



December 23, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents more than 94,000 family physicians and medical students nationwide. Specifically, I am writing to offer our comments on the final rule with comment regarding "Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B," as published in the *Federal Register* on November 21, 2005.

CMS invited comments on the physician self-referral designated health services listed in tables 32 and 33 of the final rule as well as interim relative value units for (RVUs) for selected codes identified in Addendum C. We do not have any comments on the designated health services list. However, we will offer comments on certain codes in Addendum C and selected other topics included in the final rule, including the (un)sustainable growth rate (SGR).

Withdrawal of Practice Expense (PE) Methodology Proposal

In August, CMS proposed the following changes to its PE methodology:

- Use a bottom-up methodology to calculate direct PE costs
- Eliminate the non-physician work pool
- Use the current indirect PE RVUs, except for those services affected by supplementary survey data accepted by CMS
- Transition the resulting revised PE RVUs over a four-year period

In the final rule, CMS states that due to an error in its indirect PE program, it did not calculate the indirect costs as intended. As a result, almost all of the PE RVUs published in the August proposed rule were incorrect. Consequently, CMS is concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology and did not have a sufficient opportunity to submit meaningful comments on the proposal. As a result, CMS is withdrawing its entire PE methodology proposal and, instead, will use the 2005 PE RVUs to value all services for 2006. CMS goes on to state that it wants to work with the medical community from now through the next proposed rule to discuss issues and questions related to its PE methodology and that it intends to hold meetings on these topics early in 2006.

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As supporters of the bottom-up methodology, we were disappointed that CMS withdrew its proposal to switch to a bottom-up methodology for PE RVUs. However, given the apparent errors in the data published by CMS, we understand its decision to withdraw its proposal. We appreciate CMS's commitment to meet and work with the medical community on these issues in early 2006, and we stand ready to participate in such meetings whenever they occur.

Phase-In for Multiple Procedure Payment Reduction for Diagnostic Imaging

In August, CMS proposed to extend its multiple procedure payment reduction to technical component (TC)-only imaging services and the TC portion of global imaging services for certain imaging modalities (i.e., ultrasound, computed tomography (CT), computed tomographic angiography, magnetic resonance imaging (MRI), and magnetic resonance angiography) that involve contiguous body parts within a family of codes. In the final rule, CMS indicates its intent to generally implement this reduction as proposed. However, to allow for a transition of the changes in payments for these services attributable to this reduction policy and to provide a further opportunity for comment, CMS has decided to phase-in the policy over two years.

We concurred with CMS's proposal in August, and we support its adoption by CMS in the final rule. We also support CMS's decision to phase-in the policy over a two-year period for the reasons cited by CMS. We continue to believe that CMS should consider applying a reduction to the professional component in such situations as well. Just as with the technical component, there are certain efficiencies when a physician is reading images of contiguous areas of the same patient on the same date. For instance, the interpreting physician only has to review the patient's history once to know what he or she is seeking, and often, some portion of the scan is an overlap (i.e., a scan of the pelvis often includes a portion of an abdominal scan). Also, usually there is only one dictation for the multiple scans. Accordingly, there is less physician work involved than would be the case if the scans were interpreted independently at different points in time, and CMS should also consider applying the multiple procedure reduction to the professional component as it evaluates further comments on this policy.

Addendum C – RVUs for Moderate Sedation

As regards the codes in Addendum C of final rule, CMS indicates its intent to carrier price the new codes for moderate sedation services, which essentially replace the current codes for conscious sedation. CMS states, "We are uncertain whether the RUC assigned values are appropriate and have carrier priced these codes in order to gather information for utilization and proper pricing." We appreciate CMS considering payment of sedation services not previously covered and understand this is an interim position. We request that you consider the following arguments in revising that position.

These new CPT codes (99143- 99150) were surveyed by several specialty societies in order to provide the RUC with data necessary to appropriately value the service. Codes were developed to simplify reporting these services into age specific categories. The RUC recommended values for these six codes were based on valid surveys and carefully vetted through the RUC process. We are confident in the accuracy of the values assigned. CMS has listed this service under Status Indicator C, carrier priced. We believe they should be listed with Status Indicator A with the actual RUC recommended relative values listed.

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Providing moderate (conscious) sedation to patients undergoing certain out-patient procedures requires a certain level of provider skill and training, as well as medical legal liability, but is associated with greater patient satisfaction and improved outcomes and overall cost savings than if the same procedure were provided with anesthesia in an operating room.

As you know, CPT developed Appendix G to identify services in which sedation is an inherent part of the procedure. We firmly believe that any service performed that is not listed in Appendix G should be appropriately reimbursed when reported with moderate (conscious) sedation. There is significant additional cognitive skill required and this is reflected in JCAHO mandates addressing specific credentialing criteria for individuals providing moderate sedation. The work involved in providing sedation is not included in the assigned value for procedures not included in Appendix G, and we believe they should be adequately compensated.

For these reasons, we respectfully ask CMS to reconsider the decision to list the moderate sedation codes as carrier priced and instead publish the RUC approved RVUs and pay these services under the Medicare Physician Fee Schedule as Status Indicator A codes.

(Un)sustainable Growth Rate

We would be remiss if we did not address CMS's comments relative to the SGR and update in the conversion factor for 2006. As expected, CMS states in the final rule that the 2006 conversion factor for physician fee schedule services will be \$36.1770. This is approximately 4.4% less than the 2005 conversion factor, and it is less than the conversion factor in 2000. We anticipate Congress will finalize the Deficit Reduction Act and implement a "freeze" in the conversion factor that will avoid the 4.4% decrease. Absent Congressional action, as CMS notes, the conversion factor is projected to decrease about 27% from 2006 to 2012, while the Medicare Economic Index (a measure of inflation in physicians' costs) is projected to increase 19% over the same time period.

We understand that the formula behind the SGR is statutory in nature, which is why we and every other national medical specialty society are actively lobbying Congress to make the necessary changes. However, there are things CMS could do to help but chooses not to do for reasons we do not find defensible. For instance, as we noted in our comments on the proposed rule, CMS could immediately remove, retroactive to the inception of the SGR, the physician-administered drugs from the SGR. Indeed, key members of Congress have told CMS they should do this. Yet, CMS has refused to do so. As CMS admits in the final rule, "retrospective removal of drugs from the SGR is statutorily difficult." However, "difficult" is not "impossible" or "illegal. CMS believes it is "difficult" because the statute requires the estimated SGR to be refined twice based on actual data and CMS does not see a legal basis to re-estimate the SGR and allowed expenditures for a year after it has been estimated and revised twice. This may explain why CMS does not make the requested change back to the beginning of the SGR (although we don't think so), but it does not explain why CMS continues to include physician-administered drugs in its estimated and revised SGRs, thus precluding (in CMS's view) their removal later on. We know, as CMS notes, that removing drugs retroactively from the SGR will not result in a positive update for 2006 or the succeeding few years. But, it will ameliorate the reduction and make a long term, Congressional solution more affordable. We believe CMS should correct the problem, not continue to perpetuate it.

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Recently, CMS proposed to link a portion of Medicare payments to "valid measures of quality and effective use of resources." In this regard, CMS notes that in January 2006, it will start the process of collecting quality information on services provided by physicians in certain specialties and subspecialties through the voluntary reporting of G-codes for quality indicators.

We agree with CMS that "Medicare needs to encourage and reward efficiency and high quality care." The AAFP has had substantial involvement in efforts to improve the quality of care, particularly through the Physician's Consortium on Practice Improvement, the National Quality Forum (AAFP was the first medical specialty to join) and as a founder of the Ambulatory Care Quality Alliance. Additionally we spearheaded with the American Medical Association a framework for moving toward pay for performance in the Medicare program, a framework that was subsequently agreed to by many other specialties. Further, we provide our members with extensive information and resources related to quality improvement. These resources include our Practice Enhancement Program and METRIC (Measuring, Evaluating and Translating Research Into Care), an innovative online practice improvement program that allows members to earn continuing medical education credit in their office while improving patient care.

We have shared our initial concerns about the voluntary reporting program with CMS staff in face-to-face meetings and through separate correspondence, and we want to emphasize our efforts to work with CMS to craft a workable program. However, it is important that work on the voluntary reporting program neither distract nor detract from efforts to fundamentally solve the SGR problem, because allowing the payment rate to fall below what it was five years ago will neither encourage nor reward efficient and high quality care.

We appreciate this opportunity to comment on matters related to the Medicare Fee Schedule. As always, the American Academy of Family Physicians looks forward to working with CMS in its continued efforts to ensure access to appropriate physician services.

Sincerely,

Mary E. Frank, M.D.

Mary E. Frank, M.D., FAAFP
Board Chair

THE UROLOGICAL INSTITUTE OF NORTHEASTERN NEW YORK

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DEC 28 2005

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist, I am delighted that CMS has "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, as you know, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

As you know, CMS has attributed the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We can understand that CMS has the view that interested parties were not provided adequate notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error could and should have been handled through the use of a correction notice rather than withdrawing the proposals. The result of the current policy is that for the moment, practicing physicians are paying a significant financial penalty for the agency's error. This is from a loss of reimbursement for moneys rightfully due them for the loss of practice expenses that are well documented.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. I believe it is extremely unfair and inequitable that implementation of the AUA's survey has been delayed and that our organizations should have to go through this process to determine whether supplemental urology data will be used. Other groups have not had to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,



Hugh A.G. Fisher, MD
Associate Professor of Surgery
Albany Medical College
Hfisher@communitycare.com

Cc: Honorable Charles Schumer
Honorable Hillary Clinton
Honorable Michael McNulty
American Urological Association

- Barry A. Kogan, M.D.**
Falk Chair in Urology
Professor, Surgery and Pediatrics
Chief, Division of Urology
Albany Medical College
- Elise J.B. De, M.D.**
Assistant Professor of Surgery
- Hugh A.G. Fisher, M.D.**
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- Ronald P. Kaufman, Jr., M.D.**
Associate Professor of Surgery
- Badar M. Mian, M.D.**
Assistant Professor of Surgery
- Mark D. White, M.D.**
Associate Professor of Surgery
- Harry J. Wilbur, M.D.**
Associate Professor of Surgery
- Carl E. Diaz-Parker, R.P.A.-C.**
Instructor of Surgery
- Karla M. Giramonti, R.N., M.S., F.N.P.**
Instructor of Surgery
- Jenny Dinh, R.P.A.-C**
- Gennadi V. Glinski, M.D., Ph.D.**
Adjunct Professor of Surgery
- Robert M. Levin, Ph.D.**
Adjunct Professor of Surgery
- Anita S. Mannikarottu, Ph.D.**
Adjunct Assistant Professor of Surgery

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DEC 28

Joel Sherman, MD
2454 Hylan Blvd.
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718-233-1300

December 20, 2005

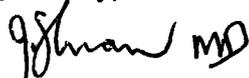
To whom it may concern,

I am **opposed** to the decision of the Centers for Medicare & Medicaid Services (CMS) to withdraw Urology's practice expense (PE) increases. CMS has demonstrated blatant disregard for the requirements of the 2006 Medicare Modernization Act (MMA) regarding the use of urology supplemental PE survey data. The American Urological Association has commented as well as had in-person meetings with CMS regarding the **selective** use of PE data which has only been applied to urology drug administration CPT codes and has held the PE Relative Value Units (RVUs) constant between 2005 and 2006 for **all other** urology procedures.

The MMA contained 2 requirements regarding CMS's use of Urology supplemental PE survey data: (1) that CMS use this survey data to revise the PE RVUs for 2006; and (2) that any changes to PE RVUs for urology drug administration CPT codes should be exempt from a budget neutrality adjustment.

It is wrong not to use the urology supplemental PE data. CMS should live up to its obligations as spelled out in the MMA.

Respectfully,



Joel Sherman, MD



December 19, 2005

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DEC 28 2005

**UROLOGY
CENTER
OF
FLORIDA**

Mark McClellan, MD, PhD
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
PO Box 8017
Baltimore, MD 21244-8017

D. Russell Locke, M.D.
Ira W. Klimberg, M.D.

Dear Doctor McClellan,

Marianna Szabo, M.D.
Pathology

As a registered nurse practicing in a urology group practice with a large Medicare patient population, I am writing to urge you to **order CMS to immediately use the AUA's supplemental practice expense data to update PE RVU's for all urologic procedures.**

Roger Madore, P.A.-C.
William Smith, P.A.-C.
Rick Sessions, P.A.-C.

I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA).

Raymond McNeal
Administrator

Dick Lloyd, R.N.
Director of Nursing

However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

Eileen McGowan, L.P.N.
Clinic Director

Diane Burroughs, R.N.
OR Director
Risk Manager

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity.

Ellen Metivier
Clinical Research Director

It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process.

3201 SW 34th Street
Ocala, Florida 34474
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Fax: (352) 237-5684

Stonecrest Medical Offices
10973 SE 175th Pl, Ste 103
Summerfield, FL 34491
(352) 347-8100
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As a registered nurse, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVU's for all procedures performed by urologists.

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Fax: (352) 237-4121

Thank you,

A handwritten signature in cursive script that reads "Sarah Gonzalez".

Sarah Gonzalez, RN

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Sean Tirney, M.D.
Urology Spokesperson
Watson Clinic LLP
1600 Lakeland Hills Blvd.
Lakeland, FL 33805
(863) 680-7659

DEC 28 2005

12/16/2005

Mark McClellan, M.D., Ph.D.
Administrator Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1502-FC
P. O. Box 8017
Baltimore, Maryland 21244-8017

Dear Dr. McClellan:

In reviewing the actions by CMS recently regarding the urologist practice expense supplement, I am concerned that CMS did not fully comply with the Medicare Modernization Act, as the MMA requires that CMS "use urology supplemental practice expense data" to calculate the 2006 relative value units for all urology procedures, not just urology drug administration.

I disagree with CMS' withdrawing of the proposals. I understand that withdrawal of the entire PE proposal was done due to errors of the computer program, which caused almost all the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned, that the interested parties were not provided notice of the actual effects of opposed changes in the PE RVU methodology; however, correction of this error should have been done with correction notices rather than withdrawal of the proposal. Now, we are forced to endure the loss of practice expense payments due to your error.

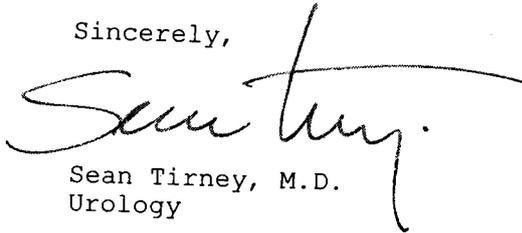
An objectivity issue may also be inferred due to CMS' decision to accept the data provided by the supplemental survey but not to utilize it. The AUA exercised the option that was given to all specialty societies. The AUA submitted practice expense supplemental survey data under the good faith assumption that if our survey met the criteria established by CMS the data would then be used to adjust urology's practice expense costs to more accurately reflect their costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data for other medical societies.

I am unclear as to why the AUA surveys have been delayed and that we would need to go through further meetings on the topic to have this implemented in 2007 when the AUA clearly submitted this on time to be addressed by CMS for 2006. This is unfair as you have not performed this across the board with other subspecialty groups.

Mark McClellan, M.D., Ph.D.
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Page Two

As a practicing urologist I strongly urge CMS to do whatever is necessary to ensure that AUAs supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Sincerely,



Sean Tirney, M.D.
Urology

CC: The Honorable Adam Putnam, Republican Congressman from FL's 12th District, 710 East Main Street Bartow, FL 33830

DT: mjc/12/20/2005 11:11:35
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December 22, 2005

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Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Attention CMS-1502-FC

Dear Dr. McClellan:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Medicare program final rule on revisions to payment policies under the physician fee schedule for calendar year 2006. The CAP is the national medical specialty society for pathologists representing more than 16,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in independent laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

We welcome the opportunity to submit comments on the interim RVU included in Addendum C of the final physician fee schedule for calendar year 2006 for new CPT code 88334, *Pathology consultation during surgery; cytologic examination (eg, touch prep, squash prep), each additional site*. In the final rule, CMS disagreed with the RUC approved work relative value unit (RVU) of 0.80 and assigned a value 0.59 work RVUs for 88334. We disagree with CMS' determination of this work RVU and are requesting that this interim value be restored to the RUC approved value of 0.80.

In the final rule, CMS states that the RUC reviewed CAP's survey data and noted that 88334, when compared to the reference code 88332 has higher intensity/complexity measures and an additional five minutes of intra-service time. The final rule further states that "although 88334 has an additional five minutes of intra-service time, we believe that 88334 is very similar in work to 88332, and therefore, should be valued the same."

Mark B. McClellan, MD, PhD

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We take issue with the comparison of the reference code 88332, *Pathology consultation during surgery; each additional tissue block with frozen section(s)*, to the new CPT code 88334 as "very similar in work." To equate the work of the 88334, a cytologic examination based on review of cellular material imprinting on a slide where each and all fields are at risk for harboring neoplastic cells which are few, to 88332, frozen section evaluation, is fallacious. If the tumor were identifiable grossly, the specimen would be evaluated by frozen section, which is more easily interpretable by virtue of the architectural arrangement of the cells, which is not present on cytologic review.

CAP believes that additional data or rationale would be necessary to substantiate CMS' claim that the two codes are equivalent work, since those of us who routinely perform both services know that there is increased work mainly vested in the necessity to examine every field under at least 10X magnification, which is not inherent in the frozen section process. This additional work was reflected in the RUC survey data which were internally consistent and showed increases in time as well as intensity and complexity measures over the reference code 88332 which is the code to which CMS chose to crosswalk. Both the RUC and a pre-facilitation committee examined the data and rationale carefully and both concurred with the code valuation without issue.

The College of American Pathologists welcomes the opportunity to request that the interim work value for new CPT code 88334 be restored to the RUC approved value of 0.80. Any questions regarding the CAP comments should be directed to Pam Johnson, in the CAP Division of Membership and Advocacy, at 202-354-7132 or pajohns@cap.org.

Sincerely,



Thomas M. Sodeman, MD, FCAP
President

December 21, 2005

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2005 DEC 22 P 12: 10

Via Email and Hand Delivery

Mark McClellan, Administrator, CMS
U.S. Department of Health and Human Services
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Room 445-G, Hubert H. Humphrey Building
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Washington, DC 20201

RE: CMS- 1502-FC: New CPT codes and interim RVUs for Kyphoplasty Procedures

Dear Mr. McClellan:

We are pleased to submit comments on the CMS Final Rule with comment: Medicare Physician Fee Schedule (MPFS) Update for 2006 (70 Fed. Reg. 70,116). Our comments focus on the new Category I CPT codes and the interim relative values units (RVUs) established for kyphoplasty. Specifically, we --

- Support the creation of new Category I CPT codes for kyphoplasty;
- Appreciate CMS's recognition of the new CPT codes for kyphoplasty in the Final Rule;
- Believe the expert panel at the RUC meeting may have overlooked the "biopsy" procedure and a "post-service hospital visit," among other things; and therefore, we
- Request CMS re-examine the "physician work" RVUs assigned to kyphoplasty procedures.

By way of background, kyphoplasty is a unique surgical treatment for vertebral compression fractures. The clinical and scientific data related to kyphoplasty are compelling. Kyphoplasty improves patient outcomes by restoring vertebral body height; correcting the angular deformity (kyphosis); stabilizing the compression fracture; reducing back pain; and improving patients' quality of life and ability to perform activities of daily living. On September 14, 2005, we met with CMS staff to discuss our concerns regarding the "physician work" RVUs for kyphoplasty procedures. We wish to reiterate these recommendations and urge CMS to re-examine the RVUs for kyphoplasty. Such action is needed to establish appropriate Medicare payment for kyphoplasty and to preserve patient access to these important and valuable procedures.

I. Recommendations for Physician Work RVUs

Our recommendations for the physician work RVUs are as follows.

CPT code	Brief description	Recommended Work RVUs
2252X1	Thoracic kyphoplasty, with biopsy	10.16 to 12.00
2252X2	Lumbar kyphoplasty, with biopsy	9.72 to 11.34
2252X3	Each additional level, kyphoplasty	4.65 to 6.64

These recommendations are supported by our findings which are summarized below.

- The "biopsy of vertebral body," which is part of the intra-service work time may have been overlooked by the expert panel in its recommendations.
- The immediate post-service same day time for each kyphoplasty code was underestimated as compared to the other related spinal procedures.

- One post-service hospital visit should be added for the kyphoplasty codes because 60% of the survey respondents indicated they conducted a post-op visit on the day of surgery and discharged the patient the next day.

II. Validation and Support for Increasing the RVUs

Our recommendations, particularly the upper range of RVUs, are validated by numerous Medicare carrier medical directors who have examined the work involved for kyphoplasty. Payment policies exist in all 50 states and the District of Columbia.

As you may know, physician payment policy at the Medicare Carriers level is established by the Medicare Carrier Medical Directors (CMDs). Their payment value decisions for kyphoplasty have been based on a series of individual judgments regarding the relative value of work required for kyphoplasty, most likely compared to similar reference codes (procedures) such as discectomy and vertebroplasty. In the tables below, we have summarized the current physician "work" RVUs established by various Medicare CMDs.

About 40% of the Medicare CMDs have established physician payment rates which, when divided by the current conversion factor appear to be based on the physician work RVUs listed below.

		Medicare MCDs value of physician "Work"
2252X1	Thoracic kyphoplasty, with biopsy	13.37
2252X2	Lumbar kyphoplasty, with biopsy	12.51
2252X3	Each additional level, kyphoplasty	6.47

Approximately 35% of the Medicare CMDs have established physician payment rates using the physician work RVUs listed below.

		Medicare MCDs value of physician "Work"
2252X1	Thoracic kyphoplasty, with biopsy	17.82
2252X2	Lumbar kyphoplasty, with biopsy	16.68
2252X3	Each additional level, kyphoplasty	8.62

The Medicare CMDs' current payment policies confirm the significant amount of physician work involved for kyphoplasty, especially when these values are compared to other spinal procedures.

III. Conclusion

Collectively, we have performed over 1000 kyphoplasty procedures. Based on our knowledge of the procedure, the work involved for kyphoplasty, and the work involved for other spinal procedures, and the current established Medicare Carrier payment policies, we urge CMS to re-examine the physician "work" RVUs for kyphoplasty procedures and implement appropriate adjustments, consistent with the existing CMD payment policies and our "conservative" recommendations.

In sum, to reiterate, our recommendations to CMS are as follows:

2252x1 Thoracic Kyphoplasty

- Increase immediate post-service time to 26 minutes
- Allow one post service hospital visit 99232 and the associated 1.06 RVUs

- Recommend refined "work" RVU of 10.16 to 12.00

2252x2 Lumbar Kyphoplasty

- Increase immediate post-service time to 26 minutes
- Allow one post service hospital visit 99232 and the associated 1.06 RVUs
- Recommend refined "work" RVU of 9.72 to 11.34

2252x3 Lumbar Kyphoplasty, each additional level

- Recommend intra-service time of 56 minutes
- Recommend refined "work" RVU of 4.65 to 6.64

We appreciate the opportunity to submit these comments and we would appreciate the opportunity to continue to work with CMS to implement these changes. Please feel free to contact us if you have any questions or if we can provide further information. Specifically, if CMS does convene a panel to discuss validation of the RVUs for kyphoplasty, we would be pleased to participate.

Sincerely,



Jon Ledlie, M.D.
President- Tyler Neurosurgical Associates
Past- President, Texas Assoc. of Neurological
Surgeons
Ex-Chief of Staff- East Texas Medical Center



Michael Marks, M.D., M.B.A.
President – Coastal Orthopaedics, PC
Chief of Staff – Norwalk Hospital
Immediate Past-President of CT Orthopedic
Society

cc: Carolyn Mullen, CMS
Ken Simon, M.D., CMS
Edith Hambrick, M.D., J.D., CMS
Carol Bazell, M.D. CMS



26

Randel E. Richner
Vice President
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Washington, DC 20004

RECEIVED - CMS

DEC 20 2 09

December 20, 2005

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1502-FC: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule [42 CFR Part 405, et al.]

Dear Administrator McClellan:

Boston Scientific Corporation (Boston Scientific) appreciates the opportunity to present these comments and policy recommendations on the Centers for Medicare and Medicaid Services' (CMS's) Physician Fee Schedule Final Rule for Calendar Year 2006 (Volume 70, No. 223, November 21, 2005).

As the world's largest company dedicated to the development, manufacturing, and marketing of less-invasive therapies, Boston Scientific supplies medical devices and technologies used by physicians representing the following medical specialty areas:

- Electrophysiology;
- Endoscopy;
- Gastroenterology;
- Gynecology;
- Interventional Cardiology;
- Neurovascular;
- Oncology;
- Peripheral Interventions;
- Urology; and
- Vascular Surgery.

We are commenting on three policy issues addressed in the Calendar Year 2006 Physician Fee Schedule Final Rule that have important implications for physicians and their continued ability to offer Medicare beneficiaries the latest advances in clinical care:

1. Discussion of Codes for Which There Were No RUC Recommendations or for Which the RUC Recommendations Were Not Accepted (page 70281);
2. Assignment of In-Office Inputs for CPT Code 52648, Contact Laser Vaporization; and
3. Resource-Based Practice Expense Relative Value Units (PE RVUs) (page 70121).

Discussion of Codes for Which There Were No RUC Recommendations or for Which the RUC Recommendations Were Not Accepted

The American Medical Association (AMA) recently established two new CPT codes, 61630 and 61635, to describe intracranial stenting and angioplasty. In the Final Rule, CMS assigned an "N" status indicator to these codes, indicating non-covered services under Medicare, and declined to publish the associated RVUs for the new codes.

Boston Scientific estimates that approximately 50% of intracranial stenting and angioplasty cases involve non-Medicare insurers. As such, Medicare's actions can adversely impact non-Medicare patients' access to a therapy of last resort that has been endorsed by American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and American Society of Neuroradiology (ASN) as the standard of care for symptomatic patients with a >50% intracranial stenosis who have failed medical therapy.¹

CMS' decision not to assign values to these codes and not to designate them with an "C" status indicator has far-reaching implications for privately insured patients whose payers use the Medicare Physician Fee Schedule as a basis for payment. More importantly, the decision not to assign RVUs to the codes makes it extremely difficult for private payers to determine how much to pay for the associated physician services. The Medicare Physician Fee Schedule is currently the only venue where the RVU assignments are published. Therefore, it is inappropriate for CMS to decline to publish the values simply because Medicare does not pay for the procedures.

In addition to the difficulties associated with the lack of assigned values for the intracranial angioplasty and stenting codes, CMS incorrectly assigned an "N" status indicator to the new vasospasm treatment codes (codes 61640, 61641, and 61642). These procedures are not addressed by a Medicare national non-coverage policy. Intracranial vasospasm is a narrowing of an intracranial vessel due to neurovascular trauma such as subarachnoid hemorrhage. Balloon dilatation for vasospasm is considered an acceptable, established intervention in the medical literature.²

We respectfully request that CMS assign a "C" status indicator and publish the RVUs assigned to CPT codes 61630 and 61635 as soon as possible, either through a correction notice or a quarterly fee-schedule update. The "C" status indicator still allows Medicare contractors to make local edits to indicate non-coverage, and it prevents non-Medicare payers' systems from automatically rejecting claims when they do not have a non-coverage policy in place. The publication of the RVUs will provide non-Medicare payers with the information they need to assign appropriate value to the procedures, should they elect to cover them. We also request that CMS remove the "N" status indicator, assign the appropriate status indicator, and publish the RVUs for the three new vasospasm CPT codes (codes 61640, 61641, and 61642) in a correction notice or quarterly update.

¹ Higashida, *et al.* Intracranial Angioplasty & Stenting for Cerebral Atherosclerosis: Current Position Statement of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASN). *Journal of Vascular & Interventional Radiology*. 16(10):1281-1285, October 2005. Also published in *American Journal of Neuroradiology*. 2005 26: 2323-2327.

² Hoh BL, *et al.* Endovascular treatment of cerebral vasospasm: transluminal balloon angioplasty, intra-arterial papaverine, and intra-arterial nicardipine. *Neurosurg Clin N Am*. 2005 Jul;16(3):501-16, vi.

Assignment of in-office inputs for CPT code 52648

We strongly support the American Urological Association's (AUA) request to assign direct cost inputs to CPT code 52648 (Laser Vaporization of the Prostate) when performed in the non-facility (office) setting. We urge CMS to take this step as soon as possible, as it would ensure that Medicare patients have access to the latest less-invasive technologies to treat benign prostatic hyperplasia (BPH).

In their September 2005 comments, the AUA urged CMS to take this step on an interim basis, by establishing appropriate in-office RVUs for this procedure by cross-walking the inputs from CPT code 52647 (Laser Coagulation of the Prostate). CPT codes 52647 and 52648 describe exceptionally similar procedures that use single-use laser fibers passed through resectoscopes to deliver ablative energy to the prostate for the treatment of BPH. Laser treatments are less-invasive and generally do not require inpatient stays, unlike the gold standard for treating BPH, transurethral resection of the prostate (TURP).

While there were historical reasons for originally assigning in-office inputs to only CPT code 52647 in 2001, today's laser technology allows both prostate coagulation and vaporization procedures to be performed in many office settings. Therefore, **we urge CMS to assign in-office direct cost inputs to CPT code 52648**. This would be consistent with Medicare policy and would ensure Medicare patient access to all BPH laser surgery procedures, regardless of site of service.

We hope that this change is effectuated through a correction notice or a quarterly fee schedule update for CY 2006, and through the rulemaking process for CY 2007.

Resource-Based PE RVUs

Boston Scientific applauds CMS's efforts to simplify the methodology for calculating the PE for 2006, and its flexibility in extending the deadline for physician specialties to submit supplemental survey data to improve the accuracy of the indirect practice expense. However, **we are disappointed by CMS's decision to freeze 2006 PE RVUs at the 2005 values and the decision not to utilize the supplemental data provided by the following professional societies:**

- Association of Freestanding Radiation Oncology Centers (AFROC);
- American Urological Association (AUA);
- American Academy of Dermatology Association (AADA);
- Joint Council of Allergy, Asthma, and Immunology (JCAAI); and
- Joint survey from the American Gastroenterological Association (AGA), the American Society of Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG).

By using 2005 values when more up-to-date data are available, CMS is neither following the statutory guidance nor its own administrative processes. CMS is required by Section 212 of the BBA to establish a process to supplement the Socioeconomic Monitoring System (SMS) data gathered by the American Medical Association with data collected by specialty societies. CMS's acceptance of the supplemental survey data from the submitting societies as appropriate for use in calculating indirect PE values creates an obligation to use these data, because it is a tacit agreement that the data are more reliable than previously available information. Therefore, to not apply the supplemental survey data in calculating PE is a contradiction of CMS's intent, as stated in the proposed rule dated August 8, 2005, "to ensure that the PE payments reflect, to the greatest extent possible, the actual relative resources required for each of the services on the PFS."³

³ Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Part 405, 410, 411, 413, 414, and 426. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule. Federal Register. 70(151); August 8, 2005: Page 45775.

- The error in CMS's PE calculation in the proposed rule should have been handled through a correction notice and/or an extended comment period rather than a withdrawal of the proposed changes. While we appreciate CMS's concern that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology, the decision to maintain the "status quo" for 2006 penalizes certain physician specialties by maintaining lower PE payments.
- It is inappropriate to penalize specialties that met CMS's criteria and submission timelines because other specialties have not yet conducted or submitted their surveys. As detailed in the proposed rule, *all professional societies were given the option and opportunity to provide supplemental data.* However, at no point did CMS suggest that it intended to refrain from acting on submissions until all societies had submitted survey data. Moreover, multiple societies expended considerable time, effort, and financial resources to collect and submit data meeting CMS's criteria for acceptance within the timelines allowed by CMS. The decision not to utilize the supplemental data penalizes those groups that responded to CMS's request. In addition, other societies may question the need to expend similar resources if they are not held to a timeline and if they do not anticipate that the data they provide will be used.

We respectfully request that at the next possible opportunity, CMS consider the following actions:

- **Utilize the data submitted by AFROC, AUA, AADA, JCAAI, AGA, ASGE and ACG in the calculation of physician payment for relevant procedures for the 2006 Medicare Physician Fee Schedule.**
- **Revise the submission timetable to allow for continued submission of indirect PE data to provide the opportunity for other specialty groups to survey their memberships.**
- **In future updates, incorporate data from other specialties if such data meet CMS's criteria.**
- **To avoid constant revisions to each specialty's indirect PE calculations, limit the number of times an individual society or group of societies can submit data within a given time period.**

Enacting these changes will enable CMS to meet its objective of representing procedure value as accurately as possible. It will also recognize the effort undertaken by the submitting societies and motivate other professional societies to gather and submit updated PE information.

We thank CMS for the opportunity to comment on the 2006 Physician Fee Schedule Final Rule. Please contact me via phone at 508-652-7410 or via e-mail at randel.richner@bsci.com if you have any questions.

Sincerely,



Randel E. Richner, BSN, MPH
Vice President, Federal Affairs and Reimbursement & Outcomes Planning

Attachment

Cc: Steve Phillips
Marc Hartstein
Carolyn Mullen
Ken Simon

DEC 30 2005

SERGIO J. RYBKA, M.D., P.C.

ADULT AND PEDIATRIC UROLOGY
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Key Points: CMS Withdrawal of Proposed Practice Expense Increase

- I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA).
- However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.
- CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology.
- However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.
- CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity.
- The AUA exercised the option that was given to *all* specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.
- CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process.
- As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.



DEC 30 2005



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December 30, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1502FC and CMS-1325-F Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule

American Thoracic Society Physicians Comments on: SGR, Education and Training Codes, Supplemental Practice Expense Surveys, Respiratory Therapy G0237-G0239, Inhalation Drugs and Dispensing Fees, Missing Equipment Pricing Data

Dear Dr. McClellan:

On behalf of the members of the American Thoracic Society (ATS), I would like to express our appreciation for the opportunity to comment on the final rule for the 2006 Medicare Physician's Fee Schedule published on November 21, 2005. The ATS represents over 13,000 physicians, researchers, and allied health professionals, who are actively engaged in the diagnosis, treatment and research of respiratory disease and critical care medicine. We are most interested in quality care and access to care for the beneficiaries you represent, and those same patients we serve.

The ATS offers the following comments and wishes to again challenge the calculation of the SGR formula.

Workforce and Other Issues Impacting Medical Practice

The ATS, like many of our colleagues, is quite dismayed with the national division between the cognitive specialties and the procedural, primarily, surgical specialties over the review of the Evaluation and Management codes as part of the CMS third-Five Year Review. This division occurs naturally because of the Medicare physician fee schedule total available funds being capped. We are reviewing a final rule with a -4.4% reduced conversion factor from the 2005 CF. The 2004 and 2005 conversion factors each had a positive 1.5% update, which did not fix the problem. This Act of Congress only delayed the real problem, of fixing the Sustainable Growth Rate (SGR) methodology as part of the Medicare Physician Fee Schedule. As we write this letter, we are anxiously awaiting a late decision by Congress to increase the conversion factor, which will continue the frustration of physicians around the country, without really fixing the problem. All specialties are having significant Workforce issues because of their decreasing reimbursements, onerous government and other insurer's requirements.

Every medical specialty society agrees unanimously that the SGR formula needs to be abolished and replaced with the annual updates based on the Medicare Economic Index. We cannot keep working with these minor fixes and delays. We need to permanently fix the formula. ATS continues to strongly urge CMS to exercise its discretionary authority to remove the costs of Medicare-covered physician-administered drugs (increased from \$1.8 billion in 1996 to \$8.7 billion in 2004) from the SGR calculation. Nearly the entire medical community has commented on this issue and continues to remain frustrated that this SGR-adjustment has not been made.

ATS has serious concerns with the "Value-based purchasing" or initiative as proposed by CMS. We strongly recommend that CMS work with the physician community to implement a workable system rather than rush to impose a significant new system on the health care community. The 36 measures that CMS has put forward have not been reviewed by all involved medical specialties. Computers cannot report such numbers without having a dollar value (or even 1 cent) attached to the number, and surely there is no incentive and additional administrative hassles to implement reporting of such performance measurement measures. We also agree that CMS should work through the long-established AMA Performance Measures Advisory Group's Category II CPT codes and implement in 2009 after there has been review and consideration and time for medical specialties to educate their members on the new system.

CMS Open Door Forum

ATS applauds the efforts of CMS with increased communication through monthly conference calls and information being readily accessible on the CMS Web site. Our staff just participated in an Open Door Forum where the theme of the discussion was related to helping your beneficiaries understand the new Part D Drug Benefit being effective in 2006. It is helpful for physicians to know about the program. But where is that administrative task of helping seniors understand Part D the responsibility of physicians who are providing care to your beneficiaries? There was quite an interesting question asked by staff from NY asking about CMS requiring a uniform appeals process related to the possibility of each of the carriers having various complicated, confusing and contradictory appeals processes. CMS' response was that they would monitor, but could not dictate a uniform appeals process. WHY NOT? CMS needs to review carefully that any major programmatic changes send the marketplace into complete chaos, and physicians and their staff are on the front-line, face-to-face, one-on-one with your beneficiaries, hearing their complaints and dealing with their chronic illnesses, such as asthma, that are exacerbated by their being under stress, due to such significant changes as Part D being integrated into the health care system.

A Major Suggestion

ATS requests to have additional monies added to the Medicare Physician Fee Schedule. We need real dollars added for all the ancillary costs associated with the new preventive benefits being added for beneficiaries. We know that prevention saves dollars.

Respiratory Therapy "G" Codes Transitioning to CPT (page 70150)

ATS does not understand the continued resistance in supporting this service provided by respiratory therapists or other physician-employed providers such as nurses and physiologists, using G0237-G0238 at about \$19 per 15 minutes (G0239 the group code is paid about \$13 each), when the same service, if provided by a physical or occupational therapist is reported with CPT 97110, paid about \$28 per 15 minutes, about 50% more per quarter hour.

ATS, ACCP, NAMDRRC, and AARC have a meeting scheduled for January 24 to meet with CMS at their headquarters in Baltimore to discuss the CPT proposal being reviewed in February 2006 by the CPT Editorial Panel to move G0237-G0239 into CPT. If CMS chooses to maintain an old "profiling" system that went out with RBRVS in 1992, for RTs, at least do not hinder us for getting codes approved in CPT and valued in RUC that would be recognized by other third party payers. We are looking forward to the opportunity for the discussion.

ATS, as part of a group of specialties, ACCP, ATS, NAMDR, and AACVPR had submitted a request to CMS for a National Coverage Decision on April 3, 2003, and to date have not had a response to our request. We understand that there are rules in coverage about a time limit to responding to requests. We are long past that time limit, and want to discuss with the coverage group if we can work out the issues with respiratory therapy services with the CMS payment group. We are requesting that respiratory therapy services as a component of pulmonary rehabilitation be a covered benefit, and valued equivalent to the same service provided by PT/OT.

Education and Training Codes Request for Coverage

On behalf of the asthma patients we serve, ATS requests CMS reconsider their decision to not cover the new Education and Training codes, CPT 98960-98962 for Patient Self-Management. These codes are used to report educational and training services prescribed by a physician and provided by a qualified, nonphysician healthcare professional using a standardized curriculum to an individual or group of patients for the treatment of established illness(es)/disease(s) or to delay comorbidity(s). Physician education is appropriately included and reported in an evaluation and management code.

CMS actively participated in the process of dividing the group code into two codes so that the practice expenses could be accurately calculated. We were surprised to see that these codes were not covered. We ask your reconsideration of this issue and offer to meet with you to discuss this benefit for your beneficiaries. Education is a key to assisting our patients, your beneficiaries in understanding their illness and medication compliance. If you continue to choose not to cover these codes, we ask that you publish the relative values for the codes so that other insurers would know the values, since the RUC database is proprietary and not available to other third party insurers. There is CMS precedence in reporting such values with other preventive services.

Supplemental Practice Expense Surveys (page 70132-70133)

ATS members believe that CMS should incur the costs of an all physician practice expense survey, and not transfer any additional costs to AMA and all other specialties in performing such a survey. We are sure that those specialties that have already expended at least \$30,000 will not want to share in any additional costs of an all-physician, ie former AMA SMS survey.

ATS strongly encourages CMS to continue with the transition to the bottom up, instead of the current top-down PE methodology, as a result of all the work of the PEAC and PERC.

Payment for Inhalation Drugs and Dispensing Fee (page 70225-70233)

ATS noted the decision on page 70229: Thus beginning in 2006, we will pay a dispensing fee of \$57 for the first month an individual uses inhalation drugs as a Medicare beneficiary, and \$33 for a 30-day supply of inhalation drugs for all other months, and on page 70230 establishing a fee of \$66 for a 90-day supply of inhalation drugs for 2006. There are no data provided by CMS to reduce the fee to \$33 for months after the first month, and to reduce the 90-day supply fee from \$80 to \$66. We ask that this be monitored very closely. We expect that the 90-day supply will become the dispensing method after the first trial month....and potentially waste medication for the noncompliant or if the drug doesn't become effective during the second month, and the third month a new prescription is written. A reduction in fees may cause pharmacists to stop providing nebulized medications to pulmonary patients which will cause a decline in their pulmonary status. This can only be avoided by not decreasing the fees below the 2005 level.

Supplies and Equipment Requests

Table 14 Supply Items Needing Specialty Input for Pricing

Page 70144, SA091 ATS has already provided the tray contents to Pam West, CMS, which is sufficient information for pricing the tray at \$750.

Page 70144, SA091 ATS has already provided the tray contents to Pam West, CMS, which is sufficient information for pricing the tray at \$750.

Table 15 Equipment Items Needing Specialty Input for Pricing and Proposed Deletions (page 70145, 70147)

Code	Description	Price	Specialty	CPT Codes Associated with Equipment
EQ131	Hyperbaric chamber	\$125,000	FP, IM, EM	99183
EQ221	Review master	\$23,500	Pulmonary disease, Neurology	95805, 95807-11, 95816, 95822, 95955-6

ATS will provide information directly to Pam West on these two pieces of equipment. Sechrist Industries provided a quote for the hyperbaric chamber at \$128,000. The ATS also recommends that CMS check with the website of the Undersea and Hyperbaric Medical Society (www.uhms.org) for additional information on hyperbaric oxygen chamber pricing. The monoplace chamber is the most frequently purchased.

The ATS appreciates the opportunity to comment on the proposed policies under the Medicare Physician Fee Schedule. Should you or your staff have any questions, please do not hesitate to contact me or Gary Ewart at gewart@thoracic.org or 202-785-3355 x 226.

Sincerely,



Peter D. Wagner, MD
President, American Thoracic Society

Cc: ATS Clinical Practice Committee

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

DEC 29 2005

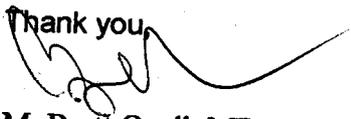
Dear Doctor McClellan,

As a practicing urologists on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

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CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,

M. Brett Opell, MD

DEC 30 2005

December 23, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8016
Baltimore, Maryland 21244-8018

Dear Dr. McClellan:

On behalf of the American Association of Neurological Surgeons (AANS), the American College of Radiology (ACR), the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the American Society of Neuroradiology (ASNR), the Congress of Neurological Surgeons (CNS) and the Society of Interventional Radiology (SIR), we appreciate the opportunity to comment on the Notice *Final Rule* for the 2006 Medicare Physician Payment Schedule, published in the November 21, 2005 *Federal Register*. In these comments we will address issues specifically related to Intracranial Angioplasty and Stenting (CPT® codes 61630, 61635, 61640, 61641 and 61642).

General Comments

Neurointerventional techniques such as angioplasty and stenting expand the therapeutic options for patients with symptomatic cerebrovascular atherosclerosis. These procedures are intended to treat impaired cerebral circulation due to arterial narrowing that may result in symptoms of ischemia, such as repeated transient ischemic attacks, stroke, or death. After subarachnoid hemorrhage occurs, arterial vasospasm develops in a high percentage of patients. In some patients, this results in significant cerebral ischemia that contributes to the high morbidity and mortality of aneurysmal subarachnoid hemorrhage. Balloon dilatation of narrowed vasospastic arteries is widely recognized to be beneficial when medical therapy is unsuccessful.

Request for Change in Medicare Coverage Decision

We would urge coverage of all of these codes as the services are critical to the delivery of optimal care to patients when no other viable treatments are available.

Angioplasty and Stenting for Medical Failures of Intracranial Atherosclerotic Stenosis

Studies such as the Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) at the Stanford Stroke Center have shown that the medical management of intracranial atherosclerotic stenosis has been unsatisfactory, with extremely high rates of subsequent strokes reported in conservatively managed high-risk patients. In contrast, both the Guidant (SSYLVIA) and the Boston Scientific (Wingspan) trials of intracranial stenting verified the ability to deliver stents to intracranial stenoses safely, improving cerebral perfusion to reduce the risk of stroke.¹ These studies represent the worlds largest reported experiences with intracranial arterial stenting. Both of these studies

confirmed procedural success rates with contemporary techniques and devices of greater than 95%.² Both of these studies supported the FDA approval of the stent systems used.

Intracranial angioplasty for atherosclerosis is not a substitute for medical therapy, but a rescue therapy for patients who have failed medical therapy. Therefore we recommend that Centers for Medicare and Medicaid Services (CMS) reimburse intracranial angioplasty and stenting for this condition because we believe that this treatment saves lives and lessens the occurrence of neurological catastrophe.

Angioplasty for Cerebral Vasospasm

“Angioplasty” for the treatment of cerebral vasospasm must be differentiated from angioplasty of atherosclerotic stenosis. “Angioplasty” of cerebral vasospasm is performed using highly compliant, low pressure micro balloons that would produce no effect upon an atherosclerotic stenosis.

Angioplasty for vasospasm is performed in patients that are failing standard medical management consisting of induced hypertension, hypervolemia, and hemodilution (“triple H therapy”). Vasospasm is the primary cause of morbidity and mortality after subarachnoid hemorrhage and up to 20% of patients will die from brain damage secondary to vasospasm.^{3,4}

Angioplasty for vasospasm is not a substitute for medical therapy. This procedure is undertaken as a last resort to save lives and prevent disability caused by vasospasm in patients who are failing intensive medical therapy. Furthermore, angioplasty of vasospasm is the recognized standard of care for patients failing medical therapy. In fact, the Brain Attack Coalition’s guidelines for comprehensive stroke centers specify that the ability to perform angioplasty for vasospasm is an essential component of a comprehensive stroke center.⁵

Data from California Blue Shield as well as a national review of medical practice indicate conclusively that access to interventional neuroradiological services, primarily endovascular therapy for vasospasm utilizing angioplasty, improves patient outcomes. Therefore, we urge CMS to cover and reimburse intracranial angioplasty for patients for whom medical therapy fails.

In addition, the existing non-coverage policy for intracranial angioplasty and stenting clearly relates only to the treatment of atherosclerotic stenoses. We believe this policy does not apply to the treatment of cerebral vasospasm following subarachnoid hemorrhage.

Publishing the Relative Value Units (RVUs) for Non-covered Services

The final issue we would like to address is the CMS decision not to accept the Relative Value Update Committee (RUC) approved relative values of these codes. This decision puts our specialties at an extreme disadvantage to have physician payment determine by private payors and/or Medicaid. In addition as the American Medical Association (AMA) RUC noted in their comments there is no mechanism by which the RUC approved values can be disseminated unless they are first published in the *Final Rule*. As such, we would strongly urge that CMS reconsider their decision not to publish these values.

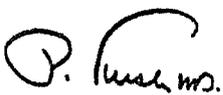
We appreciate the opportunity to provide comments on these issues and we look forward to working together in the future. Should you have questions on these issues or require additional information, please feel free to contact Maurine S. Dennis, ACR Senior Director of Economics and Health Policy at (800) 227-5463, ext. 4559 or msdennis@acr.org

Sincerely,

[Signature Arriving Via Fax Copy by AANS]
Fremont P. Wirth, MD, President
American Association of Neurological Surgeons


Bibb Allen Jr., MD, Chair, CAC Network
American College of Radiology


John D. Barr, MD, President
American Society of Interventional and Therapeutic Neuroradiology


Patrick A. Turski, MD, Chair, Clinical Practice Committee
American Society of Neuroradiology

[Signature Arriving Via Fax Copy by CNS]
Richard G. Ellenbogen, MD, President
Congress of Neurological Surgeons

[Signature Arriving Via Fax Copy by SIR]
Michael E. Edwards, MD, SIR Health Policy and Economics Councilor
Society of Interventional Radiology

cc: Steve Phurrough, MD (CMS)
Marie Williams (ASITN)
Margaret Klys (ASNR)
Catherine Hill (AANS/CNS)
Michael Mabry (SIR)
Maurine Dennis (ACR)

Cited References

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December 21, 2005

By Hand Delivery

2005
Eric P. Loukas
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11:27
CMS

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Comments on Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule with Comment, 70 Fed. Reg. 70116 (Nov. 21, 2005) [CMS-1502-FC and CMS-1325-F]

Dear Dr. McClellan:

MGI PHARMA ("MGI") appreciates the opportunity to comment on the Medicare Physician Fee Schedule final rule with comment period for calendar year 2006 (the "Final Rule"). MGI is an oncology and acute care focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients in the United States. MGI markets Aloxi® (palonosetron hydrochloride) injection, Kadian® (sustained release morphine sulfate) capsules, Salagen® Tablets (pilocarpine hydrochloride) and Hexalen® (altretamine) capsules.

We are concerned about the potential for manufacturers of generic drugs to unfairly benefit from the time lag between manufacturers reporting average sales price

("ASP") data and CMS setting the related reimbursement rates for separately reimbursed Part B drugs. In the Final Rule, CMS acknowledged the time lag in response to comments to the Proposed Rule indicating that manufacturer price increases are not being reflected timely in payment amounts. 70 Fed. Reg. 70,116, at 70,218. What the comments to the Proposed Rule did not emphasize, however, is that the time lag can be even more detrimental to the Medicare program in the case of price *decreases*, such as those that typically occur when a generic manufacturer introduces a new product to market. The generic manufacturer may benefit from the time lag by selling its product at a price significantly less than the ASP+6 percent reimbursement rate calculated based on the information reported by the manufacturer(s) of the branded product(s) that share the same billing code as the generic product. Further, as a result of CMS's volume weighted average calculation to determine ASP reimbursement rates where multiple products crosswalk to the same NDC, the benefit to generic manufacturers may continue even after CMS begins calculating the reimbursement rate for the billing code based, in part, on information reported by the generic manufacturer. Such a scenario may create economic incentives that influence physician decision-making and could adversely affect patient quality of care. In short, this is one of the very situations that Congress sought to address by implementing the ASP payment reforms in the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA").

We urge CMS to continue to study this issue and implement an appropriate remedy by refining the ASP calculation to account for price disparities between generic and branded forms of a drug that likely result when a generic product is introduced to market. We believe such a change is necessary to enable CMS to realize appropriate cost savings on generic products and ensure that physician decision making is not improperly influenced.

* * * * *

MGI appreciates this opportunity to present this comment to CMS. Please do not hesitate to contact us if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to be "Eric Loukas", written over a large, light-colored oval shape.

Eric Loukas

Senior Vice President, General Counsel and
Secretary

January 3, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC and CMS-1325-F
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final Rule

Dear Dr. McClellan:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, submits comments on the following areas of the "Revisions to Payment Policies Under the Physician Fee Schedule" published in the Federal Register on November 21, 2005.

Please see below for our comments on 1) Multiple Procedure Reduction; 2) Nuclear Medicine Services; 3) Implementation of Practice Expense; 4) Malpractice RVUs; 5) Miscellaneous Practice Expense; 6) New Codes in 2006; and 7) NCS Timeframes.

Multiple Procedure Reduction

The ACR appreciates CMS's decision to not implement the 50 percent reduction on multiple procedures done on contiguous body areas in the same session for 2006. However, the ACR is disappointed and concerned with CMS's decision to implement a 25 percent reduction in 2006 and phase-in of a 50 percent reduction in 2007. The ACR agrees that there are some efficiencies in clinical labor activity when certain combinations of multiple imaging procedures are performed in the same session. However, we do not agree that these efficiencies are uniform across all families and we do not believe the data supports either the 25 or 50 percent reductions. **The ACR strongly believes that implementation of any multiple procedure reduction should have been delayed at least one year to allow further analysis to determine the appropriate "multiple procedure families" and percent reduction.** The ACR looks forward to beginning a working process with CMS in January 2006 to determine the appropriate percent reduction for imaging procedures in each of the families.

Same Session Versus Separate Sessions

The ACR appreciates CMS's clarification in the definition of "same session". In this final rule, CMS clarified that a single session is "when more than one of the imaging service in a single family is provided to the patient during one encounter and therefore, the subsequent procedure would be subjected to the multiple payment reduction rule. However, if the patient has a separate encounter on the same day for a medically necessary reason and receives a second imaging service from the same family, CMS considers this as a separate session and the multiple payment reduction does not apply. For the latter, CMS established that physicians use modifier -59 to indicate "separate sessions." There is limited familiarity with the proper use of modifier -59 among physicians at large. As such, **the ACR remains concerned that physician payment will be unfairly discounted when no economies have occurred and therefore, requests that this process be closely monitored and that CMS provide ACR with quarterly analysis of the frequency of claim submissions for "same session" as well as "separate sessions"**.

Nuclear Medicine Services

The ACR applauds CMS's decision to incorporate diagnostic and therapeutic nuclear medicine services into the definition of "radiology and certain other imaging services", which are already subject to physician self-referral prohibition. The ACR further supports CMS's decision to delay the effective date of this new policy until January 1, 2007 and not "grandfather" existing arrangements.

Practice Expense

Supplemental Survey

The ACR is very disappointed and remains concerned that CMS decided to not utilize the supplemental survey data, which it had previously accepted, for radiology practice expense values for 2006. The ACR followed strict guidelines outlined by CMS and used an approved contractor submitting that data in the time frame defined by CMS. The ACR also invested significant financial resources, staff time and physician volunteer time to complete the survey.

Specialties that conducted the supplemental survey and submitted data, which was ultimately accepted as valid by CMS, should not be penalized for their efforts. CMS specifically requested all specialties to conduct a supplemental survey and extended the deadline to ensure that as much data was submitted as possible. The ACR complied with CMS's request. By initially proposing a change from top-down to bottom-up methodology, CMS effectively precluded the opportunity for public comment on the supplemental surveys. By the subsequent complete reversal of its initial proposal, CMS has created a technicality by which it can now defend exclusion of this rigorously acquired data from direct practice expense values in 2006.

While the ACR appreciates CMS's initial willingness to work with specialties to determine how to handle the practice expense data collected through the supplemental survey, it does not appreciate the regulatory gridlock into which this process has fallen. **The ACR therefore strongly encourages CMS to reconsider using the radiology supplemental data for the 2006 practice expense values.** The ACR is available to discuss this further and looks forward to working closely with CMS to have its data incorporated into the Medicare Physician Fee Schedule (MFS).

Multi-specialty Survey

According to this final rule, CMS is exploring the idea of conducting a multi-specialty indirect practice expense survey. The ACR appreciates CMS's efforts to ensure that the practice expense methodology treats all specialties equitably. Going forward, a multi-specialty survey may be an option to capture the general change in cost of delivering medical services across all specialties however the survey performed by the ACR should not be supplanted by other data without thorough review. In the meantime, **the ACR recommends CMS use the accepted supplemental survey data from specialties that invested time and resources to provide CMS with accurate specialty practice expense data.**

Malpractice RVUs

In this final rule, CMS decided to exclude data for all specialties that perform less than 5 percent of a particular service from the malpractice calculation. The ACR is concerned that this 5 percent threshold will inappropriately remove some specialties performing radiology codes, especially interventional radiology services, in the calculation of malpractice RVUs. **The ACR recommends that CMS reconsider its decision and continue to calculate the malpractice RVUs based on the 1 percent threshold.**

New Codes in 2006 (Intracranial Codes)

In this final rule, CMS assigned a status indicator of N for intracranial codes 61630, 61635, 61640, 61641, and 61642 on the basis that these codes are noncovered under Medicare due to a National Coverage Decision. The ACR is concerned with CMS's decision to not accept the RUC approved work values for these codes. These are critical procedures performed when no other viable treatments are available. Since these codes were valued by the RUC, **the ACR recommends that CMS reconsider its decision and publish the values in the MFS.** CMS has set precedence by publishing RVUs for other procedures for which it does not cover in the RBRVS. Private insurers can use the published values as a reference for payment of these services.

Neurointerventional techniques such as angioplasty and stenting provide additional therapeutic options for patients with cerebrovascular atherosclerosis and vasospasm and in some circumstances have become the standard of care. **The ACR requests that CMS reconsider its decision to not cover these life-saving procedures under Medicare.**

Miscellaneous Practice Expense

PET and PET/CT Codes

The ACR appreciates CMS reassigning the indirect practice expense values to PET and PET/CT codes 78811, 78812, 78813, 78814, 78815, 78816, 78491, 78492, 78459, 78608, and 78609 on the professional component side. However, the technical component remains carrier priced for these codes. **The ACR seeks explanation as to why the RUC approved inputs have not been translated into RVUs similar to all other new RUC approved codes and why the technical component for these codes, especially for codes 78811 to 78816, new codes effective January 1, 2005, have been assigned to be carrier priced.**

Imaging Rooms

The ACR would like to thank CMS for accepting ACR's recommendation on various imaging rooms. The ACR appreciates CMS's willingness to work with the College to ensure appropriate cost and equipment items for these rooms.

Practice Expense for Codes 36475 and 36476

In this final rule, the ACR agrees with CMS's decision to add the tilt table for codes 36475 and 36476. However, since a tilt table is necessary for both methods of endovenous ablation and their respective primary and add-on codes, the ACR recommends that CMS add the tilt table to codes 36478 and 36479 as well. However, the ACR does not support the additional 15 minutes clinical labor time being added to these codes as the description of physician work for the endovenous ablation codes describes the patient being placed in the Trendelenberg position, when needed, by the physician.

Price for Film Alternator

CMS has \$27,500 listed for the cost of a film alternator in their database. The ACR would like to verify this with the manufacturer and submit the appropriate price to CMS staff in the near future.

NCD Timeframes

CMS proposed to implement a 30-day comment period and eliminate the reference to the 90-day implementation for the national coverage process time-line. The ACR supports CMS's decision to adopt this proposal.

Conclusion

Thank you for the opportunity to comment on this final rule. While recent legislative action has created even more uncertainty and instability for the technical component reimbursement of



imaging services, the ACR hopes that the Agency will continue to embrace its philosophy of working with physicians and their professional societies in order to create a stable and equitable resource-based payment system.

We anticipate that the Practice Expense Advisory Committee (PEAC) approved direct practice expense data as well as the indirect practice expense data derived from our CMS and The Lewin Group approved supplemental survey will have significant value and weight as the future Technical Component (TC) payments in the Physician Fee Schedule are developed. These data represent the best and most accurate cost data available to the Agency and should not be discarded.

The ACR looks forward to continued dialogues with CMS officials about these and other issues affecting radiology and radiation oncology. If you have any questions or comments on this letter or any other issues with respect to radiology and radiation oncology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Harvey L. Neiman, MD".

Harvey L. Neiman, MD, FACR
Executive Director

cc: Herb Kuhn, CMS
Ken Simon, MD, CMS
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Pamela West, CMS
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JAN 3 2006

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January 4, 2006

Mark B. McClellan, M.D., Ph.D., Administrator
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Attention: CMS-1502-FC
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Baltimore, MD 21244-8017.

**RE: Final Rule with Comment: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule"
[CMS-1502-FC and CMS-1325-F]**

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 37,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments. They concern the final rule for physician payment policies and finalization of certain provisions of the interim final rule to implement the Competitive Acquisition Program (CAP) for Part B Drugs. Relevant regulations of interest are 42 C.F.R. Parts 405, 410, 411, 413, 414, 424 and 426, published in the Federal Register on November 21, 2005, with the title, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule."¹

APA remains highly concerned about the restrictive economic context in which physicians, including psychiatrists, find themselves at present. Effective January 1, 2006, multiple, administratively burdensome Medicare programs will require physician

¹ CMS Final Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule;" [CMS-1502-FC and CMS-1325-F] [Federal Register: November 21, 2005 (Volume 70, No. 223)].

compliance: Part D drug plans; electronic prescribing;² "Pay for Performance" with an upcoming three-year, budget-neutral demonstration project³ and the Part B Competitive Acquisition Program (CAP).⁴

All of these administrative burdens upon physicians' practices must be fairly considered and compensated within any proposed physician fee schedules. To the contrary, CMS projects that physicians will have to endure negative updates, instead of increases, under the Sustainable Growth Rate (SGR) system for future years, starting in 2006.⁵ As CMS notes, "the physician fee schedule update for CY 2006 is -4.4 percent . . ."⁶

The inescapable result of starkly diminishing Medicare payments to physicians, especially as their other administrative tasks become more burdensome, is to financially discourage them from taking new Medicare patients or keeping existing ones. APA is highly concerned that the Medicare system cannot continue with its complexity of disincentives for physician participation and still ensure that beneficiary-patients receive access to health care.

While APA commends CMS's efforts to update RVUs to provide more accurate, data-driven physician payments, several aspects of this process would benefit from further attention. One is to more comprehensively compensate physicians for their practice expenses by including the cost of typical, major office equipment in practice expense (PE) RVUs. CMS should create RVUs that more accurately reflect current resource usage through timely data. Another is to update underlying data for malpractice RVUs and to revise the attendant risk factor for non-physician psychological practitioners. An essential third element is to rework the SGR system, by which

² CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23)].

³ "CMS Demonstrations Projects under the Medicare Modernization Act (MMA) as of January 25, 2005 Section 649 -- Medicare Care Management Performance Demonstration: The Secretary is required to conduct a three-year demonstration program where physicians will be paid to adopt and use health information technology and evidence-based outcome measures to promote continuity of care, stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. The statute limits the program to four sites meeting eligibility criteria. Payment can vary based on performance, however total payments must be budget neutral." Retrieved September 26, 2005: <http://www.cms.hhs.gov/researchers/demos/MMAdemolist.asp>

⁴ CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-IFC [Federal Register: July 6, 2005 (Volume 70, No. 42)].

⁵ CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45856.

⁶ CMS Final Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule;" [CMS-1502-FC and CMS-1325-F] [Federal Register: November 21, 2005 (Volume 70, No. 223)], at 70116.

physicians are financially penalized by costs of the healthcare services required by the aging Medicare population. CMS should also exercise its authority to make administrative adjustments in the SGR system, calculations and methodology to provide more realistic, equitable payments to physicians.

Practice Expense RVUs (PE RVUs)

Practice expense (PE) RVUs were developed to take into account office rent and personnel wages (but not malpractice insurance). These were phased in from 1999-2002.⁷ During the phase-in of PE RVUs, malpractice RVUs to cover the cost of professional liability insurance premiums were developed to apply to physician services provided in 2000 and thereafter.⁸

As we pointed out in APA's comments to CMS' proposed rule, of the six direct and indirect cost categories for calculating practice expense (PE) RVUs, none comprises commonly used office equipment, apart from the telephone, which is included within the indirect cost category of "office expenses."⁹ Since most psychiatrists do not use medical equipment in their practices, as other physicians do, the type of office equipment they require for their practices may be only non-medical equipment. We note that the final rule has not remedied this category to include office equipment other than the telephone.

For psychiatrists, especially those in solo or small group practices, common office equipment, such as computers, printers, scanners, shredders, answering machines, copy machines and fax machines, constitutes a substantial financial outlay which is not reimbursed through the current definitions for PE RVU categories. It is neither fair, nor reasonable, to continue to exclude typical office equipment expenses from PE RVU calculations. This is especially so, since CMS is encouraging physicians to become computerized for the first time or to expand existing computer and electronic communication infrastructures. Without implementing physician incentives to invest in electronic office equipment required for federal programs such as electronic prescribing and Pay for Performance data gathering, CMS' goals are less likely to be reached.

Recommendation- Update PE RVUs and Include Typical Office Equipment: APA encourages CMS to continue with its process of updating PE RVUs based on current supporting data, including that from the Practice Expense Advisory Committee (PEAC).

⁷ CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45766.

⁸ CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45767.

⁹ APA Comments, dated September 30, 2005, to CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45768.

As part of this updating process, APA continues to strongly urge CMS to include typical office equipment used by physicians within the category of office expenses. This would include not just phones but computers, printers, scanners, shredders, answering machines, copy machines and fax machines. All of these require a substantial financial outlay which is not taken into account and remains unreimbursed, under current PE RVU categories.

Making this change will more fairly reimburse physicians, especially psychiatrists, whose primary office equipment does not fall into the category of medical equipment. This will also confer the added incentive for physicians to purchase the electronic computer and communications equipment necessary for full participation in various federal programs. In addition, it would prove useful for CMS to provide the underlying data for the PE RVUs to be revised under the proposed rule.

Medical Malpractice RVUs

These are relatively new additions to the RVUs formula, the rules for which were implemented in November 1999.¹⁰ They were based on medical malpractice premium data from 1995 on insurers in all U.S. states, Washington, D.C., and Puerto Rico, collected through Allied Technology Group, Inc.'s survey.¹¹ Therefore, the underlying data for the malpractice RVUs is currently a decade old. The first 5-year review of these malpractice RVUs was only implemented by a final rule published in November 2004, the year the 5-year review should already be taking place. This is nine years after the 1995 premium data was originally gathered for these RVUs.¹²

In the decade since 1995, there have been dramatic increases in professional liability insurance premiums that the malpractice RVUs have not yet captured, but from which physicians incur costs. According to a Medicare Payment Advisory Commission (MedPAC) release from August 12, 2003, "(t)he increase in PLI premiums in 2002 was

¹⁰ CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45767.

¹¹ "Development of Resource-Based Malpractice RVUs;" HCFA contracted with KPMG, L.L.P., to develop resource-based malpractice relative value units ("RVU") and allocated malpractice premium RVUs by existing total RVUs by CPT code. These malpractice premiums are weighted by provider specialty within CPT codes. KPMG relied on 1995 malpractice premium data collected through Allied Technology Group, Inc.'s survey. Retrieved from CMS website September 21, 2005: http://www.cms.hhs.gov/physicians/pfs/kpmgrept.asp#_Toc448071070

¹² CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45767: "In the November 15, 2004, PFS final rule (69 FR 66236), we implemented the first 5-year review of the malpractice RVUs (69 FR 66263)."

the highest in over a decade, at 11.3 percent.”¹³ Clearly, the underlying premium data must be updated in order to calculate meaningful, current malpractice RVUs.

Recommendation- Update Malpractice RVUs: APA continues to urge CMS to work with AMA’s RUC, as well as other medical organizations, to identify sources for and obtain updated professional liability insurance premium data for the purpose of updating malpractice RVUs.

Malpractice RVUs and Specialty Crosswalk Issues

APA commends CMS for adopting a more realistic "crosswalk" to re-calculate malpractice RVUs for non-physician psychotherapists. CMS now plans to use the lowest risk factor of 1.00, instead of CMS's originally proposed risk factor of 1.11, for non-physician psychotherapists.¹⁴ CMS' current approach more accurately reflects the differential risk factors for professional liability that exists, between non-physician psychotherapists, such as clinical psychologists or social workers, and psychiatrists. APA advocated for this change in its comments to CMS' proposed rule on the physician fee schedule.¹⁵

Sustainable Growth Rate (SGR)

As CMS notes in this final rule, "the physician fee schedule update for CY 2006 is -4.4 percent . . ."¹⁶ The American Medical Association (AMA) conducted a survey in 2005 on projected Medicare physician payment cuts. Survey responses indicated that:

“ . . . if Medicare payments are cut by about 5 percent in 2006, 61 percent of physicians plan to defer purchase of new medical equipment and 54 percent plan to defer purchase of information technology. . . .

“A majority of physicians (53 percent) said the 2006 cuts would make them less likely to participate in a Medicare Advantage plan. . . .

¹³ Medicare Payment Advisory Commission (MEDPAC) release, “Medicare payment to physicians for professional liability insurance;” August 12, 2003. Retrieved January 4, 2006: http://www.medpac.gov/publications/other_reports/Aug03_PLI%20_2pgrKH.pdf

¹⁴ CMS Final Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule;" [CMS-1502-FC and CMS-1325-F] [Federal Register: November 21, 2005 (Volume 70, No. 223)], at 70316.

¹⁵ APA Comments, dated September 30, 2005, pgs. 5-7, to CMS Proposed Rule: “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;” CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)].

¹⁶ CMS Final Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule;" [CMS-1502-FC and CMS-1325-F] [Federal Register: November 21, 2005 (Volume 70, No. 223)], at 70116.

“The projected cuts also will adversely affect access to care for patients in rural areas. Fully one-third (34 percent) of physicians whose practice serves a rural patient population said they would be forced to discontinue rural outreach services if payments are cut in 2006.”¹⁷

In addition to adversely affecting patient access, the Medicare payment cuts will create a strong disincentive, across specialties, to purchase information technology (IT). This financial disincentive will substantially interfere with CMS’ own goals of increasing physicians’ use of IT for electronic health records, electronic prescribing, patient data collection for Pay for Performance and other CMS programs that heavily rely upon IT. This situation is untenable and requires immediate action by CMS to facilitate fair Medicare payments for physicians and to ensure Medicare patients’ access to healthcare services.

Within this context of lowering Medicare physician payments, increasing administrative demands are being imposed upon physicians through federal program requirements without a concomitant financial offset through payments. Examples of these demands include those related to the upcoming effective date of January 1, 2006, at which time various burdens from several demanding CMS programs will simultaneously come into play. Those are: the transition of new and dually eligible Medicaid-Medicare beneficiaries into Medicare Part D drug plans; electronic prescribing;¹⁸ a national demonstration project on physicians’ “Pay for Performance;”¹⁹ and the Medicare program for Competitive Acquisition of Outpatient Drugs and Biologicals under Part B (CAP).²⁰ While CMS recognizes that the aging Medicare population with complex co-morbidities has increased its intensity of services utilization, APA maintains that these services need to be funded.²¹ In addition, expansions and revisions of the Medicare program affect the number and type of physicians’ services provided to beneficiaries.

¹⁷ American Medical Association (AMA) news release, “AMA Member Connect survey: Medicare payment cuts will hurt access to care;” April 5, 2005, referencing AMA Member Connect survey of February-March 2005, released April 5, 2005. Retrieved January 4, 2006: <http://www.ama-assn.org/ama/pub/category/14925.html>

¹⁸ CMS Proposed Rule: “Medicare Program; E-Prescribing and the Prescription Drug Program;” CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23)].

¹⁹ “CMS Demonstrations Projects under the Medicare Modernization Act (MMA) as of January 25, 2005 Section 649 -- Medicare Care Management Performance Demonstration: The Secretary is required to conduct a three-year demonstration program where physicians will be paid to adopt and use health information technology and evidence-based outcome measures to promote continuity of care, stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. The statute limits the program to four sites meeting eligibility criteria. Payment can vary based on performance, however total payments must be budget neutral.” Retrieved September 26, 2005: <http://www.cms.hhs.gov/researchers/demos/MMAdemolist.asp>

²⁰ CMS Proposed Rule: “Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;” CMS-1325-IFC [Federal Register: July 6, 2005 (Volume 70, No. 42)].

²¹ CMS Proposed Rule: “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;” CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45856.

Physicians cannot and should not bear the brunt of the under-funding of this program in the form of unrealistic and sub-par Medicare payments. To the extent that it is within CMS' authority to make administrative adjustments in the SGR calculations and methodology, CMS should do this immediately, to avoid further disincentives to physicians who care for Medicare beneficiaries. For example, CMS should remove Part B payments for physician-administered drugs and biologicals from calculations for projected and actual expenditures to set the Medicare spending target.²²

As the pool of these beneficiaries increases dramatically by January 1, 2006, when Medicaid-Medicare dually eligible patients flow into the system, they will diffuse nationally into physicians' existing practices. Especially for psychiatrists, whose patients may require help to navigate their Part D drug plans, the administrative time input for dealing with the new program will be substantial and may discourage some psychiatrists from dealing with Medicare patients.

Recommendation- SGR: CMS should exercise its authority to make administrative adjustments in the SGR calculations and methodology to provide more realistic, equitable payments to physicians. CMS should also work closely with Congress to revise the SGR system and remove other barriers to creating a reasonable, fair physician fee schedule. Further, CMS should erase financial disincentives within the Medicare program that impact physicians who care for Medicare beneficiaries.

Private Contracts and Medicare Opt-Out Provision

CMS plans to revise and expand Sec. 405.435 that addresses the consequences for a physician's failure to adhere to required conditions during the physician's two-year Medicare opt-out period. APA agrees with the commenter CMS references in the final rule, who "urges the agency to establish standardized language for the violation notice and clear guidelines for carriers to execute timely notice of opt-out violation."²³ Standardized language and guidelines would facilitate compliance and reduce the need for interpretative conflict.

²² CMS Proposed Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006;" CMS-1502-P [Federal Register: August 8, 2005 (Volume 70, No. 151)], at 45857.

²³ CMS Final Rule: "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule;" [CMS-1502-FC and CMS-1325-F] [Federal Register: November 21, 2005 (Volume 70, No. 223)], at 70260.

CONCLUSION

APA urges CMS to revise and improve the physician fee schedule with updated information and better calculation methods. An essential part of this equation is for CMS to advocate for Congress to change the outdated, untenable SGR system.

Thank you for allowing APA the opportunity to communicate its concerns.

Sincerely,

A handwritten signature in cursive script, appearing to read "James H. Scully Jr.", with a long, sweeping flourish extending to the right.

James H. Scully Jr., M.D.
Medical Director and C.E.O., American Psychiatric Association

December 29, 2005

Mark McClellan, MD, Ph.D.
Administrator
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CMS 1502-FC and CMS 1325-F
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**Re: Medicare CY 2006 Physician Fee Schedule;
Final Rule with Comment Period**

Dear Dr. McClellan:

The American Society of Transplant Surgeons (ASTS) appreciates this opportunity to comment on the final CY 2006 Medicare physician fee schedule, as published in the November 21, 2005 Federal Register.

Our comments relate to the treatment of standard backbench preparation services of cadaver donor organs (CPT Codes 32855, 32856, 33933, 44715, 47143, 47144, 47145, 48551, 50323 and 50325). These codes were new in 2005 and describe backbench surgical work that must be performed on all cadaver donor organs prior to transplant. At the same time, CPT approved several backbench reconstruction codes which describe preparation of the donor organ to meet the specific needs of the transplant recipient.

Because ASTS believes that the standard backbench services are part of organ acquisition, paid for under Part A of Medicare, our organization did not seek valuation of these codes from the RUC and, in fact, the RUC did not recommend RVUs for these codes. In contrast, we did submit recommendations to the RUC on RVUs for the backbench reconstruction codes – recommendations which were accepted by the RUC and by CMS. Consequently, the backbench reconstruction codes are paid under the physician fee schedule – a policy with which we agree entirely.

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WORLD TRANSPLANT CONGRESS

July 22-27, 2006
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In the 2005 Medicare physician fee schedule, CMS assigned all of the standard backbench codes a status indicator "C" indicating that they were carrier priced. ASTS disagreed with this designation and submitted comments in connection with the proposed 2006 fee schedule requesting that the status be changed to "X" indicating that the services were not covered under the Part B physician fee schedule. CMS has declined to make this change on the grounds that it believes these services are similar to other transplant surgeries that are paid under the Medicare PFS.

ASTS continues to disagree with the agency's position. Backbench services are, in our view, most similar to organ excision in that they describe services necessary to prepare an organ for transplantation. Because they must be performed on all donor organs, it is often done before a recipient has been identified and may occur at a remote site by surgeons other than the transplant team. Further, it is not uncommon to split a graft for transplantation into more than one recipient. Given the variability of these services and the fact that they will not always be performed by the recipient transplant team at the recipient hospital, we believe it is logical to treat them as organ acquisition costs covered under Part A of Medicare.

We thank you for the opportunity to submit these comments.

Sincerely,

A handwritten signature in cursive script that reads "A. Benedict Cosimi".

A. Benedict Cosimi, M.D.
President