITH $25+K		4.2	1.3

Source: Center for Health Policy Research, American Medical Association, 1995-1997 SMS Surveys.