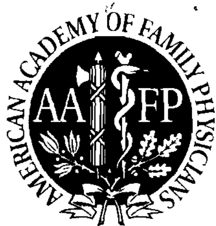

American Academy of Family Physicians

December 15, 2006

Leslie V. Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Norwalk:

I am writing on behalf of the American Academy of Family Physicians, 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 period regarding "Medicare Program: Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007," as published in the *Federal Register* on December 1, 2006.

CMS invited comments on the interim relative value units (RVUs) for selected codes identified in Addendum C of the final rule as well as the physician self-referral designated health services listed in Tables 18 and 19 of the final rule. We will comment on each of these areas in turn; however, we first want to comment on some of the decisions CMS made related to the Five-Year Review and the practice expense methodology. We will also comment on some aspects of CMS's estimate of the Sustainable Growth Rate (SGR) for 2007. Our comments may be summarized as follows:

- We want to thank CMS for finalizing its proposal to accept the American Medical Association (AMA)/Specialty Society Relative Value Scale Update Committee (RUC) recommendations for evaluation and management (E/M) services and for implementing those recommendations in full beginning January 1, 2007.
- We are deeply disappointed that CMS chose to proceed with its proposal to institute an adjustment to the work RVUs in its payment allowance formula.
- We want to compliment CMS on its decision to proceed with its proposed changes to its practice expense methodology; however, CMS appears to have used work RVUs with budget neutrality applied in the indirect practice expense allocation, despite CMS's clear written statement that this would not occur.
- We believe that CMS should change its decision to consider the newly created anticoagulation management codes (99363 and 99364) bundled into the E/M codes.
- We appreciate CMS's delay in issuing final regulations regarding proposed changes to its reassignment and physician self-referral rules relating to diagnostic tests.
- We believe that CMS's estimate of the SGR for 2007 includes two estimations that hold down the SGR in ways that do not appear supported by CMS's own data.

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Above all, the AAFP wants to do its part to ensure Medicare patients' access to primary care services.

Five-Year Review

First, we want to thank CMS for finalizing its proposal to accept the RUC recommendations for E/M services and for implementing those recommendations in full beginning January 1, 2007. Like CMS, we understand how contentious this issue has been, and we appreciate CMS's validation of the RUC recommendations in this regard, particularly in light of the large budget neutrality adjustment necessitated by acceptance of the RUC recommendations. The adjustment in the RVUs for E/M services is a first step in restoring viability to primary care offices.

Regarding the final budget neutrality adjustment, we are deeply disappointed that CMS chose to proceed with its proposal to institute an adjustment to the work RVUs in its payment allowance formula. For the reasons outlined in our comments on the proposed rule, we continue to believe that an adjustment to the conversion factor was the more appropriate option. As noted in the final rule, the AMA, the RUC, and many other organizations representing those directly affected by this issue also believe an adjustment to the conversion factor is the preferred option. We regret that CMS chose to ignore this prevailing opinion and corresponding rationale. The AAFP strongly encourages CMS to rectify this adjustment methodology at the earliest possible time, no later than for the 2008 Medicare Physician Fee Schedule.

Practice Expense Methodology

We want to compliment CMS on its decision to proceed with its proposed changes to its practice expense methodology, including the move to a bottom-up approach and elimination of the non-physician work pool. While not perfect and still difficult to understand, the new methodology is preferable to the previous top-down approach and should be more intuitive and stable in the long run.

Regarding the new methodology, CMS stated in the final rule that it would not use the budget-neutralized work RVUs to calculate indirect practice expenses. However, Addendum B in the final rule appears to reflect practice expense RVUs that were computed using adjusted work RVUs. Thus, CMS appears to have used work RVUs with budget neutrality applied in the indirect practice expense allocation, despite CMS's clear written statement that this would not occur. We urge CMS to immediately correct this error and use the unadjusted work RVUs in the methodology.

Codes with Interim RVUs

We reviewed the new and revised codes in Addendum C, which will have interim RVUs for 2007. Among them were:

- 99363 Anticoagulation management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; initial 90 days of therapy (must include a minimum of 8 INR measurements)

- 99364 Anticoagulation management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; each subsequent 90 days of therapy (must include a minimum of three INR measurements)

CMS accepted the RUC recommended RVUs for these codes but assigned them a status indicator of "B," which denotes that CMS believes these services are bundled into E/M services. CMS did not offer any rationale for its decision to bundle these new services.

We believe that CMS should change its decision to consider the newly created anticoagulation management codes (99363 and 99364) bundled into the E/M codes. We are hard-pressed to identify any rationale for this decision. During the creation of the code, the CPT Editorial Panel was very careful to create protections in the code that would prevent work from anticoagulation management being included in selecting the level of E/M codes. The RUC also observed these protections and clearly thought that these services were unique, stand-alone services. We note that its recommendations for the E/M services as part of the Five-Year Review did not include the value of these new services.

The new CPT codes are recognition of the important work of managing serious disease, and the CMS decision to not pay separately for this service appears arbitrary. <u>Accordingly, we strongly urge CMS to change the status indicator of these codes from "B" to "A" (Active code), so they may be paid appropriately.</u>

<u>Re-assignment and Physician Self-Referral</u>

We reviewed the list of additions and deletions to physician self-referral designated health services as presented in Tables 18 and 19 of the final rule. Upon review, the proposed additions and deletions appear appropriate.

We also noted CMS's decision not to issue final regulations at this time regarding proposed changes to its reassignment and physician self-referral rules relating to diagnostic tests. Instead, CMS indicates its intent to study these issues further and issue a final regulation in the future. We appreciate CMS's delay in issuing final regulations in this instance, so it may study the matter further. We are hopeful that this further study will help CMS address the concerns that we and others raised in response to the proposed changes, so the final regulations do not unduly impact legitimate group practice arrangements that enable Medicare beneficiaries to have the convenience of receiving medical services at one location.

<u>Sustainable Growth Rate</u>

As we reviewed CMS's estimate of the SGR for 2007, we were struck by two estimations that hold down the SGR in ways that do not appear supported by CMS's own data. The first of these is the estimated change in fees for drugs used to calculate the change in fees for physicians' services. In the final rule, CMS estimates a weighted-average change in fees for drugs included in the SGR (using the Average Sales Price (ASP) plus 6% methodology) of 4.0% for 2007. However, in Table 20 of the final rule, in which CMS estimates the increase in the Medicare Economic Index (MEI) for 2007, CMS estimates the percentage change in pharmaceuticals (based on the Producer Price Index) as 7.7% in 2007.

We fail to understand why CMS believes the price of drugs is increasing 7.7% for purposes of the MEI but is only allowing for a 4.0% increase in the fees for drugs for purposes of calculating the SGR. From our perspective, if CMS believes the price of drugs will increase 7.7% in 2007, then the same percentage should be used in the SGR calculations, since physicians normally set their fees to at least cover their costs. We calculate that use of the 7.7% figure in the SGR calculations would increase the 2007 SGR estimate from 1.8% to 2.1%.

We continue to believe that drugs should not be included in the SGR calculations, but if CMS is going to include them, then they should account for them consistent with the MEI. As it is, CMS's disparate estimates simply represent an admission that Medicare fees for physician administered drugs (based on the ASP plus 6% methodology) are not keeping pace with the actual price of drugs paid by physician practices.

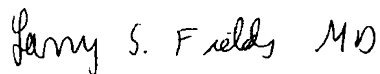
The second estimate with which we would like to take issue is the estimated decrease in traditional Medicare enrollment of 0.9%. Our problem with this estimate is that Medicare consistently underestimates the growth or overestimates the decline in traditional Medicare enrollment when making its initial estimates. For instance, according to the final rule, for the 2005 SGR, CMS initially estimated that enrollment would decrease 0.3%. A year later, CMS revised that estimate to an increase of 0.3%. Likewise, for the 2006 SGR, CMS's initial enrollment estimate was a -3.1%. Now, a year later, it is -2.2%.

Thus, we have to wonder if the 0.9% decrease estimated for the 2007 SGR is also off by 0.6-0.9%. We note it has already gone from -2.9% in March of this year to -0.9% in November. Assuming CMS's estimate is off by at least 0.6 percentage points would raise the SGR from 1.8% to approximately 2.3%. Combined with the change in the drug fee percentage noted above would increase the estimated SGR to 2.7%. All of which has implications for future updates in physician fees.

We understand that the SGR is a flawed formula, which is why we are working diligently to have Congress replace it with a truly "sustainable" growth rate. We realize that estimating the various components in the SGR is difficult. However, we do not believe that is an excuse for CMS to not learn from its own track record and to not be consistent in the way it estimates elements such as drug fees.

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,



Larry S. Fields, M.D., FAAFP
Board Chair

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December 14, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1321-FC
P.O. Box 8014
Baltimore, MD 21244-8014

RE: CMS-1321-FC
Comments on Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; Final Rule (71 Fed. Reg. 69624, December 1, 2006)

Dear Ms. Norwalk:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's foot and ankle surgeons, is pleased to submit comments on the final rule with comment period that includes discussion of the five-year review of work relative value units.

<u>Five-Year Refinement of Relative Value Units</u> (p. 69719)
The APMA is disappointed that the Centers for Medicare & Medicaid Services (CMS) did not adopt the original Health Care Professionals Advisory Committee (HCPAC) work relative value unit (RVW) recommendations for codes 10060, 11040, 11041, 11042 and 29580. These codes underwent additional review as part of the CMS refinement panel process, and while APMA appreciates that slight modifications were made to the RVWs for codes 10060 and 11040, we continue to believe that the original HCPAC recommendations were appropriate and should have been adopted. The following table summarizes the outcome of the 5-year review process for the 6 codes presented by APMA that went through the five-year review at CMS's request:

Code	2006 RVW	HCPAC RVW	CMS Proposed RVW	CMS Final RVW
10060	1.17	1.50	1.17	1.19
11040	0.50	0.55	0.48	0.50
11041	0.82	0.82	0.60	0.60
11042	1.12	1.12	0.80	0.80
11730	1.13	1.10	1.10	1.10
29580	0.57	0.60	0.55	0.55

In describing the refinement process, CMS states:

> "We convened a multi-specialty panel of physicians to assist us in the review of comments. We submitted 30 codes for evaluation by the panel. The panel discussed the work involved in each procedure under review in comparison to the work associated with other services on the fee schedule. We assembled a set of reference services and asked the panel members to compare the clinical aspects of the work for services they believed were incorrectly valued to one or more of the reference services. In compiling the reference set, we attempted to include: (1) Services that are commonly furnished for which work RVUs are not controversial; (2) services that span the entire spectrum of work intensity from the easiest to the most difficult; and (3) at least three services performed by each of the major specialties so that each specialty would be represented. Group members were encouraged to make comparisons to these reference services. The intent of the panel process was to capture each participant's independent judgment based on the discussion and his or her clinical experience. Following the discussion for each service, each participant rated the work for that procedure. Ratings were individual and confidential; there was no attempt to achieve consensus among the panel members.
>
> "We then analyzed the ratings based on a presumption that the RVUs published in the proposed notice were correct. To overcome that presumption, the inaccuracy of the proposed RVUs had to be apparent to the broad range of physicians participating in the panel. Ratings of work were analyzed for consistency among the groups represented on the panel. In general terms, we used statistical tests to determine whether there was enough agreement among the groups on the panel, and if so, whether the agreed-upon RVUs were significantly different from the proposed RVUs that appeared in the June 29, 2006 proposed notice to demonstrate that the proposed RVUs should be modified. We did not modify the RVUs unless there was a clear indication for a change. If there was agreement across groups for change, but the groups did not agree on what the new RVUs should be, we eliminated the outlier group, and looked for agreement among the remaining groups as to the basis for new RVUs. We used the same methodology in analyzing the ratings that we first used in the refinement process for the CY 1993 physician fee schedule final rule published in the November 25, 1992 Federal Register which described the statistical tests in detail (57 FR 55938).
>
> "Our decision to convene a multi-specialty panel of physicians and to apply the statistical tests described above in this section was based on our need to balance the interests of those who commented on the work RVUs against the redistributive effects that would occur in

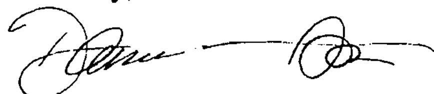
> other specialties. Of the 30 codes reviewed by the multi-specialty panel, all were the subject of requests for increased values. Of the proposed codes that were reviewed, 11 increased, and 19 were not changed."

The APMA was under the impression that CMS would discuss the results of the refinement panel in greater detail in the final rule and would provide the specifics of each code reviewed, including the recommendations submitted by the panel members. We are interested in analyzing those results as they pertain to each of our codes subjected to refinement and request that CMS provide us with the detailed information we are seeking.

Conclusion

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,



David M. Schofield, DPM
President

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December 21, 2006

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1321–FC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: ***Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B - CMS-1321-FC***

Dear Administrator Norwalk:

The American Society for Therapeutic Radiology and Oncology (ASTRO)[1] appreciates the opportunity to provide written comments to the Centers for Medicare and Medicaid Services (CMS), on the "Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B" published in the *Federal Register* as a final rule with comment period on December 1, 2006.

Our comments focus on: (1) the Five-Year Review of work relative value units (RVUs); (2) the supplemental survey data on practice expenses for radiation oncology; (3) the reduction in technical component (TC) payments for imaging services under the physician fee schedule to the outpatient department payment amount; (4) the global period for remote afterloading high intensity brachytherapy procedures; (5) Cobalt 60 and direct practice expenses for CPT® code 77371; *Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of 1 session; multi-source Cobalt 60 based*; (6) the assignment of RVUs to CPT codes for proton beam treatment delivery services; (7) the unnecessary HCPCS codes for stereotactic radiation treatment delivery; and, (8) the interim practice expense (PE) RVUs for CPT code 55876; *Placement of interstitial device(s) for*

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[1] *ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.*

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radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple.

1. Five-Year Review of Work RVUs

CMS submitted eight (8) radiation oncology CPT® codes to the AMA/Specialty Society Relative Value Scale Committee (RUC) for review. We conducted standard RUC surveys for these services. The survey results indicated that these codes are appropriately valued relative to other services on the fee schedule and we recommended no change in the work RVUs. The RUC agreed with the survey results and supported our recommendations.

In the proposed rule, CMS agreed with all the RUC-recommended work RVUs for radiology oncology and proposed to maintain the current values. We supported this proposal in our comments on the proposed rule and the RVUs have been made final for 2007. We wish to express our appreciation for this decision and for all the hard work of the dedicated CMS staff who worked tirelessly to complete this difficult task.

2. Supplemental Survey Data on Practice Expenses for Radiation Oncology Services

In the proposed rule for Calendar Year (CY) 2007, CMS calculated the practice expense per hour (PE/HR) for radiation oncology based on supplemental survey data from ASTRO and the Association of Freestanding Radiation Oncology Centers (AFROC) that was blended in the proportion of 75 percent hospital-based radiation oncology and 25 percent freestanding radiation oncology. The resulting PE/HR was $161.08. Both ASTRO and AFROC submitted comments citing an independent analysis of claims that found a 62/38 proportion was more appropriate, resulting in a PE/HR of $213. The Lewin Group reviewed the analysis and applied its physician time-weighting methodology using CMS time and utilization data for FY 2005. The result was a hospital-based to freestanding weight of 63 percent to 37 percent, respectively. The combined average using this weighting results in a PE/HR for radiation oncologist of $209.19, as shown in Table 2 of the final rule.

We support and appreciate the CMS decision to accept our recommendations. The result is an increase of nearly 30 percent in the PE/HR for radiation oncology. Unexpectedly, this dramatic increase in PE/HR had an insignificant impact on the PE RVUs for radiation oncology services. The impact table in the proposed rule showed that the proposed PE changes (including the PE/HR figure of $161.08 for radiation oncology) would result in a one percent increase in allowed charges for radiation oncology in 2007. The impact table in the final rule showed that the PE changes (including the revised PE/HR figure of $209.19 for radiation oncology) would result in only a two percent increase in allowed charges for radiation oncology in 2007. It seems that an increase of nearly 30 percent in the PE/HR for a specialty that provides the vast majority of radiation oncology services should have resulted in a greater impact. We ask that CMS re-examine its' calculations of PE RVUs to be certain that the corrected PE/HR data was used in the final rule and that no other inadvertent errors in the complex methodology for calculating PE RVUs were made.

3. Reduction in TC for Imaging Services Under the PFS to OPD Payment Amount

As required by Section 5102(b)(1) of the Deficit Reduction Act (DRA), beginning January 1, 2007, CMS will cap the physician fee schedule (PFS) payment amount for the technical component (TC) of imaging services (including the technical component portion of a global fee) at the CY 2007 outpatient prospective payment system (OPPS) payment amount. They will then apply the PFS geographic adjustment to the capped payment amount.

The DRA defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography.''

ASTRO concurs with the CMS decision to exclude radiation oncology services that are "not imaging or computer-assisted imaging services" since radiation therapy services clearly cannot be considered "imaging." However, we continue to believe CMS has misinterpreted Congressional intent by including on the list of "imaging services" CPT® codes that describe services performed in conjunction with radiation therapy that are never performed for diagnostic purposes. ASTRO again recommends that CMS remove the following radiation oncology services from the list of services subject to the DRA cap because they are associated with the treatment and not the diagnosis of cancer:

- CPT code 76950; *Ultrasonic guidance for placement of radiation therapy fields;*
- CPT code 76965; *Ultrasonic guidance for interstitial radioelement application;*
- CPT code 77014; *Computed tomography guidance for placement of radiation therapy fields.*
  - (Formally CPT code 76370);
- CPT code 77417; *Therapeutic radiology port film(s); and*
- CPT code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy.*

4. Global Period for Remote Afterloading High Intensity Brachytherapy Procedures

All of the CPT codes in the family of remote afterloading high intensity brachytherapy procedures (CPT codes 77781 through 77784) are currently designated as 90 day global services. Due to the increasing variability in treatment regimens, it is difficult to assign RVUs for a ''typical'' patient based on a global period of 90 days. Therefore, CMS proposed that this family of codes be assigned a global period of ''XXX'' to permit separate payment each time the services are provided and to allow payment to be based on the actual service(s) provided. However, CMS also proposed to revise the work RVUs and PE inputs "to reflect the removal of the postoperative visit, CPT code 99212; *Office or other outpatient visit for the evaluation and management of an established patient, which requires at least two of these three key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or*

family's needs. Usually, the presenting problem(s) are self limited or minor. Physicians typically spend 10 minutes face-to-face with the patient and/or family, that is currently assigned to these services."

In our comments on the proposed rule, we supported the CMS proposal to change the global period from 90 days to "XXX." However, we strongly objected to the arbitrary reduction in work RVUs because there is no evidence that the current work RVUs include the work RVUs of a postoperative visit (CPT® code 99212). Previous final rules demonstrate that during the first two years of the fee schedule, these codes had global periods of "XXX." In 1994, the global period was changed to 90 days but there was no corresponding increase in work RVUs.

We appreciate the point that CMS makes in the final rule that our members will now be allowed to bill for postoperative visits. Nonetheless, that does not mean that the work RVUs for the brachytherapy codes should be reduced. Their proper values were established at the onset of the fee schedule when the global period was "XXX." For more than 10 years, the designation of a 90 day global period without a corresponding increase in RVUs to cover the work of postoperative visits means that these brachytherapy procedures have been undervalued. We strongly believe that it was inappropriate to reduce the work RVUs in the final rule in the face of the evidence we presented.

In the final rule, CMS also indicates they will request the RUC to revalue the work RVUs and the PE inputs for these services. We are prepared to work with the RUC to complete this task. However, we believe it is premature to review these codes during the February 2007 RUC meeting. We are currently working on editorial revisions for these four brachytherapy codes because the process of care for High Dose Rate (HDR) brachytherapy has evolved over the past decade and we feel that the present descriptors do not optimally describe physician work. Once the necessary code changes have been made, we will conduct the necessary surveys in accordance with the usual RUC process. In the interim, we believe it is unfair to reduce the RVUs in 2007 and we urge CMS to restore the work RVUs to their 2006 level pending completion of the CPT/RUC process.

5. Cobalt 60 and Direct Practice Expenses for CPT® Code 77371

For the new CPT code 77371; *Radiation treatment delivery, stereotactic radiosurgery (SRS) (complete course of treatment of cerebral lesion[s] consisting of 1 session); multi-source Cobalt 60 based*, CMS designated the $15,000 radiation source (Cobalt 60) as an indirect expense because it does not meet the criteria for inclusion as a direct expense. CMS made this interim decision to give specialty societies the opportunity to provide documentation that the radiation source should be considered a direct expense.

We appreciate the opportunity to comment because we feel strongly that Cobalt 60 is a direct expense. Medical equipment is considered to be a direct expense if it: 1) is purchased or leased by a physician practice; 2) has a purchase price of $500 or more; and, 3) it is easily attributable to the service in question.

In the case of CPT® code 77371, Cobalt 60 meets all three (3) criteria. First, physicians must purchase Cobalt 60 as a separate item; it is not included in the price of the equipment used to deliver the radiation. Second, its cost of $15,000 exceeds the $500 threshold. Third, the cost of Cobalt 60 is clearly attributable to the procedure of stereotactic radiosurgery as evidenced by inclusion of the term "Cobalt 60 based" in the code description itself. We urge CMS to recalculate the practice expense RVUs for CPT code 77371 with Cobalt 60 treated as a direct rather than an indirect expense.

6. Assignment of RVUs for Proton Beam Treatment Delivery Services

At the present time, payment for these services is established at the carrier level. The carriers have discretion to establish payment using available information about these services. In the final rule, CMS indicated that providers who wish to have RVUs established for these services, should use the AMA–RUC process that has been established for recommending RVUs and direct PE inputs used to compute national RVUs for PFS services to CMS.

We support the CMS decision. As we stated in our comments on the proposed rule, ASTRO would be pleased to participate in the development of work and practice expense RVUs for these services should CMS decide that carrier-pricing for these services is no longer appropriate.

7. Unnecessary HCPCS Codes for Stereotactic Radiation Treatment Delivery

CPT 2007 includes three (3) new CPT codes for stereotactic radiation treatment delivery (CPT® codes 77371-77373). The codes were reviewed by the RUC and CMS published interim RVUs in the PFS final rule. We have identified what we believe to be an oversight in the proposed rule related to code 77373; *Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions.*

ASTRO notes that CMS continues to list the following two (2) temporary HCPCS codes as carrier-priced and payable under the physician fee schedule even though these temporary codes have been replaced by the permanent CPT code 77373; *SBRT treatment delivery,* for which RVUs have been established:

> G0339; *Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment*; and
>
> G0340; *Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment.*

We are not certain why these G codes were retained into 2007. ASTRO, along with other medical specialty societies, has committed considerable time and resources to develop the full family of radiosurgery and stereotactic body radiation therapy codes. We understand that CMS acknowledges the new CPT codes as appropriate for these services. Nonetheless, maintaining

the G codes is misleading to the appropriate process of care and is confusing to the users of this treatment modality.

8. Interim PE RVUs for CPT® Code 55876

For CPT® code 55876; *Placement of interstitial device(s) for radiation guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple*, CMS states in the final rule: "We deleted one package of gold markers (contains 3 markers each) because we believe that the typical number of gold markers used in this procedure is 2 or 3 and we entered an interim price of $119 per 3-pack. We are asking the specialty to provide us with: (a) Verification of the typical number of gold markers used in this procedure; and (b) documentation as to the typical price of these markers." Based on this statement, it is not clear to us whether the PE RVUs for this new code includes the cost of the fiducial markers. Informal contacts with Carrier Medical Director (CMD) staff cause us to believe that the cost has not been included.

We would not object to the exclusion of the fiducial markers from the PE RVUs for CPT code 55876 as long as CMS provides payment for these supplies through some other means. In fact, to avoid the potential for confusion regarding the correct reporting for this service, separate payment would be preferable so that the CMS payment policy would be consistent with the CPT instructions that state: "Report supply of device separately." We have been advised informally by CMS staff to report Q3001 in addition to code 55876. However, HCPCS code Q3001; *Radioelements for brachytherapy, any type, each*, is generally reserved for radioelements. Our concern with utilizing this code is that the medical definition for a radioelement is "any element possessing radioactivity," and the gold markers that are utilized when performing this procedure are not radioactive sources.

The typical number of markers used during a procedure is four. A price of $119 per three-pack is reasonable and corresponds to a price of $39.67 per marker. Thus, the typical supply cost for four fiducial markers is $158.67. We have identified two (2) options for recognizing the cost of fiducial markers:

1. Direct the temporary use of HCPCS code A4649; *Surgical supply; miscellaneous*, pending the creation of a permanent HCPCS code for fiducial markers. This option would be consistent with the CPT instructions to report the supply of the devices separately and would permit equitable payment for the complete procedure.

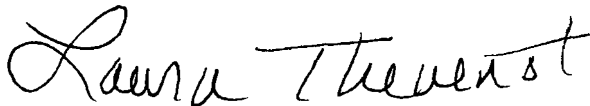
2. Incorporate the cost of four (4) fiducial markers into the calculation of the direct PE costs of CPT code 55876. This option would be consistent with the usual CMS policy of incorporating supply costs into the PE RVUs. However, if the cost of the markers is not included in the current PE RVUs, then CMS will need to implement a temporary policy permitting separate payment for the fiducial markers (e.g., the use of HCPCS code A4649) until the PE RVUs appropriately reflect their cost.

We favor the first option, using HCPCS code A4649 to report the device, because it is consistent with the instructions in CPT®, HCPCS definitions, and it would permit equitable payment for the complete procedure.

Conclusion

Thank you for this opportunity to comment on this final rule. We look forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Trisha Crishock, MSW, ASTRO's Director of Health Policy at (703) 502-1550.

Respectfully,



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Edith Hambrick, M.D.
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December 18, 2006

VIA FED EX

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1321-FC;
INDEPENDENT DIAGNOSTIC TESTING FACILITY ISSUES;
Comments to Medicare Program; Revisions to Payment Policies; Final Rule with Comment Period

Dear Mr. McClellan:

This firm submits these comments on behalf of Sutter Health, a charitable nonprofit health system that operates in California and Hawaii. Affiliates of Sutter Health operate imaging centers that are certified under the Medicare program as independent diagnostic testing facilities ("IDTFs"). These comments concern IDTF issues only.

Our comments are limited to the certification standard for IDTFs that would prevent IDTFs from utilizing any form of self-insurance. (See changes to 42 C.F.R. sec. 410.33(g)(6) set forth at 71 Fed. Reg. 69784 (Dec. 1, 2006).)

The new IDTF standard would require IDTFs to:

> Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried

> by a non-relative owned company and list the serial numbers of any and all diagnostic equipment used by the IDTF, whether the equipment is stationary, in a mobile unit or at the beneficiary's residence.

Id. at Section 42 CFR sec. 410.33(g)(6).

a. Refinement of Insurance Description. The term "comprehensive liability insurance" generally refers to general liability insurance. We presume this is the only insurance to be required of IDTFs, although the proposed coverage describes liabilities that would be insured by general liability insurance (place of business and customers), workers' compensation insurance (injury to employees) and professional liability (injuries that result from malpractice). In addition, the requirement in the new rule that equipment serial numbers be included on the insurance certificates suggests that CMS may be concerned with the purchase of casualty insurance for repair or replacement of damaged or destroyed medical equipment.

Proposed Change: The description of the insurance should be refined to confirm that only general liability insurance is required. If this is not the case, the limit applicable to each type of insurance should be specified.

b. Apparent Prohibition on Self-Insurance. The new rule precludes IDTFs from meeting the insurance requirements by legitimate and well regulated self-insurance programs. The preamble to the proposed IDTF insurance requirement explains that precluding self-insurance is a "good business practice" for the protection of IDTF patients. 71 Fed. Reg. at 49061. In addition, CMS assumed in its commentary relating to the final rule that no "legitimate businesses would . . . oppose these changes." Id. at 69700.

Sutter Health is a long-standing and well reputed health system that operates self-insurance programs for its professional liability, general liability and workers' compensation insurance that are thoroughly regulated by state law.

Sutter Health's relative-owned insurance company currently provides general liability and professional liability to Sutter Health-affiliated IDTFs. This relative-owned insurance company has obtained a certificate of authority as a captive insurance company from the State of Hawaii, Commissioner of Insurance, after approval of an application that contained evidence of the amount and liquidity of its assets relative to the risks assumed; the adequacy of the expertise, experience and character of the person or persons who will manage it; the overall soundness of its plan of operation; and the adequacy of the loss prevention programs of the Sutter insurance captive and its affiliated entities. See 431 Hawaii Rev. Stat. 19-102. In addition, the Hawaii captive insurance rules require the Sutter captive to file annual financial reports and be subject to an examination no less often than every three years by the Insurance Division of the Hawaii Department of Commerce and Consumer Affairs. See 431 Hawaii Rev. Stat. 19-107, 19-108. In addition, Sutter Health, in its capacity as an employer, has similarly obtained from the State of

California a certificate of consent to self-insure its workers' compensation liabilities after an application demonstrating its financial strength and competence. See 8 Cal. Code of Regs. 15203.

Requiring that an insurance company issuing an insurance policy be "non-relative owned" does not ensure the legitimacy of the operation or the company issuing the certificate, which we understand is CMS' concern in issuing this regulation. We understand from informal discussions with representatives from CMS that CMS is concerned with IDTFs that procure insurance certificates from related organizations that are essentially a sham (*e.g.*, the issuing company is not a legitimate insurance company or lacks assets from which to pay claims). Permitting insurance programs that have been granted certificates of consent by a state insurance agency after a meaningful review is a better basis for addressing CMS' concern than merely precluding self-insurance and captive insurance programs. The standard as adopted does not appear to advance CMS' goal at all. Only large and financially solvent companies have the capacity to meet the requirements for self-insurance and captive insurance programs that have been approved under state law. State Insurance Departments will be much better suited, and can devote more significant resources, to determine the legitimacy of an insurance program than would a Medicare carrier reviewing a one page insurance certificate that accompanies an 855 form. Truly, we can think of no good reason for CMS to preclude larger entities such as Sutter Health from using such risk-management programs for IDTFs. After all, these self-insurance programs also insure acute care hospitals whose operations are vastly larger and more complex than IDTFs. Precluding insurance from being provided by a captive insurance company would simply increase the cost of caring for Medicare beneficiaries by requiring self-insured entities to purchase ADDITIONAL insurance (for claims that are sufficiently provided for) for its IDTFs. There is no compelling reason that the risk management resources available to IDTFs should be limited to policies purchased from commercial insurance companies. Requiring IDTFs to purchase additional insurance from commercial insurers would unnecessarily increase the cost of providing diagnostic imaging services to Medicare beneficiaries, while benefiting only the commercial insurance industry.

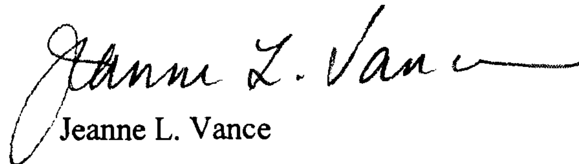
Proposed changes:

Preferred Option: Remove the restriction on acquiring insurance coverage from an affiliated company, so long as the affiliated company arrangement has been approved as an insurance captive by a state regulatory agency after review of the captive's financial solvency and ability to pay claims. Allow self-insurance for workers' compensation programs that have obtained a certificate of consent to self-insure from a state regulatory agency so long as the insurance department has reviewed the company's financial solvency and ability to pay claims.

Alternative Option: If CMS is not inclined to adopt the preferred option in all cases, CMS could adopt an exception to the insurance requirements permitting both (a) self-insurance for entities maintaining a net worth of at least the greater of Three Million Dollars ($3,000,000) or the total value of coverage required under the regulation and (b) purchase of insurance from an affiliate, so long as the affiliate maintains a net worth of that amount. Frankly, we believe that financial regulation of insurers and self-insurance arrangements is far better left to state law, but this alternative would be far superior to a ban on self-insurance and affiliated insurers.

Thank you in advance for your consideration. If you have any questions concerning any of these comments, please do not hesitate to contact me.

Most respectfully submitted,



Jeanne L. Vance

JLV:jj
JLV-SecondSetComPropIDTFReg (01005-112)

22

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Comprehensive Adult Medicine
Diagnostic Medicine of Indiana Family Practice
HMS Medical Consultants
Meridian Adult Medicine
Meridian Family Practice
Moore Family Care
Northside Internal Medicine
Lafayette
Horizon Oncology Center
Richmond
James R. Lewis, MD Internal Medicine
Zionsville
Northwest Internal Medicine

November 27, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Physician Fee Schedule for Calendar Year 2007 - Diagnostic Cardiac Catheterization Procedure Codes and Peripheral Vascular Intervention Codes

Dear Ms. Norwalk:

The Care Group is a medical practice that sees over 350,000 patients each year in the greater Indianapolis area. Our 134 physicians and 760 employees respectfully urge you to address the catheterization laboratory issue that will reduce physician's Medicare reimbursement by 16% next year and, ultimately, will result in a decrease of up to 64% in 2010. This is on the technical reimbursement issue alone. Reductions of this magnitude will force our practice to close our catheterization laboratories and lay-off staff members. The patients will have to go to the hospital for their cardiac catheterization procedures. This would increase a patient's co-pays, to potentially double, due to the service being provided in a hospital setting. Also, the hospital setting will cost Medicare more than it does in the outpatient setting and the hospitals cannot absorb this volume of cases in their inpatient catheterization laboratories.

This letter addresses issues related to providers who provide catheterization-related procedures in outpatient cardiac centers. The issues are related to Medicare payment policy decisions that appear in the Final Rule with comment period-Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B ("Final Rule").

We are concerned about the CMS decision to allow carriers to establish the price for diagnostic cardiac catheterization procedure codes rather than the current practice of basing payment on a national fee schedule. Inconsistent policies by carriers can impact Medicare beneficiaries' in a variety of ways. Access to these important diagnostic cardiac services in an outpatient, non-hospital setting could be significantly impacted. Some carriers have already made non-coverage decisions. As carriers set

individual prices you may find that beneficiary co-pays could be significantly different for the exact same service. Most carriers will not have the background or in-depth understanding of the issues leading to the CMS decision that these codes be carrier priced for 2007.

We would request that carriers receive clear instructions to standardize the approach by which carrier prices are established so that beneficiary access is consistent across the nation and not subject to local variation that is unrelated to clinical need and adversely impacts the beneficiary and providers.

We encourage CMS to inform carriers to base the 2007 relative value units for seven codes (93508 TC, 93510 TC, 93526 TC, 93543, 93545, 93555 TC, and 93556 TC) on the 2006 values and not those that were published in the June 29, 2006 Notice in the Federal Register that addressed the new practice expense (PE) methodology and the fees that were published by CMS on November 1, 2006. The 2006 relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three technical component CPT codes included in the Ambulatory Procedure Classification ("APC") for diagnostic left heart catheterizations are 93 percent of the relevant 2007 APC rate.

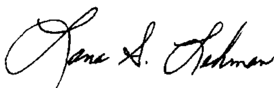
We are also concerned about the apparent inconsistency of establishing separate approaches for setting payment rates for the full range of procedure codes that are performed in the outpatient cardiac center setting. Specifically, peripheral vascular intervention procedure codes were left in the 2007 Physicians Fee Schedule at the same time that cardiac catheterization codes were sent for carrier pricing. The same issues that prompted CMS to commit the cardiac catheterization procedures cited above to carrier pricing apply to these procedures, and the same concerns about the lack of cost data and an appropriate methodology for setting pricing also apply. We encourage the agency to determine whether there is a systematic bias in the method that leads to the lower values for procedures performed in the non-facility setting.

Thank you for the opportunity to describe our concerns about the final rule, specifically as it relates to carrier pricing for cardiac catheterization-related procedures and payment rates for peripheral vascular intervention procedure codes.

Carriers have already begun to post the 2007 fee schedule on their websites and most have simply not listed these carrier priced codes. As providers we will be scheduling meetings with carrier medical directors in the next few weeks in order to attempt to minimize the problems we anticipate January 1, 2007.

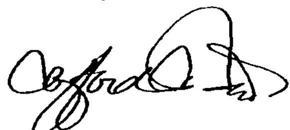
We would appreciate CMS providing carrier background and guidance at your earliest convenience.

Sincerely,



Lana S. Lehman
Executive Vice President
The Care Group, LLC

Sincerely,



Clifford C. Hallam, M.D.
CEO / Managing Partner
The Care Group, LLC

2006 NOV 20 PM 2:49

November 19, 2006

Leslie Norwalk, Esq. Administrator
Centers for Medicare and Medicaid Services Dept. of Health and Human Services
200 Independence Ave. SW
Room 341H
Washington, DC 20210

FAX 202-690-6262

Dear Ms Norwalk,

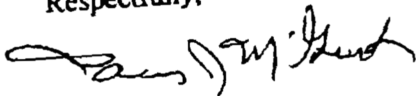
I am very concerned with the proposed Medicare cuts slated to take effect in January 2007. These proposed cut would seriously affect the ability of citizens, especially seniors, from getting their needed heart care.

Additionally, these cuts may result in heart doctors leaving our state and as such making it much more difficult for all Florida residents to obtain heart related medical help.

This great nation of ours certainly should be able to provide for the needed medical care for all of our citizens.

Thank you for your attention to this matter.

Respectfully,



Larry J. McGurk
357 Wekiva Cove Road
Longwood, FL 32779

DHPPC (illegible) RegStaff-FYI
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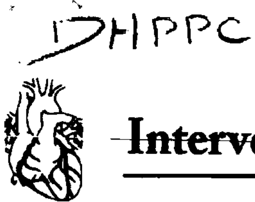

Interventional Cardiology and Vascular Consultants, P.L.C.

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Ashish Pal, M.D., F.A.C.C.

October 9, 2006

NOV 22 2006
7:50 A.M.

Leslie Norwalk, Esq.
Acting Administrator
CMS
Central Building
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Leslie:

Cardiovascular disease is the number one killer in the United States. Given the magnitude of cardiovascular morbidity and mortality, a reasonable person would expect Medicare to make it a priority to support cardiovascular specialists who lead the way in the battle against this dreaded disease. Instead, Medicare plans to make crippling cuts in the reimbursement we receive for diagnostic procedures in our office practices. The current range of cuts is from 40-62% and involve essential diagnostic procedures including echocardiography, nuclear stress testing, and outpatient diagnostic cardiac catheterization. Over the last several years, Medicare reimbursements to physicians have failed to keep pace with medical inflation and cost of living increases. Nonetheless cardiologists have managed to maintain high levels of care for both Medicare and the non-Medicare patient alike, including those patients who have no health insurance and receive care for free. Current Medicare proposals that will take effect in January 2007 threaten our ability to deliver care to these patients. The net office setting will actually be greater than the reimbursement. Compounding the problem is the fact that private insurance companies use Medicare as a guideline and this reduction in fees will impact our ability to deliver care to non-Medicare patients as well. The magnitude and depth of these cuts will have a rippling catastrophic effect on cardiovascular care throughout Central Florida. It is unlikely that physicians will be able to afford to make new medical and information technologies available through their office practices. I anticipate many cardiologists will be forced to close their practices in the State of Florida and move to other states with a smaller Medicare population. The remaining practices will have no choice but to reduce office staff substantially and reduce or eliminate services in order to survive in this environment. Many cardiologists may find that they are unable to see new Medicare patients, others will have no choice but stop seeing Medicare patients at all.

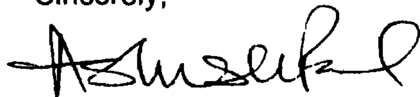
In an effort to reverse these unfair cuts, the major cardiology groups in Central Florida have been meeting to discuss possible solutions. We have been meeting with our representatives who include Senator Bill Nelson, Congressman Ric Keller and Thomas Feeney. In addition, we have met with representatives from the Florida Medical Association

and the Florida Chapter of the American College of Cardiology. We are all in agreement that the proposed cuts will destroy our practices and force many of us out of business. Therefore, we would ask that you freeze the reimbursement rates for the current office diagnostic procedures which include echocardiography, carotid ultrasound, nuclear stress testing, and diagnostic cardiac catheterization at the current levels.

We would ask that you develop a fair solution that addresses the issues of compensation for these services. Any solution that is fair should include the participation of clinical cardiologists like ourselves who have a vital stake in this process and actually take care of the patients.

Thank you so much for considering these comments.

Sincerely,



Ashish Pal, M.D.

AP:stat

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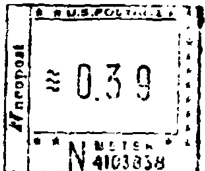

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Rec'd 11-27-06

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November 7, 2006

Leslie Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-FC
Mail Stop C5-11-24
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: **CMS-1321-FC and CMS-1317F – Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Values, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B.**

Dear Ms Norwalk:

It has come to the American Society of Anesthesiologists' attention that the Centers for Medicare and Medicaid Services (CMS) used budget neutralized work relative value units (RVUs) in its calculation of practice expense relative value units published in CMS-1321-FC. This is contrary to the Agency's published intention to use the unadjusted work units (see page 87 of CMS-1321-FC as posted on the CMS website on November 1, 2006) and results in practice expense relative values that are lower than they should be. While anesthesia codes do not have procedure-specific work and practice expense RVUs, the error impacts anesthesiology because CMS calculated the practice expense share of the anesthesia conversion factor using work RVU proxies that had been subject to the budget neutrality adjustor.

We understand that AMA/Specialty Society RVS Update Committee (RUC) staff has alerted you to this error. It is essential that CMS not only publish the corrected practice expense values for codes subject to the RBRVS payment methodology, but also recalculate the anesthesia conversion factor using the correct values.

We appreciate your prompt attention to this matter.

Sincerely,

Mark J. Lema, MD, PhD
President

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

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December 4, 2006

2006 DEC -8 AM 9:20

Leslie Norwalk, Esq
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Department of Health and Human Services
Mail Stop C5-11-24
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Final Rule With Comment Period; **CMS-1321-FC**

Dear Ms Norwalk:

The American Academy of Pediatrics (AAP) appreciates the opportunity to provide comments on the November 1st Final Rule titled "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B." Although very few pediatric services are included in the Medicare program, payment policies introduced in Medicare are frequently adopted by the Medicaid program and eventually by private payers. Therefore, the Academy offers these comments on the proposed rule to ensure that new policies appropriately accommodate the unique aspects of health care services delivered by primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

Noncovered Services

The Academy commends the Centers for Medicare and Medicaid Services (CMS) for publishing the American Medical Association (AMA)/Specialty Society Relative Value Scale Update Committee (RUC) recommendations for noncovered Medicare services. We are very pleased that the four codes that we specifically addressed in our proposed rule comments (92551, 99173, 99339, and 99340) are now included among those with published values on RBRVS.

Other Services

The Academy strongly applauds CMS for agreeing with the RUC-recommended relative value units (RVUs) for the lumbar puncture code (62270), the circumcision code (54150), the surfactant administration code (94610), and the thirty-five evaluation and management codes (99201-99205, 99211-99215, 99221-99223, 99231-99233, 99238-99239, 99241-99245, 99251-99255, 99281-99285, and 99291-99292).

Practice Expense for Immunization Administration

The Academy respectfully requests reconsideration of the direct practice expense (PE) inputs for the immunization administration codes (90465-90474). Several factors have arisen since these codes were last before the RUC for PE refinement, namely:

- Vaccines for Children program requirements have become stricter, specifically regarding vaccine storage (ie, dedicated vaccine freezer and refrigerator)
- The volume of total vaccines has increased significantly
- There is an increased use of unit dose syringes, which occupy more space than multi-dose vials

For these reasons, the Academy requests re-refinement of the direct PE inputs for the immunization administration codes through the RUC Practice Expense Review Committee (PERC).

Budget Neutrality Factor

We are disappointed by CMS' decision to apply a separate budget neutrality factor to all work relative value units (RVUs) rather than to the conversion factor. The Academy strongly objects to using work relative values as a mechanism to preserve Medicare budget neutrality. These adjustments to the work relative values cause confusion among the many non-Medicare payers that adopt the RBRVS payment system. According to a recent AMA survey, 77% of all public and private insurance payers rely on the RBRVS. We believe that this adjustment should have been transparent and advocate that any Medicare budget neutrality adjustments be made to the conversion factor rather than to the work relative values. The potential negative impact on the delivery of key Medicaid preventive services such as Early Periodic Screening, Diagnosis, and Treatment (EPSDT) is great in the several states that adopt the RBRVS reduced relative value units for the preventive medicine service codes (99381-99385, 99391-99395) and immunization administration (90465-90468, 90471-90474).

Moderate (Conscious) Sedation (99143-99150)

The moderate sedation codes continue to be included on the fee schedule as Status Indicator "C" (Carrier Priced), with no published RVUs. Given CMS' direct involvement in the development of these codes, it disappoints us that the Status Indicator for the codes is "C." Furthermore, we are dismayed that CMS continues not to accept the April 2005 RUC recommendations for the codes and publish them in the 2007 RBRVS final rule.

In its November 21, 2005 *Federal Register* 2006 Medicare Physician Fee Schedule comments, CMS stated that it was "uncertain whether the RUC assigned values are appropriate and has carrier priced these codes in order to gather information for utilization and proper pricing." While we appreciate CMS' reconsideration of paying for sedation services not previously covered and understand this is an interim position, we request that CMS consider the following arguments in revising its position.

These 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. While CMS has assigned these codes to Status Indicator "C," the Academy believes that they should be listed with Status Indicator "A" (Active) and their RUC-recommended RVUs published.

Providing moderate sedation to patients undergoing certain outpatient procedures requires a certain level of provider skill and training and incurs medical legal liability, but is also associated with greater patient satisfaction, improved outcomes, and cost savings over similar procedures provided with anesthesia in an operating room. Furthermore, the far-reaching shortage of pediatric anesthesiologists at children's hospitals has created the need for moderate sedation services provided by other hospital-based physicians. In most metropolitan areas of the United States, these children's hospitals form the safety net for subspecialty care provided to children in the Medicaid program. This critical service is directly supported by the publication of relative values of these codes.

Appendix G ("Summary of CPT Codes That Include Moderate Sedation") in the CPT manual was developed to identify services where 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 paid when reported with a moderate sedation code. 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 RVUs for any procedure not included in Appendix G and the Academy believes that physicians should be adequately compensated for providing such services.

For these reasons, the Academy respectfully requests that CMS reconsider its decision to list the moderate sedation codes as carrier-priced. We urge CMS to publish the RUC-approved RVUs and assign these codes as Status Indicator "A" (Active) codes.

Preventive Medicine Services and the Medicare Primary Care Exception

Over the past three years, the Academy has made several requests for CMS to consider including preventive medicine services as part of the Medicare primary care exception. We take this opportunity to reiterate our request.

When CMS revised teaching physician rules (Medicare Carriers Manual Transmittal 1780, November 22, 2002), a "primary care exception" was established (§15016(C)(3)). This exception permitted the teaching physician to submit claims to Medicare for certain low and medium intensity Evaluation and Management services (99201-99203, 99211-99213) furnished by residents, subject to certain oversight rules, in a primary care clinic.

While the transmittal names pediatrics as one of the "residency programs most likely qualifying for this exception..." the rule itself has actually placed these residencies at a disadvantage. The primary reason is the available exempt codes. Medicare generally does not pay for the preventive medicine visits (99381-99387, 99391-99397). However, these are among the most common codes to be used in the pediatric primary care clinic.

Preventive well child care and EPSDT visits are responsible for a significant number of pediatric primary care clinic visits. By their nature, they are similar in intensity to the codes already included in the exempt list. Because these codes are not listed on the primary care exception list, it places an undue burden on the pediatric teaching physician who is unable to report these codes in the pediatric primary care setting under the exception. The fact that the primary care exception does not presently include preventive medicine services prohibits pediatric residents from partaking of the educational advantages enjoyed by their adult-based colleagues. Furthermore, given that the "introduction to Medicare" exam was added to the exempted list last year establishes a precedent for other preventive services of similar intensity and importance to be included.

Preventive services are key services in the teaching setting, particularly considering that most children's hospitals serve as the Medicaid safety net for children in their service regions and deliver preventive services for children through age 18 under the federal EPSDT program.

While the original intent of Transmittal 1780 was for Medicare reimbursement, it has become the de facto standard for many Medicaid and commercial payers, and the compliance policies of teaching hospitals now reflect these rules.

For these reasons, we ask that the pediatric preventive medicine and EPSDT codes be added to the primary care exception list. This will have no financial impact on Medicare or residency GME reimbursement, but will help improve and make more equal the educational experience for the pediatric resident as compared to non-pediatric residencies.

Preventive Medicine Service	New	Established
Infant (<1 year)	99381	99391
Early childhood (1-4 years)	99382	99392
Late childhood (5-11 years)	99383	99393
Adolescence (12-17 years)	99384	99394

S0302 Early Periodic Screening, Diagnosis, and Treatment (EPSDT)

The Academy appreciates the opportunity to provide comments on the November 1st final rule and looks forward to working with CMS to ensure that the physician fee schedule accurately reflects the work value of physician practice and pediatric care.

Sincerely,

Jay E. Berkelhamer, MD, FAAP
President

JEB/ljw