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September 29, 2005

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O.Box 8017
Baltimore, MD 21244-8017

RE: CMS-1502-P
'Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006'

Dear Dr. McClellan:

The American Society of Nephrology (ASN) is a professional association with approximately 8,500 members. Of this membership, about 95% are physicians, with the remaining members basic scientists with a primary interest in renal disease. Virtually every licensed nephrologist in the United States is a member of the ASN, with an additional 3,000 nephrologists from 82 other countries comprising the remainder of our membership. The Society is focused on promulgating innovative research related to renal disease, and on providing continuing medical education to physicians and scientists dedicated to the improved understanding and treatment of renal disease.

The ASN welcomes the opportunity to respond to the recent proposed revisions by Centers for Medicare and Medicaid Services (CMS) regarding reimbursement for physicians for outpatient dialysis care. The ASN recognizes the critical role of nephrologists in the care of dialysis patients. ASN supports the intent of the CMS proposals to optimize the care provided to dialysis patients and increase the satisfaction that patients derive from the opportunity to routinely interface with their nephrology physicians.

ASN wants to commend CMS for its willingness to work with the renal community this past calendar year on many important issues and challenges facing ESRD patients, physicians and dialysis providers.

The ASN submits the following comments on various aspects of the CMS proposals "*Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006*", published in the *Federal Register* on August 8, 2005.

I. TELEHEALTH

The ASN supports Medicare reimbursement for Medical Nutrition Therapy (MNT) services, provided via telehealth arrangements, for individuals with chronic kidney disease (CKD). We support the MNT provision because MNT is one of the factors that can improve long-term outcomes of kidney (disease) patients.

We recognize the fact that the MNT benefit appears to be underutilized. Implementation of a telehealth provision will enhance access to this important service for CKD patients. This is particularly true for patients who live in rural and in some instances urban settings where distance (and transportation issues) would constitute a barrier to keeping appointments with Medicare approved providers of MNT services. Assuming appropriate equipment is available; the following settings could be used for MNT telehealth, either as the originating site or the receiving site: nephrology group practice offices, hospital outpatient departments, rural health clinics, CKD clinics and centers approved for Diabetes Self-Management Training. It would also seem appropriate that a dialysis facility could provide telehealth services if there is dedicated space –for such services - in the dialysis unit.

ASN applauds CMS for recognizing that dialysis patients can benefit from telehealth services.

Case Mix Adjustments to the Composite Rate

Section 623 of the Medicare Modernization Act required the establishment of basic case-mix adjustments to the composite payment rate for dialysis services. The November 15, 2004 Final Rule implemented three categories of patient characteristic adjustments (age, body mass index (BMI), and body surface area (BSA)) that were implemented April 1, 2005. CMS is proposing to retain these categories and patient characteristics as case-mix adjustments for 2006.

The ASN urges CMS to evaluate different case-mix adjustments, and make the necessary coding changes to put them in to affect. We are concerned that the existing case-mix adjustments will not improve survival rates or significantly improve the quality of life of kidney disease patients. The current case-mix adjustments do not compensate providers for other resource utilization demands or the intensity of care required by frail, elderly dialysis patients or dialysis patients with co morbidities and/or ambulatory problems.

We suggest that CMS should consider an adjustment after the first six months of End-Stage Renal Disease (ESRD) because many beneficiaries/patients require additional

attention and medical care. For example, ASN suggests that CMS develop a new code to reimburse dialysis providers for the care of ESRD patients with diabetes.

II. ESRD – Pricing Methodology

The ASN urges CMS to adopt a drug reimbursement (and pricing) methodology that is sustainable and predicable. Beginning January 1, 2006, CMS proposes to reimburse dialysis providers for separately billable ESRD drugs based on Average Sales Price (ASP), rather than the Average Acquisition Payment (AAP) methodology. The advantage of the ASP methodology is that ASP can be updated periodically by calculating data routinely provided by pharmaceutical companies. If CMS plans to use an ASP-based methodology, the Agency should use the most recent available ASP data when calculating the initial payments and update it quarterly.

ASN is concerned that significant lag times in updating pricing data results in a decrease in reimbursement that no facility has the ability to make up. To address this issue, we encourage CMS to provide retrospective payments to dialysis facilities particularly small or independent dialysis providers so they will not be forced to cut back on services provided to dialysis patients or close. In either case, patients will suffer, especially if the small, independent dialysis provider operates the only dialysis facility in remote, rural or under-served areas.

ASN encourages CMS to work closely with the renal community to examine principles carefully before issuing the Final Rule.

III. ESRD – Drugs and Biologicals

The ASN recommendations that CMS recognize that there is a need for well-designed drug add-on adjustments that compensates both hospital-based and dialysis facilities for the actual loss of revenue due to changes in reimbursement for separately billable drugs. ASN highlighted this in our 2005 Proposed Physician Fee Schedule comment letter.

CMS proposes that hospital-based dialysis facilities should receive the same add-on adjustment as independent dialysis providers, even though independent providers were reimbursed on the basis of the average wholesale price (AWP) before 1, 2004, for all drugs except erythropoietin. Hospital-based facilities were reimbursed for these same drugs at cost, and will continue to be reimbursed at cost in 2006, if the provision in the current draft Physician Fee Schedule rule is finalized.

We acknowledge CMS' public response to errors identified by the renal community with some of the calculations related to the drug add-on adjustment. ASN encourages CMS to work with the renal community to address other add-on adjustment concerns such as the calculation of the update factor for estimating the CY 2006 drug reimbursement. In

addition, we urge the Agency to establish separate add-on adjustments consistent with the requirements of MMA § 623(d) and congressional intent.

IV. ESRD Composite Rate Wage Index

The ASN believes the revising the ESRD composite rate wage index is long overdue. The current composite payment rates are calculated using a blend of two wage indexes, one based on hospital wage data for fiscal years ending in 1982, and the other developed from 1980 data from the Bureau of Labor Statistics (BLS). The failure to update the ESRD composite wage index has made it difficult to recruit and retain professional staff, especially in areas where the cost of living is high. The ASN applauds CMS on its decision to address this issue in the 2006 Proposed Rule.

We are concerned however that the proposed revisions will dramatically reduce the payments that many facilities, especially those in rural areas, will receive. It has been estimated that reimbursement for rural facilities could be cut by as much as $22 per treatment. If this estimate is accurate, we have serious concerns that rural and remote facilities will be able to survive. This is of critical importance because dialysis patients in rural and remote areas may be required to travel long distances, three times per week, for treatment at dialysis facilities far from their homes.

The ASN encourages CMS to establish an appropriate transition period for revisions to the ESRD composite wage index. We recommend that the ESRD composite rate wage index adjustments be phased in over five years and that CMS provide annual updates of the wage index in each of these years. It is critically important that CMS implement the necessary revisions to the wage index in a manner that does not undermine the stability of the ESRD community.

V. ESRD – Exceptions Process

CMS should clarify that the Agency will continue to recognize the exception status of non-pediatric facilities being paid through this process until these facilities relinquish their status in writing. The current regulations contain procedures on how dialysis providers can request exceptions to ESRD facility composite payment rates, and establish five criteria for approval of exception requests.

ASN recommends that CMS retain the exceptions process for all five criteria in order to preserve access to care for dialysis patients and to foster evolution in the patterns of dialysis care. The recent experience with Hurricanes Katrina and Rita underscore the need for an exceptions process to provide continuity of dialysis care during extraordinary circumstances.

We believe that self-dialysis and more frequent dialysis should be preserved as options for appropriate patients. In particular, patients with congestive heart failure – a fast-

growing segment of the ESRD population - may require four dialysis treatments per week. Finally, the exception for isolated essential facilities should be retained because of the potential impact on access to care resulting from the proposed changes in the composite payment rate wage index and reimbursement for ESRD drugs.

VI. Closing

The ASN shares your goals of improving outcomes for dialysis patients and is committed to working with CMS to foster optimal physician care for individuals with chronic kidney disease. We believe our proposed recommendations and a constructive dialogue between ASN, through its Dialysis, Hypertension, Acute Renal Failure, Transplantation and Chronic Kidney Disease Advisory Groups, and CMS will prove helpful in the exchange of ideas and viewpoints when formulating workable solutions now and in the future.

Thank you for the opportunity to respond to the recent CMS Proposed Rule and your consideration of our comments. We welcome your response to our recommendations and the opportunity to contribute to the final guidelines.

Sincerely,

Tomas Berl, M.D.
President

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September 30, 2005

Dr. Mark McClellan
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

Re: CMS-1502-P: Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006

Dear Administrator McClellan:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year [CY] 2006 (Proposed Rule). 70 Fed. Reg. 45764. KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[1] Specifically, KCP urges CMS to:

- Adopt a drug reimbursement methodology that is sustainable and predictable, incorporates the most current pricing data available, minimizes any lag time, and recognizes the needs of smaller dialysis facilities;

- Correct the remaining errors related to the calculation of the drug add-on adjustments and comply with the congressional mandate to establish separate add-on adjustments for hospital-based providers and independent facilities;

- Implement the revised geographic wage index and provide a more appropriate transition to minimize the negative impact the revisions will have on some facilities;

[1] A list of Kidney Care Partners coalition members is included in Attachment A.

- Clarify that the Agency will continue to recognize the exception status of non-pediatric facilities being paid through this process until these facilities relinquish their status in writing; and

- Include dialysis facilities as originating sites for purposes of telehealth services and implement the proposal to include medical nutritional therapy as a telehealth service.

I. ESRD-Pricing Methodology/Payment for ESRD Drugs: CMS should adopt a drug reimbursement methodology that is sustainable and predictable, incorporates the most current pricing data available, minimizes any lag time, and recognizes the needs of smaller dialysis facilities.

KCP encourages CMS to adopt a drug reimbursement methodology that reflects the following principles. As a threshold matter, we acknowledge that the previous Average Wholesale Price (AWP) methodology was flawed. However, as Congress and MedPAC recognize, modifying the drug reimbursement methodology addresses only half of the problem with the ESRD prospective payment system. To truly fix this system, Congress and CMS must reform the composite rate methodology by providing an annual update mechanism. Although the drug add-on adjustments serve an important role in the reform effort, they alone are not enough. Therefore, to ensure the success of any drug reimbursement methodological change, we urge CMS to work closely with Congress to establish an annual update mechanism to the composite rate as quickly as possible.

As a first principle, the drug reimbursement methodology selected must be sustainable and predictable. Drugs play an important role in the treatment of dialysis patients. This significant component of dialysis treatment accounts for approximately 40 percent of facility expenditures related to patient care. It is, therefore, critically important to patients, facilities, and the kidney care community that Medicare reimbursement for drugs does not fluctuate significantly and that it accurately reflects as closely as possible the actual cost of providing these drugs to patients.

Second, the drug reimbursement methodology should be based upon the most current data available. KCP understands that the Proposed Rule relies upon proxy data to estimate payments. However, it is critically important that CMS clarify that it will use the most recent data available when it ultimately calculates the payment for ESRD drugs. If CMS were to use an Average Sales Price (ASP)-based methodology, the Agency should use the most recent available ASP data when calculating the initial payments and update it quarterly. If it were to select an Average Acquisition Price (AAP)-based methodology, it should update the data quarterly to account for changes in current pricing as well. Current data will ensure that Medicare reimbursement reflects as closely as possible the actual cost of providing these drugs to patients.

Third, CMS should adopt a reimbursement methodology that minimizes the lag between the time when the list price for a drug changes and the time when it is incorporated into the Medicare payment. As MedPAC has recognized, Medicare reimbursement for dialysis does not cover the cost

of providing care to patients. With negative Medicare margins and no annual update to account for inflation, no facility would be able to cover its costs if there is a significant lag between pricing increases and Medicare's recognition of such increases. A significant lag time results in a decrease in reimbursement that no facility has the ability to make up. To address this issue, we encourage CMS to provide retrospective payments to dialysis facilities so that they do not have to bear the burden that results from a significant lag time between the increase in drug prices and an increase in payment.

Finally, CMS should pay particular attention to how its selection of a drug reimbursement methodology will affect smaller facilities. Located mostly in rural or under-served areas, these facilities do not have the same economies of scale that larger facilities do. They are less likely to be able to survive sudden changes in costs if the reimbursement methodology does not incorporate them quickly.

KCP encourages CMS to consider these principles carefully before issuing the Final Rule. We also welcome the opportunity to work closely with the Agency to ensure that the drug reimbursement methodology meets the needs of the entire ESRD community.

II. ESRD-Drugs and Biologicals: CMS should correct the remaining errors related to the calculation of the add-on adjustments and comply with the congressional mandate to establish separate add-on adjustments for hospital-based providers and independent facilities.

KCP sincerely appreciates the Agency's quick, public response to critical errors identified by its members with some of the calculations related to the drug add-on adjustment. The correction notice issued September 1 resolves our concerns related to the Proposed Rule's exclusion of three "J"-codes and the inclusion of hospital-based provider data in the calculation of the weight for erythropoietin. Even though these important corrections increase the add-on adjustment to 11.3 percent, KCP remains concerned that CMS has not corrected the calculation of the trend factor, the estimation of the cost of syringes for administering erythropoietin, and the calculation of the update factor for estimating the CY 2006 drug reimbursement. In addition, we urge the Agency to establish separate add-on adjustments consistent with the requirements of Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) § 623(d) and congressional intent.

A. Correcting the trend factor

KCP is concerned that by applying an erythropoietin-based growth estimate of 9 percent, the Agency has incorrectly calculated the trend factor it proposed to use for determining the drug add-on adjustment. We strongly urge the Agency to use a trend factor that reflects the historical growth rate of ESRD drugs and that can be validated.

The proposed 9 percent does not reflect the historical trend factors for erythropoietin or non-erythropoietin separately billable drugs, which are significantly higher. In its March 2005 report, MedPAC calculated the increase in spending for non-erythropoietin separately billable drugs

as 17 percent per year between 1996 and 2003. It determined that the historical trend for erythropoietin was an estimated 14 percent per year during the same period.[2] The Moran Company (TMC) also reports that the growth factor should be higher. Using the publicly available 5 percent sample data, TMC established a growth trend of approximately 11-12 percent.[3] The artificially low estimate will result in dollars being taken out of the system. Congress expressly indicated that the add-on adjustment should be cost neutral to the program. 42 U.S.C. § 1395rr(b)(12)(E). If the trend factor is not corrected, CMS will be ignoring this explicit congressional intent.

The Proposed Rule also assumes that the growth rate of non-erythropoietin separately billable drugs can be correlated to that of erythropoietin so that a calculation of distinct growth factors is not required. 70 Fed. Reg. at 45791. This assumption is inappropriate. When evaluating the growth of separately billable drugs, MedPAC recognizes that a difference exists between erythropoietin and non-erythropoietin separately billable drugs. As noted, in its March 2005 report and contrary to the assumption in the Proposed Rule, MedPAC was able to estimate a significant difference in the growth trends of erythropoietin and the other separately billable drugs.[4] CMS should undertake a similar analysis.

Given the MedPAC and TMC analyses, KCP strongly encourages CMS to recalculate the growth factor using the separate estimates for erythropoietin and non-erythropoietin separately billable drugs and to base these estimates on historical trends, as required by the statute.

B. Estimating the costs of syringes

KCP is also concerned that CMS has miscalculated the cost of syringes used to administer erythropoietin, which is another critical aspect of calculating an appropriate drug add-on adjustment. CMS estimates the value of these syringes to be $1.6 million for hospital-based providers and $26.8 million for independent facilities. 70 Fed. Reg. at 45791. When reviewing the math, TMC concluded that these amounts are too high given the number of treatments CMS projects. Specifically, if facilities administered erythropoietin in conjunction with each of the 34.5 million projected dialysis treatments, the total amount of payments attributable to syringes would be $0.50 * 34.5 million = $17.5 million in the aggregate,[5] which is significantly lower than CMS's estimate. However, erythropoietin is not administered to every dialysis patient during every treatment session;[6]

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[2]MedPAC, "Report to the Congress: Medicare Payment Policy," 123 (March 2005).

[3]The Moran Company, "Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System" 9 (September 2005).

[4]*See supra*, note 2.

[5]*See supra*, note 3.

[6]For example, EPO would not be provided to all patients with polycystic kidney disease, many of whom maintain normal hematocrit levels. Patients using peritoneal dialysis also do not receive EPO. Other patients would be titrated and would not receive a dose in a particular month.

therefore, it is more likely that the amount would be $15 – $16 million. CMS should re-estimate this value before calculating the drug add-on adjustments.

C. Estimating the 2006 ASP+6 percent amount for calculating the add-on adjustments

Based upon the analysis of our members, KCP believes the proposed methodology for calculating the 2006 drug reimbursement (which CMS proposes as ASP+6 percent[7]) for purposes of determining the add-on adjustments will lead the Agency to understate the correct amount and will result in a calculation that is not budget neutral. In addition to using the appropriate inflation factor, CMS should also base its calculations on the most recent manufacturer pricing data available – rather than a four-quarters average – to more accurately reflect price changes in the payments.

CMS should rely upon an inflation factor that represents historical trends of ESRD drugs only, rather than on one that includes all drugs in the aggregate. The Proposed Rule indicates that the Agency seeks to use an inflation factor of 5.7 percent, which is the forecast of the Producer Price Index (PPI) for all prescription drugs. This factor simply does not reflect the actual ESRD drug trends, as CMS's own data (described in the table below) indicates.

Drug	Jan'05 Payment Limit	Apr'05 Payment Limit	Jul'05 Payment Limit	Oct'05 Payment Limit	Oct'05 vs. Jul'05	Oct'05 vs. Jan'05	2002 Wgts	Non-Epogen
Epogen	$9.317	$9.250	$9.307	$9.313	0.1%	(0.0%)	67.9%	
Zemplar	$4.017	$3.971	$3.871	$3.809	(1.6%)	(5.2%)	15.9%	49.5%
Venofer	$0.362	$0.365	$0.365	$0.359	(1.6%)	(0.8%)	5.0%	15.6%
Hectorol	$2.797	$2.784	$1.501	$1.684	12.2%	(39.8%)	1.3%	4.0%
Ferrlecit	$4.829	$4.726	$4.713	$4.699	(0.3%)	(2.7%)	6.0%	18.8%
Infed	$11.060	$11.218	$11.223	$11.344	1.1%	2.6%	0.7%	2.0%
Carnitor	$14.649	$11.122	$12.174	$11.270	(7.4%)	(23.1%)	1.7%	5.2%
Alteplase	$30.152	$30.089	$30.772	$31.436	2.2%	4.3%	0.2%	0.6%
Calcitriol	$0.710	$0.859	$0.623	$0.817	31.1%	15.1%	1.2%	3.8%
Vancomycin	$2.419	$3.188	$2.983	$3.200	7.3%	32.3%	0.2%	0.6%
Wgtd Avg ASP+6%								
Total	$ 7.69	$ 7.58	$ 7.60	$ 7.59	(0.2%)	0.1%		
Non-Epogen	$ 4.27	$ 4.06	$ 4.00	$ 3.94	(1.5%)	(2.8%)		

The above table shows the recent ASP+6 percent trends for ESRD drugs. It indicates that the actual trend is a 1.2 percent decline in prices overall and a 6.3 percent decline for the non-

[7]Please see Section I *supra* for the KCP's comments about the CMS proposal to adopt ASP+6 percent as the drug reimbursement methodology for CY 2006.

erythropoietin drugs. Thus, based upon this data, a broad industry update trend of 5.7 percent is not an appropriate estimate for ESRD. If CMS were to use this broader trend, it would result in a significant understatement of the 2006 drug reimbursement amount, which would result in an approximate decrease of $4.42 per treatment because of the miscalculation of the add-on adjustment.

D. Establishing separate drug add-on adjustments

As KCP has discussed on several occasions with CMS, we remain gravely concerned that the Agency continues to endorse an incorrect legal interpretation to support its conclusion that it may adopt a single add-on adjustment. We believe the plain text of MMA § 623(d) and its legislative history require the adoption of separate add-on adjustments that distinguish between hospital-based providers and independent facilities. In addition, the single add-on adjustment is also inconsistent with CMS precedent and public policy because it establishes unjustifiable windfall payments to hospital-based providers.

Simply put, the most appropriate interpretation of the statute of the whole requires CMS to create separate add-on adjustments. The plain text clearly indicates that Congress did not seek to upset the existing balance between hospital-based providers and independent facilities. Congress did not require CMS to adopt a single reimbursement methodology for separately billable drugs. *See* 42 U.S.C. § 1395rr(b)(13)(A). In addition, Congress clearly instructed the Inspector General to calculate the difference between the amount of payment using 95 percent AWP and the acquisition costs for these drugs using data from independent facilities only. MMA § 623(c). By discussing changes only to the reimbursement methodology for erythropoietin and those drugs reimbursed at 95 percent of the AWP, the Conference Report also indicates that Congress intended to modify only the payments for drugs billed separately by independent facilities and erythropoietin. H. Rep. No. 108-391 at 683-87. If Congress had intended to establish a consolidated add-on adjustment, it would have also consolidated the reimbursement methodology for all drugs billed separately regardless of the setting in which they are administered. It did not.

This interpretation is consistent with the congressional intent and the interpretation of other agencies. The bill's managers acknowledge this interpretation in letters to CMS in which they stated the text and legislative history reflect their intent that CMS establish two distinct add-on adjustments as well. The Office of the Inspector General (OIG) also agrees because when it conducted its congressionally mandated study to determine the cost of separately billable drugs, it expressly excluded the hospital-based providers from its analysis, consistent with its statutory mandate.[8] Therefore, CMS should not assume authority Congress did not grant it and establish a single, consolidated add-on adjustment instead of the required separate add-on adjustments.

In the preamble to the CY 2005 Final Rule, the Agency incorrectly interprets the word "difference" as evidence that it must establish a single add-on adjustment. This interpretation not

[8]OIG, "Medicare Reimbursement for Existing End Stage Renal Disease Drugs" (May 2004).

only ignores the text and legislative history, it is also inconsistent with the Agency's initial interpretation of the statute that indicated it believed the MMA provided it with the authority to adopt separate add-on adjustments. In addition, the interpretation ignores the rule of construction that indicates that legislative terms which are singular in form may apply to multiple subjects or objects. *See Smith v Zachary*, 255 F.3d 446 (7th Cir. 2001); *Johnson v Permod Drilling Co.*, 803 F.2d 867 (5th Cir. 1986); *see also*, 1 U.S.C. § 1 ("[i]n determining the meaning of any Act of Congress ... words importing the singular number include and apply to several persons, parties, or things"). The Agency itself interprets the singular term "composite rate" in the preceding provision to be plural as well. Given this clear rule of construction, CMS's reliance on its interpretation of "difference" is misplaced.

The CY 2005 Final Rule also includes two additional erroneous arguments to support its adoption of a single add-on adjustment. First, the preamble argues that CMS plans to implement a single add-on adjustment because it must maintain higher payments for hospital-based providers. 69 Fed. Reg. at 66320. This interpretation is incorrect because the plain language of 42 U.S.C. § 1395rr(b)(7), upon which it is based, requires only that CMS establish rates for hospital-based providers and independent facilities that are <u>different</u>. The text does not specify that the hospital-based rate must be higher. 42 U.S.C. § 1395rr(b)(7). Second, the preamble also implies that CMS believes a single add-on adjustment is appropriate because if it were to adopt separate percentages it would have to establish different calculations for budget neutrality and the case-mix adjustors based upon facility type as well. This assertion has no support in the statutory text or legislation history.

In addition, the adoption of a single add-on adjustment provides hospital-based providers with inappropriate windfall payments, which result in a transfer of $54 million from independent facilities to hospital-based providers in 2006 alone.[9] Combined with the 2005 windfall, the impact would be a decrease of approximately $2.00 per treatment for independent facilities and a windfall of approximately <u>$11 per treatment increase for hospital-based providers</u>. To continue a policy that shifts funds from independent facilities to hospital-based providers in contrast to congressional intent will negatively affect access to care and could drive patients to higher cost settings.

KCP strongly urges CMS to recognize that Congress mandated separate add-on adjustments and to distinguish between payments to independent facilities for <u>all</u> separately billed drugs and those to hospital-based providers for erythropoietin.

E. Payments for separately billed drugs provided by hospital-based providers

The need for distinct add-on adjustments arises from CMS's decision to continue to reimburse hospital-based providers based on reasonable costs for separately billable drugs, while reimbursing independent facilities using a different methodology. Consistent with MedPAC's recommendations, KCP supports the use of the same reimbursement methodology across dialysis

[9] *See supra*, note 3 at 11.

settings[10] and the collection of data on acquisition cost and payment per unit for drugs from hospital-based providers.[11]

III. ESRD-Composite Payment Rate Wage Index: CMS correctly proposes to revise the geographic wage index, but should also provide a more appropriate transition to minimize the negative impact the revisions will have on some facilities.

Even though KCP is pleased that CMS seeks to: (1) revise the geographic wage index using the Office of Management and Budget (OMB) definitions; (2) update the labor share component of the ESRD market basket; (3) eliminate the ceiling; and (4) update the wage index annually, we are concerned about the immediate effect of the changes on the dialysis community. Because the current wage index values are based on data from the early 1980s, revising the wage index is long overdue. However, the revision will dramatically reduce the payments many facilities, especially those in rural areas, will receive. Therefore, KCP encourages the Agency to provide for an adequate transition and to monitor the impact closely before reducing or eliminating the floor.

As a threshold matter, KCP urges CMS to provide greater transparency regarding the calculations used to develop the new wage index. In particular, CMS should provide the data and methodology used to establish the budget neutrality factor.

While the new labor share, elimination of the ceiling, and annual updating of the wage index are essential to improving the ESRD prospective payment system, CMS should carefully consider the impact of these revisions on some dialysis facilities. KCP urges the Agency to implement a transition that recognizes the limited flexibility some facilities have in adjusting to the decreases in reimbursement they will face in light of the new wage adjusted payments. With negative Medicare margins and no annual update mechanism to account for inflation, these facilities simply do not have the ability to adapt to significant reimbursement changes. It is critically important that CMS implement the necessary revisions to the wage index in a manner that does not undermine the stability of the ESRD community.

IV. ESRD-Exceptions Process: CMS should clarify that the Agency will continue to recognize the exception status of non-pediatric facilities being paid through this process until these facilities relinquish their status in writing.

Based upon conversations individual KCP members have had with CMS officials, it appears that the Agency recognizes the Proposed Rule creates unnecessary confusion about the continued validity of exceptions elections by non-pediatric dialysis facilities. In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Congress eliminated the ability

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[10]MedPAC, "Report to the Congress: Issues in a Modernized Medicare Program" 91 (June 2005).

[11]*Id* at 96.

of dialysis facilities to seek exceptions payments, but permitted facilities that were already paid through the exceptions process to maintain their exceptions status until they notified CMS that they no longer wanted to receive the exceptions payments. BIPA § 422. In the MMA, Congress modified this phase-out of the exceptions process by reinstating exception rates for pediatric facilities. MMA § 623(b).

Most of the language of the preamble to the Proposed Rule suggests that CMS recognizes that facilities already receiving exceptions payments (such as exceptions for self-dialysis training costs) may continue to do so. 70 Fed. Reg. at 45841. However, some preamble language also appears to contradict this policy. *Id.* In addition, the proposed regulatory text eliminates the current provisions that implement the congressional mandate to allow facilities to maintain existing exception status. *Id.* at 45873-74. Given that CMS agrees that facilities that already have exceptions status may choose to maintain this status until they provide written notice to eliminate the status, KCP urges CMS to reinstate the language currently located at 42 C.F.R. § 413.180(e) and to clarify this aspect of the exceptions process in the preamble to the Final Rule.

V. Telehealth: CMS should include dialysis facilities as originating sites for purposes of telehealth services and implement the proposal to include medical nutritional therapy as a telehealth service.

KCP applauds CMS for recognizing that dialysis patients can benefit from telehealth services. To maximize these benefits, CMS should include ESRD facilities – as a whole, rather than only satellite offices – within the definition of originating sites for telehealth services. Telehealth services can play an important and vital role in providing care to patients with kidney disease.

KCP also supports expanding the definition of telehealth services to include medical nutritional therapy (MNT) provided by licensed dietitians or nutritional therapists. The limited access to nutritional therapists is problematic for patients with Stages 3 and 4 kidney disease who live in rural and remote areas.

Dietary counseling is an important tool to assist patients in improving their nutritional status and to control the levels of several critical electrolytes in their bodies, such as potassium (which can lead to fatal arrhythmias) and phosphorous (which has a long term effect on bones and cardiovascular disease). The availability of nutritional therapy via telehealth will permit greater flexibility in providing these services by allowing more frequent contact between dietitians and patients, even if they cannot be in the same physical location. Patients in rural and remote areas will especially benefit from this modification.

VI. Conclusion

KCP members sincerely appreciate your review of our concerns and look forward to working with the Agency on implementing the Rule. Please do not hesitate to contact Kathy Means at 202-457-6328 if you have questions regarding these comments.

Sincerely,

Kent J. Thiry
Chairman of the Board
Kidney Care Partners

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
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Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System

September, 2005

THE MORAN COMPANY

Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System

On Monday, August 8, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule setting forth policy and methodology changes for 2006 in the prospective payment system for End Stage Renal Disease (ESRD) services under Medicare. On August 26, CMS posted a correction notice on its Web site revising some of the data used to calculate the 2006 payment amounts, and providing corrected update adjustment factors. The Moran Company was commissioned by Kidney Care Partners (KCP) to conduct an analysis of the data and methodology used by CMS to determine its proposed payment policy, in order to identify methodology and data issues that might warrant comments on the proposed rule. This report presents our findings regarding issues of potential technical concern that KCP may wish to address in communications with the agency going forward. Our analysis is directed toward the CMS data and methodology *as amended* by the correction notice.

Policy Summary

In the Medicare Modernization Act (MMA), Congress mandated a number of important policy changes to reimbursement for treatment of dialysis patients. Prior to 2005, Medicare made two types of payments to ESRD providers:

- They were paid a flat dollar "composite rate" payment per dialysis treatment.
- They were separately reimbursed for drugs under the then-prevailing payment methodology under §1842(o) of the Social Security Act[1], which provided for reimbursement of drugs at Average Wholesale Price (AWP) minus 5% (although erythropoietin (EPO) for ESRD use was reimbursed at a separate statutory rate of $10.00 per 1,000 units.)

In the MMA:

- The Congress provided a uniform 1.6% update to the base composite rate for both hospitals and free-standing facilities.
- The Congress directed that, in lieu of prior payment methodologies, ESRD providers would be reimbursed for the actual acquisition cost of drugs.
- The statute provided a prospective adjustment to the basic composite rate, commonly called the "drug spread add-on", to reflect compensation to ESRD providers for the loss of the "spread" between prior payments and acquisition cost.

[1] Statutory references in this paper, unless otherwise noted, are to the Social Security Act, as amended by MMA.

- The statute authorized the Secretary to make case mix adjustments for ESRD patients, and to adjust the wage indexing methodology applied to ESRD payments.

CMS implemented these payment changes for 2005 by rulemaking in calendar year 2004. In that process, CMS made a number of significant policy choices:

- It elected to use pricing information collected by the Health and Human Services Office of Inspector General (OIG) to set "average acquisition cost" payments for ESRD drugs.
- It elected to implement the drug spread add-on as a percentage adjustment (8.7% in the Final Rule) applied uniformly to both the hospital and free-standing facility rates.
- It implemented a limited system of case mix adjustment.
- It deferred implementation of wage index adjustments.

For 2006, CMS is proposing to revisit some, but not all, of these policy choices. Highlights of the proposed rule include the following:

- For 2006 and later years, CMS proposes to move ESRD drug reimbursement from the current schedule based on acquisition costs to payment under §1847A, which provides for reimbursement of all ESRD drugs at average sales price (ASP) plus 6%. Beginning 1/1/06, these payment rates will be updated quarterly.

- CMS will update the drug spread add-on required by the statute in 2006 to reflect this change, and to incorporate later data.

- CMS will implement a transition to a new wage index policy based on the recently-revised structure for wage area classification implemented for other payment systems.

- CMS is proposing no changes in the case mix adjustment system implemented in the 2005 Final Rule.

Based on our review of these policy changes, and the data and methodological issues that underlie them, we believe that the primary issues of concern to the KCP members are likely to flow from the way in which CMS elected to update the drug spread add-on adjustment, which it is proposing to increase from the 8.7% adjustment provided in the 2005 rates to an 11.3% adjustment for 2006.[2]

The Drug Spread Add-On Methodology

While CMS draws on data from a variety of sources to determine the amount it proposes for the drug spread add-on adjustment, the critical variables are presented in Figure One.

[2] This amount was corrected, in the Web site notice, from the published value of 8.9%.

Figure One

$$\% \text{ ADD-ON} = \frac{\text{WTD \% CHANGE * PRIOR LAW DRUG \$\$\$}}{\text{TREATMENTS * WTD COMPOSITE RATE}}$$

As indicated in that figure, there are four key variables that drive calculation of the adjustment:

- The percentage change in payment rates for ESRD drugs between prior policy and the proposed payment methodology, weighted by volume across the drugs actually used by ESRD providers.
- CMS's estimate of the volume of drug spending that would have occurred under prior law.

These two values are multiplied together to obtain an estimate of the aggregate dollar value of the difference between prior payment policy and the proposed policy. This value is then related to the composite rate via two additional variables.

- The estimated number of dialysis treatments to be performed in the adjustment year; and
- The weighted average value of the composite rate (which we estimate, using CMS data, to be $128.81 in 2005 and later years).

First, the estimated dollar difference between prior and proposed drug payment policy is divided by the estimated treatments to convert it into a per treatment value. This value is than divided by the $128.81/treatment weighted composite rate to determine the add-on percentage.

As indicated in Figure One, this methodology creates a linear relationship between the estimate of the add-on percentage, and changes in any of these four variables. Holding the other three variables constant, a ten percent increase in the value of a variable in the numerator will increase the add-on percentage by ten percent, e.g., from 11.3% to 12.4%. Conversely, a ten percent increase in the estimated number of treatments would reduce the value of the add-on percentage by a factor of 1/1.1, or by 9.09% percent.

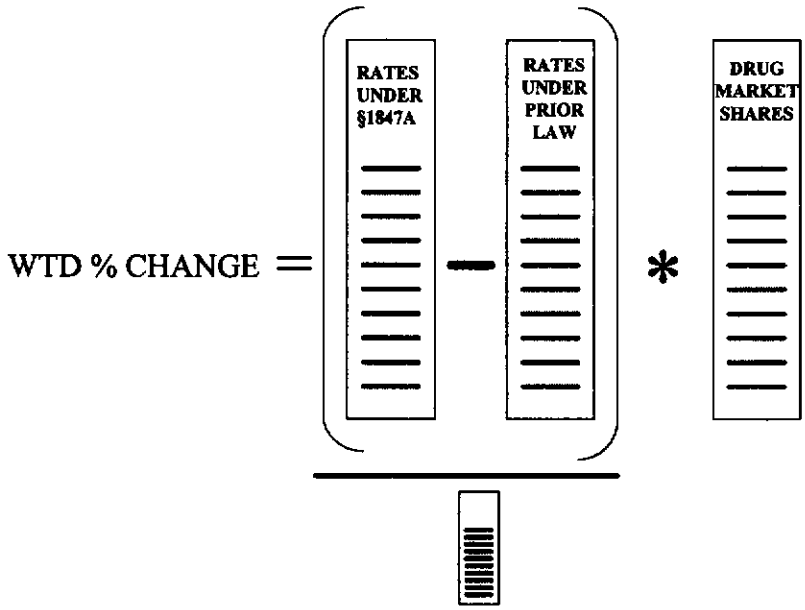
Based on our analysis, we do not believe that the variables in the denominator of this calculation have a meaningful effect on the accuracy of the CMS add-on estimate. With respect to the composite rate, this is true tautologically, since the composite rate values are fixed in statute and hence invariant. While CMS slightly reduced the estimate of treatments from the 35.8 million estimate in the 2005 Final Rule to the 35.4 million value used in the proposed rule, this change of slightly more than 1% in the numerator would cause only a comparably small change in the add-on percentage.

Variations in the data CMS uses in the numerator of this calculation, however, could have a more material effect, since our analysis suggests the potential for greater uncertainty over the appropriate values to use for each of these variables. In the sections that follow, we discuss each of these values in turn.

The Weighted Percentage Change Calculation

The methodology CMS has employed in all three rulemakings related to the ESRD prospective payment system is summarized in the graphic in Figure Two.

Figure Two



Under this methodology, CMS determines three sets of values for each of the top ten (volume) ESRD drugs:

- The dollar per unit value of the post-MMA drug payment policy (in this case, ASP + 6%) for each drug.
- The dollar per unit value of the pre-MMA drug payment policy ($10/1,000 for EPO, AWP-5% for the others); and
- The respective market share of the drug among the top ten, weighted by payment volume.

Using these variables, CMS calculates a percentage change from pre- to post-policy prices for each of the ten drugs, and then produces a composite percentage change weighted by payment market share. Table One shows the data CMS is using in this proposed rule as amended by the correction notice, to make this calculation.

Table One

Calculation of Weighted Percentage Change Due to Payment Policy Change

Drugs	Table 20 ASP+6 2Q 05	Table 21 AWP 2Q 05	Table 22 % of Top Ten	Table 23 % Change	Weighted Impact
EPO	$ 9.25	$ 10.00	69.33%	7.50%	-5.20%
Calcitriol	$ 0.86	$ 1.40	0.84%	38.70%	-0.33%
Doxecalciferol	$ 2.78	$ 3.11	1.48%	10.60%	-0.16%
Iron dextran	$ 11.22	$ 18.04	0.23%	37.80%	-0.09%
Iron sucrose	$ 0.37	$ 0.66	7.03%	45.10%	-3.17%
Levocarnitine	$ 11.12	$ 36.75	0.77%	69.70%	-0.54%
Paracalcitol	$ 3.97	$ 5.37	14.61%	26.00%	-3.80%
Sodium ferric glut	$ 4.73	$ 8.23	4.96%	42.60%	-2.11%
Alteplase, recomb	$ 30.09	$ 38.82	0.56%	22.50%	-0.13%
Vancomycin	$ 3.19	$ 5.55	0.19%	42.60%	-0.08%
					-15.59%

The data values for the pre- and post-policy prices are based on administrative data. The ASP-based payment values are derived from manufacturer ASP reports for the second calendar quarter of 2005; the values published track to the values presently reported for this period on the CMS Web site. The prior law payment values are derived from published AWP prices for the first quarter of 2005; these have been updated to the second quarter using an increase percentage that annualizes to 3.0%.

As the data suggest, the percentage change calculated using this methodology is highly sensitive to the market share assumptions, particularly that for EPO. In contrast to all other drugs, the pre- to post-policy payment change for EPO is only 7.5%, in comparison to the 10-70% changes for the other products. Since EPO is the dominant product, relatively small changes in the market share attributed to EPO can produce large changes in the reported composite percentage change – which as noted above produces a proportional increase (or decrease) in the add-on percentage.

- CMS indicates in the proposed rule that the market share values it is using are derived from 2004 claims data. Since these data were not available in time for this analysis, it is impossible, at this point, to verify this calculation.
- These data, however, were completely revised by the correction notice.
- In the proposed rule, CMS indicated that it would use full year market share data from 2004 – a period prior to the change in payment methodology – to weight this calculation. We believe that this is the correct methodology choice.
- Absent evidence that the revised data reflect errors, we believe that this calculation, as corrected, has been properly done.

Estimating Pre-Policy ESRD Drug Spending

As suggested above, the other major determinant of the accuracy of the drug spread add-on adjustment percentage is the accuracy of CMS's estimates of pre-policy drug spending. A formal statement of CMS's approach to estimate these values would be the following:

Figure Three

$$\text{PRIOR LAW DRUG } \$\$\$_{YEAR} = \text{ACTUAL } \$\$\$_{2003} * (1 + \text{TREND})^{(YEAR-2003)}$$

In its methodology description, CMS indicates that it bases its projections on actual claims data for drugs billed by ESRD providers in 2003. After conversations with CMS analysts involved in generating these estimates, we have checked their 2003 EPO spending estimates against publicly-available data from the 2003 5% Outpatient Standard Analytical File (SAF), and believe that the base values they are using are consistent with the data we see in the SAF.

To index these values forward to 2005 (and subsequently to 2006), CMS indicates that it performed an analysis involving 2005 claims data, in which they derived a year over year growth trend of 9% for EPO, and then applied that trend to update both EPO and non-EPO drug spending to 2005 (and then to 2006).

Since the 2005 claims data CMS employed in this analysis are not available to the public, we cannot verify the accuracy of this estimate, or test the applicability of this EPO-based trend to other products.

This value, however, is materially lower than the drug trend observed in the last few years for which ESRD drug claims data are publicly available. As CMS indicates in its discussion of this issue in the preamble to the proposed rule, there is no clear and consistent pattern of year-to-year changes in drug spending. In the aggregate, however, the trend is clearly upward: the 2003 drug spending totals for all ESRD drugs reflect an 11.2% compound annual increase over the level of ESRD drug spending in 2001.

Since, as noted above, the drug spread add-on percentage varies in direct proportion to changes in estimated prior law drug spending, even relatively small differences in assumed growth rates, when compounded over a 2-3 period, can produce meaningful differences in the drug spread add-on percentage. This reality is demonstrated in Table Two.

Table Two

Effect of Alternative Drug Spending Growth Assumptions

	9% Growth Rate	11.2% Growth Rate
2003 Base	100.00	100.00
2006 Estimate	129.50	137.50
% Difference		6.18%

As shown in this table, a 2.2% difference in the annual trend assumption employed in the CMS methodology would, compounded over the three year period between 2003 and 2006, result in a 6.18% difference in the value of prior law ESRD drug spending 2006, which, holding everything else constant, could increase the calculated drug spread add-on percentage from 11.3% to 12.0%%.

The exact effect of disparities in trend assumptions, over time, will depend on whether and how CMS makes future adjustments to reflect variance between forecast trends and actual changes in ESRD drug spending. The presentation in the proposed rule suggests that CMS intends to anchor its future calculations in historical drug spending data for CY 2004, and then to continually rebase the calculation to historical actuals before estimating a new prospective adjustment.

If this methodology is followed, the impact will depend on whether the variance between projected trends and actuals is random over time. If CMS overestimates trend in some years while under-estimating trend in other years, the cumulative effect of prospective adjustments would be neutral relative to the statutory intent to make budget-neutral adjustments to the drug spread add-on adjustment going forward.

If, however, there is a bias (even if inadvertent) in the relationship between forecast trends and subsequent actuals, errors relative to pure budget neutrality could accumulate over time. Table Three shows the potential magnitude of such effects.

Table Three

Effects of Lags in Adjustments to Drug Spread Add-On Calculations

	Base Year 2005	Year 1	Year 2	Year 3
Hypothetical CMS Projected Trend		9%	9%	9%
Hypothetical "Actual" Trend		12%	12%	12%
Drug Spend Add-On Units	100.00			
Contemporaneous Estimates w. Retro Adjustment		109.00	122.08	136.73
Actual Drug Spend		112.00	125.44	140.49
Disparity		(3.00)	(3.36)	(3.76)

In this table, we have applied the stated CMS estimating methodology in a scenario in which drug trend was consistently estimated at 9%, but actual trend was retrospectively determined to be 12%. In each year, we have retrospectively adjusted the prior year's drug trend to the actual before applying the 9% forecast trend off that adjusted base. As the data presented in the table indicate, a consistent downward bias in the prospective estimate would mean that, even after reconciliation to known actuals, the drug spread add-on percentage calculation would accumulate errors.[3] Since payments to providers would not be retrospectively adjusted to offset the prior underestimate, there would be a widening disparity between actual payments and true budget neutrality.

The Adjustment for EPO Syringes

In its projections of pre-policy drug spending, CMS correctly adjusts the values used to reflect the fact that, beginning in 2005, Medicare makes separate payment at $0.50 per unit for syringes used to administer EPO for ESRD use. In the proposed rule, CMS indicates that the amounts of the adjustments made were $1.6 million for hospital-based facilities and $26.8 million for free-standing facilities. While claims data for 2005 are not yet available to directly check these values, there is reason to believe that these amounts may be overstated, resulting in a corresponding understatement of pre-policy drug spending in 2005 and 2006. The reason for this conclusion is that, even were it assumed that Medicare would pay for an EPO syringe in 100% of the estimated 34.5 million dialysis treatments, total spending on syringes would be only $17.25 million across both settings of care. It is our understanding that intermediaries will reimburse only one syringe per dialysis treatment. We believe, therefore, that CMS should recheck the source of the data being used to make these adjustments.

Measuring the Effects of Uniform Adjustments on Free-standing Providers

Whatever judgment KCP members may reach about the accuracy of the drug spread add-on adjustment percentage, CMS's decision to continue to make uniform adjustments to

[3] If the prospective trend estimate reflected a consistent over-estimate, of course, the bias would work in the opposite direction.

both the hospital and free-standing rates means that a proportionate share of the adjustment will be paid to hospital-based providers in 2006, even though they will continue to be paid on a cost basis for drugs other than EPO. KCP members requested that we update our prior estimates of the magnitude of this effect to be consistent with the CMS proposed add-on percentage of 11.3%. Our findings from this analysis are presented in Table Four.

Table Four

Impact of Uniform Adjustment Policy on Free-Standing Providers

Estimates of Dollar Value of Reimbursement Policy Change

	2005 Base	2006 Increment	2006 Implied	Treatments	Base Rate	Adjustment Value	Variance
	(millions of dollars)					(millions of dollars)	
Hospital EPO	$18	$2	$20	4,946,302	$132.41	$74	+$54
Freestanding Total	$445	$50	$495	30,453,698	$128.35	$442	-$54
	$463	$52	$516	35,400,000		$516	

As these data indicate, the corrected CMS add-on percentage is consistent with an estimate that the MMA reimbursement policy change will lower EPO reimbursements to hospitals by approximately $20 million in 2006, while drug reimbursements to free-standing providers would be lower by $495 million. By applying a uniform percentage adjustment to both the hospital and free-standing rates, however, the CMS methodology weights the value of the adjustment toward hospital providers. We estimate that an 11.3% adjustment would increase hospital reimbursements by approximately $54 million in 2006. This $54 million gain relative to CMS's estimates of the reimbursement policy shortfall would be offset, however, by lowering reimbursements to freestanding providers by the same amount, or $1.53 per treatment ($54 million divided by 35.4 million projected treatments). If a uniform add-on policy is implemented in the Final Rule for 2006, the cumulative effect of this reallocation of the drug spread add-on would reduce payments to free-standing providers in 2005-2006 by $82 million.

In evaluating the appropriateness of the uniform adjustment policy, KCP members asked us to evaluate how cost-based reimbursement for non-EPO drugs in the hospital setting affects the economics of dialysis treatment by hospital-based providers. To evaluate this question, we tabulated payments to hospital-based ESRD providers for non-EPO drugs as reported in the 2003 5% Sample Outpatient Standard Analytical File. Our findings are as follows:

Table Five

Non-EPO Drug Reimbursements by Provider Type

Drug	Average Payment Per Unit, 2003		
	Free-Standing	Hospital-Based	Hospital/Free-Standing
Alteplase	$ 27.39	$ 52.03	190%
Calcitriol	$ 1.20	$ 4.62	384%
Doxercalciferol	$ 4.14	$ 9.50	229%
Iron Dextran	$ 13.98	$ 30.46	218%
Iron Sucrose	$ 0.58	$ 1.19	206%
Levocarnitine	$ 26.66	$ 28.72	108%
Paricalcitol	$ 4.34	$ 11.70	270%
Sodium ferric glut	$ 7.08	$ 18.26	258%
Vancomycin HCL	$ 5.45	$ 13.28	243%

These data are preliminary, and should be interpreted with considerable caution. This table reports the payment values, recorded at the level of individual claims, for dialysis provider bill types presented by both hospitals and free-standing providers. It is our understanding that, in paying ESRD claims from hospital-based providers, fiscal intermediaries annually establish prospective payment rates for ESRD drugs other than EPO based on hospital billed charge amounts for each drug, and the cost-to-charge ratio information presented on cost reports. This practice is consistent with the statutory payment policy of cost-based reimbursement for these drugs. We have confirmed that, in the underlying data, the drug-specific payment amounts do vary by hospital. Absent far more detailed analysis of these data, however, we cannot tell whether the significant observed disparities in reimbursement for these drugs between hospital-based and free-standing providers reflect actual reimbursement differences, rather than being artifacts of anomalies in unit coding of these drugs by hospital-based providers.[4]

Summary Conclusions

As the discussion in the preceding sections makes clear, our analysis suggests that CMS's calculation of an 11.3% drug spread add-on, while materially corrected from the calculations presented in the proposed rule, may still be subject to some degree of uncertainty. Although CMS's estimate of dialysis treatments in either 2005 or 2006 could be a potential source of error, we do not believe such an error, if any, is likely to be material. By contrast, potential errors in either the policy change percentage, or the

[4] In prior work, we have noted that unit coding errors in hospital outpatient departments for separately-reimbursed prescription drugs can be frequent. In the hospital OPPS, errors in coding translate directly into errors in payment, since the payment methodology works on a per-unit basis. In the instant case, however, if intermediaries are paying for drugs based on charge information rather than the unit count, payments for the drugs could accurately reflect the Medicare concept of reasonable cost even if the cost per observed unit appear inflated relative to the AWP-based payment policy applicable to freestanding centers in 2003.

estimate of prior law drug spending in 2005 and 2006, could be material. Though CMS has made a substantial effort to correct its calculation of the weighted change in payment rates between prior policy and current law, subsequent experience may show that CMS's estimate of a 9% drug growth trend may be understated. As noted above, consistent underestimates, if accumulated over time, could lower payments to ESRD providers relative to budget neutrality.[5]

[5] In evaluating the accuracy of compensation for policy changes in drug reimbursement, it is also important to understand that, under the ESRD prospective payment methodology CMS has implemented, the portion of the payment intended to compensate providers for changes in drug reimbursement is subject to wage indexation. While this payment policy is clearly implied by the language of §623 of MMA, it has the effect redistributing the add-on value relative to the drug costs experienced by providers, which are generally based on uniform national market prices.

903

RECEIVED - CMS
2005 SEP 30 P 4: 48

Charles N. Kahn III
President

September 30, 2005

Dr. Mark McClellan
Centers for Medicare and Medicaid
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1502-P; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

Dear Dr. McClellan:

The Federation of American Hospitals ("FAH") is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural parts of the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") revisions to payment policies under the physician fee schedule for calendar year 2006.

Wound Care Coding

The FAH strongly recommends that CMS review the assignment of status indicator B to CPT codes 97602, 97605, and 97606 (active wound care management with non-selective debridement or negative pressure wound therapy per session) for payment under the Medicare Physician Fee Schedule (MPFS). The services described by CPT codes 97602, 97605, and 97606 are frequently performed in outpatient hospital departments (i.e., wound care centers) by licensed wound care nurses incident to physician services.

CMS noted in the Medicare Outpatient Prospective Payment System (OPPS) proposed rule for 2006 that it referred the status of 97602 to the MPFS for evaluation, and that CPT

801 Pennsylvania Ave., NW, Suite 245 • Washington, DC 20004-2604 • 202-624-1500 • Fax: 202-737-6832

code 97602 is packaged into the selective wound care debridement codes 97597 and 97598 (active wound care management with selective debridement per session). The FAH disagrees with this statement because the coding guidelines indicate that CPT 97602 would not be separately reported with CPT code 97597 or 97598.

Typically, when the services performed meet the definition of CPT codes 97602, 97605, or 97606, no other service is reported. These non-selective debridement and negative pressure wound therapy CPT codes describe a complete service including wound assessment, cleansing, treatment, topical applications, dressing of the wound and instructions for ongoing care. These comprehensive codes are per session, not per wound, and according to the AMA, each of these procedures typically involve up to 30 minutes of direct one-on-one contact with the patient.

In addition, according to the AMA, non-physician practitioners performing active wound care management services are to report the appropriate CPT code from the range 97597 – 97606. Because the 97602, 97605 and 97606 active wound care management CPT codes have been classified under the MPFS as "always therapy" services, they are not covered by the Medicare program when performed by licensed wound care or enterostomal nurses incident to physician services.

CMS has not classified CPT codes 97597 or 97598 as "always therapy" services. This means selective debridement services performed by licensed wound care or enterostomal nurses are covered by the Medicare program. However, the active wound care management services that include non-selective debridement or negative pressure wound therapy (i.e., a less intensive service) are not covered when performed by anyone other than a physical therapist. CMS has indicated that this applies even when the services are performed incident to a physician's service and has also indicated that it is inappropriate to report non-covered services under another CPT code, such as an E/M code (11/15/04 Federal Register, Physician Fee Schedule).

When CPT code 97602 was assigned status indicator N under the OPPS, CMS allowed the reporting of a low level E/M CPT code when the non-selective debridement was the only service provided, but this is no longer allowable under the physician fee schedule rules. Provider-based wound care clinics cannot reasonably be expected to continue to treat patients with non-healing wounds if they receive no payment for the services rendered.

FAH recommends that CMS modify its current handling of the active wound care management CPT codes and allow separate payment under the MPFS. The FAH believes the active wound care management CPT codes 97602-97606 are misclassified as "always therapy" services, especially when the Medicare Benefit Policy Manual and most Local Coverage Determinations indicate that a physical therapist may provide wound care services only "*If wound care falls within the auspice of a physical therapist's State Practice Act*". This strongly suggests that CMS questions whether a physical therapist is

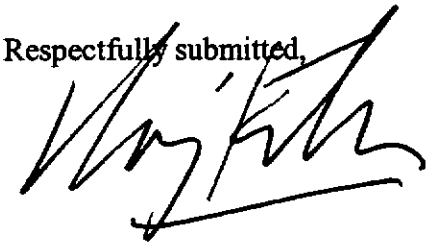
allowed to perform these services in all states. By classifying these wound care services (97602, 97605, and 97606) as always therapy services, CMS limits their coverage to services provided by individuals who may be ineligible to provide such services according to their State Practice Act.

The FAH urges CMS to modify the classification of these services to "sometimes therapy" services and assign an appropriate payment under MPFS to ensure beneficiary access to these important services.

* * *

FAH appreciates CMS's review and careful consideration of the comments in this letter, and would be happy to meet, at your convenience, to discuss them. If you have any questions, please feel free to contact Steve Speil, Senior Vice President, Health Finance, Policy and Legal Affairs, and Chief Financial Officer at 202-624-1529.

Respectfully submitted,



904

Children's Hospital of The King's Daughters

Children's Health Network

September 28, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Hubert Humphrey Building, Room 314-G
200 Independence Ave., SW
Washington, D.C. 20201

Leslie V. Norwalk, Esq.
Deputy Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

2005 SEP 29 PM 12: 59

Re: CMS-1502-P

Dear Dr. McClellan and Mr. Norwalk:

The Children's Health Network, representing 299 pediatric physicians across a variety of disciplines, is concerned about the recently published reimbursement revisions for Medicare (CMS-1502-P) slated to go into effect January, 2006.

Being pediatric-focused, we do not see a significant volume of Medicare eligible beneficiaries (ESRD and disabled). However, the impact of Medicare changes in reimbursement is echoed by many of our commercial payers, in addition to the significant Tricare volume experienced in the Hampton Roads community. Other payers often emulate CMS payment mechanisms, and follow the reimbursement values associated with the various physician specialties published by CMS.

We disagree with the anticipated 4.3% overall reduction in Medicare reimbursement. In fact, based upon the following factors, we contend that Pediatric services should be increased by a minimum of 5.0%:

1. Malpractice insurance premiums have continued to escalate.
2. Overhead and personnel expenses incurred by physician practices have increased, as we are experiencing the same inflationary pressures and shortages for professional nursing personnel as the remainder of the healthcare industry.
3. The government has required practices to fall into compliance with numerous regulatory policies through HIPAA which have resulted in additional cost.

601 Children's Lane ♦ Norfolk ♦ Virginia 23507 (Tel: 757-668-7065)

In conclusion, we respectfully submit that the anticipated 4.3% reduction in payment for primary care services should be reversed, and reflect a 5% increase to acknowledge the increases we are incurring based upon the above factors.

Thank you for your attention on this critical matter.

Sincerely,

Dennis Ryan
Senior Vice President/CFO

DR/GJ/gd:Medicare/Medicaid

905

Fresenius HemoCare

A Division of Fresenius Medical Care NA

September 29, 2005

Mark McClellan, M.D.
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

RECEIVED - CMS
2005 SEP 30 P 2: 20

Re: **CMS-1502-P: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006**

Fresenius HemoCare ("Fresenius"), a division of Fresenius Medical Care North America, is pleased to submit these comments to Proposed Rule CMS-1502-P, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 (Federal Register, Vol.70 No 151, August 8, 2005). Specifically, our comments relate to the practice expense supply item list for apheresis procedures and related disposable items required to perform therapeutic procedures with the PROSORBA® column.

Fresenius manufactures and distributes the PROSORBA® column, which is a single-use immunoadsorption therapeutic medical device approved by the Food and Drug Administration ("FDA") for the treatment of rheumatoid arthritis ("RA") and idiopathic thrombocytopenic purpura ("ITP"). PROSORBA® is the only protein A column currently approved and available in the United States for these indications. RA is a chronic and often debilitating autoimmune disease, often leading to painful inflammation and deformity of the joints. The disease is believed to affect more than 2.5 million Americans, 70% of them women, most of whom are between the ages of 25 and 60. It has been estimated that 10% of the RA patients in the United States may benefit from PROSOBRA® column treatment.

Medicare covers the use of protein A columns for the treatment of ITP as well as for the treatment of RA under certain conditions.[2] Payment for claims with dates of service on or after August 1, 2000, is made under the Hospital Outpatient Prospective Payment System (HOPPS). Starting in January 2005, payment for these procedures has also been made when they are performed in a physician's office. The ICD-9 codes that support the medical necessity of protein A columns include 287.3 (primary thrombocytopenia) and 714.0 (rheumatoid arthritis).

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[2] National Coverage Decision for Apheresis (Therapeutic Pheresis), Pub. 100-3 §110.14.

Fresenius HemoCare

A Division of Fresenius Medical Care NA

It is our understanding that protein A column treatment is the only approved procedure under CPT code 36515 "extracorporeal immunoadsorption treatment and plasma reinfusion." The specific issues as they relate to reimbursement for PROSORBA® column treatments are as follows:

Decrease in non-facility RVU for 36515 - The Physician Expense RVU for CPT code 36515 has decreased by approximately 6.4% based on the 2005 conversion factor despite the fact that the practice expense inputs remain the same for 2006 as in 2005. The proposed reduction is excessive and appears not to be based on the true costs associated with the specific procedures covered under CPT code 36515 and, therefore, cannot provide any reasonable basis for setting the 2006 Physician Expense RVUs. We have a concern that improper rate setting may have a negative impact on Medicare beneficiaries' access to these procedures.

Practice Expense Supply Items - The Proposed Rule supply cost inputs includes a disposable kit ("Therapeutic Plasma Exchange Set", supply code SA072) for apheresis treatment under CPT code 36515. However, the machine this kit is used with (AS104 Cell Separator) has become obsolete and is rarely used for the PROSORBA® column treatments. The vast majority of PROSORBA® treatments are performed using the Cobe Spectra, a cell separating system that requires use of a similar "Therapeutic Plasma Exchange Set" to perform the PROSORBA® column treatment. This set is also included in the Proposed Rule supply cost inputs file: supply code SC085, under CPT code 36514. In order to capture the true representative costs associated with performing protein A column therapy under 36515, supply code SA085 should replace SA072 under CPT code 36515.

Price of PROSORBA® Column - The price for PROSORBA® column has increased from $1,150/unit to $1,250/unit (order for a case of 1-5 PROSORBA® columns). This increase is not reflected in the Proposed Rule supply cost inputs. Fresenius would welcome the opportunity to work with CMS to update the pricing for supply items used for apheresis treatments under CPT code 36515 or to provide any additional information that might be helpful.

We thank you for considering these comments. If you have any questions, please contact me at 202-296-8632.

Sincerely,

Kathleen T. Smith/nmy

Kathleen T. Smith, RN, BS, CNN
Vice President, Government Affairs

906

Centers for Dialysis Care

18720 Chagrin Blvd.
Shaker Heights, Ohio 44122

RECEIVED - CMS
2005 SEP 30 P 1: 21

September 29, 2005

Dr. Mark McClellan
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

Re: **CMS-1502-P:** Comments of the Centers for Dialysis Care on the Physician Fee Schedule Proposed Rule

Dear Administrator McClellan:

I am writing on behalf of the Centers for Dialysis Care, CDC, to present our concerns about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year [CY] 2006 (Proposed Rule). 70 Fed. Reg. 45764. These comments focus on the End Stage Renal Disease Related Provisions.

CDC is an independent provider of dialysis services in northeast Ohio. CDC is a not-for-profit corporation and began providing dialysis services in the inner city of Cleveland in 1975. Today we operate 13 facilities and care for over 1700 patients. System wide 87% of our patients have Medicare or Medicaid as their primary insurance. There is limited ability to cost shift since most of the insurance companies in our area will only contract for rates slightly above the Medicare rates.

There are numerous issues of concern with the proposed rules however we feel that the NRAA and the KCP comments appropriately address them. CDC is a member of the KCP and I am one of the past presidents of the NRAA and currently serve on its board. CDC is primarily concerned about the impact of modifying the wage index. In general we were supportive of modifying the index which hasn't been updated in 20 years however no one expected the horrific negative impact. Using the existing wage index all facilities in Ohio were >1. Under the proposed Rule all of the areas in Ohio with the exception of the Columbus area, which is only slightly above 1, are <1. This probably occurred due to the elimination of the ceiling. For instance the Cleveland area went from a wage index of 1.19 down to .94. With the recognition that the labor component went from 40.65% to 53.711% of the composite rate, those facilities with an increase in their wage index received a much larger increase and those with a lower index had a more negative impact. If the proposed wage index is implemented the composite rate for Cleveland area providers will decrease by $13.95 per treatment!

As you know renal providers do not get an annual update and the dialysis industry is fighting to get legislation approved that will provide such an update. The proposed legislation, while a move in the right direction, was a compromise and limits the increase to only 1% until year 10 when the full market basket increase would be applied. CDC is hoping for any increase to help deal with inflation, rising salaries, health insurance, medical malpractice insurance and

non-routine drug costs, to name a few. Being hit with a 10% cut in reimbursement to the overwhelming percentage of our patients is unconscionable. Even thought the cuts are phased in over 2 years, the impact is unfathomable. All of our facilities will experience huge cuts in reimbursement with the exception of our most rural facility in Jefferson, Ohio. This facility, which opened in 1996, had an urban designation. The business plan to develop this facility was based upon the reimbursement for that area. After operating for 7 years, CDC was informed that the intermediary had been using the wrong geographic designation, which resulted in a loss of $12 per treatment in reimbursement. This was not fair. Had we been given the correct reimbursement as we planned the facility, we probably would have never opened the facility. We have been struggling to keep this facility open and the projected cut will probably put it over the edge.

Since dialysis providers do not receive an annual update it has been an on-going struggle to deal with annual increases in cost with little to no increase in reimbursement. Whenever dialysis facilities were given a modest increase in Medicare reimbursement, most of it has been taken away due to increases in the cost of EPO. The loss of almost $14 per Medicare treatment spread over 2 years along with the 4.9% increase in the cost of EPO is overwhelming to say the least. As of September 1, 2005 Ohio Medicaid lowered their reimbursement to dialysis providers for drugs to match Medicare. However Medicaid is not giving providers any "drug add-on" increase to the composite rate. This also equates to an average loss of $14 per 100% Medicaid treatment.

Since staffing is the most significant cost the only thing we can do is to increase staff to patient ratios for all disciplines to levels which we feel are very marginal from a patient safety perspective. We have already tried to implement some of these changes on a small scale resulting in tremendous staff and patient unrest. Our patients, like everyone else, are getting older and sicker. They need more staff resources and not fewer. If we lower staff salaries and don't offer competitive wages we will lose our experienced staff to the hospitals, which have many openings, and won't be able to recruit the best staff. Patient safety is at high risk if the cuts occur.

Since dialysis providers do not receive an annual update it has been an on-going struggle to deal with annual increases in cost with little to no increase in reimbursement. Whenever dialysis facilities were given a modest increase in Medicare reimbursement, most of it has been taken away due to increases in the cost of EPO. The loss of almost $14 per Medicare treatment spread over 2 years along with the 4.9% increase in the cost of EPO is overwhelming to say the least. As of September 1, 2005 Ohio Medicaid lowered their reimbursement to dialysis providers for drugs to match Medicare. However Medicaid is not giving providers any "drug add-on" increase to the composite rate. This also equates to an average loss of $14 per 100% Medicaid treatment.

During the past 2 years we have had a number of examples when we were referred patients since other providers wouldn't accept them due to unacceptable insurance coverage. One provider chain sent all of their physicians a letter 2 years ago to put them on notice that all patient referrals will be evaluated for the level of their insurance coverage and if it doesn't meet their criteria the patients will not be admitted. As a not-for-profit provider we are very concerned that this practice will only increase if the reimbursement is cut.

We are also concerned about the fact that in the near future there will be two providers with over 70% of the market. The independent providers are very concerned that if the proposed Rule is implemented as written that they will have to close or sell out. In the future it is predictable that the 2 chains will close their facilities operating at a financial loss which will create

huge access to care issues. They have already been doing this, which is understandable. They will be in a good position to demand fair reimbursement or else many patients will die. Does CMS and Congress want to put the independent providers out of business before this happens? If you do then implementation of the wage index as published will speed up the process. Access to care in the inner city and rural areas is at great risk.

The basic problem is that the base composite rate is too low. Using a base rate of $128.35 20 years ago and today is absurd. In addition to the wage index issue this is compounded by the fact that the "drug add-on" is applied to the "wage adjusted" composite rate even though the cost of drugs has absolutely nothing to do with the variability of the wages. Therefore all facilities that receive an increase in their composite rate get a larger increase due to the drug add-on and providers with a loss get an even larger loss. Continuing with the Cleveland example, the drug add-on amounts to an addition loss of $.45 per treatment, which is very significant.

While we are very concerned about the impact on our facilities in northeast Ohio as well as all others in the state, we know that there are numerous other states in the same or similar position. Under the budget neutral methodology, for every facility with an increase in their reimbursement another provider gets a loss. The implementation of the wage index might be the last straw for many providers especially the independent ones in the inner city and rural areas where the ability to cost shift to other third party payors is very limited.

Therefore CDC offers the following recommendations for your serious consideration;

1) delay the implementation of the wage index until an impact analysis can be conducted
2) maintain the wage index floor of .9 – facilities at the lowest levels of reimbursement are in the worst position to be able to deal with on-going cuts in reimbursement just because other areas have larger increases
3) increase the ceiling from 1.3 to 1.4 but don't eliminate it as long as we are in a budget neutral environment
4) for facilities who will experience a decrease in their reimbursement due to the wage index extend the transition period from 2 years to 5 years or at least do this for providers with a loss of 3% or more

The CDC greatly appreciates the opportunity to comment on the proposed Rule and your review of our concerns. We are more than wiling to respond to any questions that you have and look forward to work with CMS on all matters affecting the dialysis community. Please don't hesitate to contact me if you have any questions at (216) 295-7003 ext 252 or dpw@cdcare.org.

Sincerely,

Electronic Signature-Original on File

Diane Wish
President and CEO

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American
Clinical Laboratory
Association

September 29, 2005

VIA HAND DELIVERY

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: Comments on the Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006 – File Code CMS–1502–P

Dear Sir or Madam:

Enclosed please find the comments of the American Clinical Laboratory Association on the Centers for Medicare and Medicaid Services' proposed revisions to payment policies under the physician fee schedule for calendar year 2006. 70 Fed. Reg. 45764 (Aug. 8, 2005).

If you have any questions or comments, please feel free to contact me.

Sincerely yours,

Alan Mertz /ELD

Alan Mertz
President

1250 H Street, N.W. • Suite 880 • Washington, DC 20005 • (202) 637-9466 Fax: (202) 637-2050

ACLA
American
Clinical Laboratory
Association

Comments of the American Clinical Laboratory Association on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

[CMS–1502–P]

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the proposed revisions to payment policies under the physician fee schedule for calendar year 2006 (the "Proposed Rule"). 70 Fed. Reg. 45764 (Aug. 8, 2004). ACLA is an association representing independent clinical laboratories throughout the United States, including local, regional and national laboratories. ACLA members perform a variety of services that are reimbursed under the physician fee schedule. Thus, ACLA members will be significantly affected by the changes in the Proposed Rule. ACLA's comments on the Proposed Rule focus on the revisions to the practice expense for flow cytometry services, the new method for calculating relative value units for independent laboratories, the sustainable growth rate methodology, the development of quality measures for physician services, and the monitoring of the effect of recent changes to the reassignment rules.

Practice Expense for Flow Cytometry Services

CMS is proposing to revise the Practice Expense ("PE") inputs for the flow cytometry CPT codes 88184 and 88185, based on additional data provided by the laboratory community regarding the time and equipment required for this testing. ACLA applauds CMS' decision to make these revisions to the technical component of flow cytometry services in order to more accurately pay for these services. This action will ensure that patients have access to life-saving technology used to diagnose, treat, and monitor serious health conditions.

Practice Expense – New Relative Value Units for Independent Laboratories

In 2002, the Centers for Medicare and Medicaid Services ("CMS") proposed recalculating the technical component ("TC") for pathology services based on a "default" Practice Expense ("PE") value, which was an average across all physician specialties. Ultimately, CMS decided to delay this change until more accurate information could be obtained related to the Practice Expense of independent laboratories that furnished pathology services. That information is now complete and CMS has used the College of American Pathology ("CAP") survey in calculating the new PE Relative Value Units ("RVUs"). ACLA supports the use of the CAP survey data in establishing the PE per hour for independent clinical laboratories. ACLA believes that these data are more accurate and current than previous estimations of the PE value, and appreciates CMS' efforts to obtain this information to ensure that PE values reflect the true costs of providing the services.

Sustainable Growth Rate ("SGR")

According to the Proposed Rule, underlying the projected rate reductions in the physician fee schedule is substantial growth in Medicare spending. The Proposed Rule states that the vast majority of spending growth in 2004 is attributable to five areas, one of which is an increase in

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laboratory and other physician-ordered tests. 70 Fed. Reg. at 45856. CMS should be cautious in assessing the reasons for these increases. For example, the Proposed Rule notes that there was a 17 percent rate of increase in laboratory tests (lipid panels) consistent with more patients receiving statin therapy (since new prescriptions require more frequent visits and more lab tests). ACLA would like to point out that there has been an increase in laboratory testing in recent years as a result of Congressional action to create new statutorily covered screening services under the Medicare program, such as those for PSA, diabetes, colorectal cancer, and cardiovascular health (many of these were mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA")). In addition, payments for Pap tests were finally increased from their historically deficiently low levels. Even with the increases, total spending for laboratory services is only a small percentage of Part B spending.

Furthermore, the inflationary (CPI) update that was established as part of the laboratory fee schedule has been completely eliminated or reduced in 13 of the past 15 years; thus, any increases in spending are not necessarily the result of increased per-test payments. To the extent increases were due to increased utilization, those changes may be due to the availability of new and more sophisticated types of testing. Further, because independent laboratories cannot order tests themselves, but must perform tests only at the request of a physician, laboratories are themselves unlikely to be the primary cause of increased utilization.

Lab testing plays an essential part in the delivery of quality health care. Laboratory tests provide physicians with objective data needed to promptly diagnose and effectively treat and monitor disease. It is estimated that lab testing has an impact on over 70 percent of medical decisions, yet laboratory services account for only three percent of health care spending (and two percent of Medicare expenditures). By equipping physicians with critical information, laboratory tests ultimately save lives and reduce overall health care costs. In the future, as the baby-boom generation reaches retirement and there are more Americans over age 65, clinical laboratory services will play a vital role in screening and prevention efforts, which will result in health benefits for Medicare beneficiaries and a healthier financial outlook for the Medicare program.

ACLA is working with the Medicare Payment Advisory Commission ("MedPAC"), which has also expressed a desire to look at increases in lab utilization and spending. ACLA looks forward to working with CMS as well, in helping to understand the underlying causes of these increases in laboratory testing volume.

The Proposed Rule also discusses CMS' efforts to work with the physician community to ensure that the Medicare payment system encourages physicians to provide quality care and prevent avoidable health costs, and specifically solicits comments on how to build upon recent progress on these issues. *Id.* at 45857. ACLA members share CMS's vision to improve access and quality of care for Medicare beneficiaries by initiating value-based purchasing. Diagnostic tests comprise only five percent of total hospital costs and only 1.6 percent of Medicare costs, but they influence a much larger portion (over 70 percent) of clinical decision-making that improves care and decreases cost. Today's laboratory tests inform treatment decisions, allow physicians to prescribe targeted therapies, and monitor disease progression – all significant value

added services, and independent labs have been in the business of providing these for many years.

Clinical laboratory tests are critical to measuring performance in quality programs. ACLA looks forward to collaborating with CMS in designing such a program; however, it is paramount that CMS recognize that the clinical laboratory fee schedule has not been fully updated for inflation in 13 of the past 15 years and is frozen until 2009. As CMS moves toward a pay for performance approach, the additional administrative cost to collect, submit and analyze performance and access measure data needs to be accounted for in the reimbursement schedule.

Section 952 of the MMA – Reassignment Provisions

In our comments on both the proposed and final rules for the 2005 Physician Fee Schedule, ACLA expressed concern about the new exception to the "Reassignment Rule" for contractual arrangements, which was added by the MMA. *See* 69 Fed. Reg. 66236 (Nov. 15, 2004). As we have discussed previously, ACLA members have been particularly concerned about the new contractual arrangement exception because it has helped to fuel the increase in certain abusive relationships involving "Pod" or "condo" laboratories. In the 2005 Final Rule, CMS reviewed the comments that were received on this issue and specifically noted the concern over the growth of "pod, salon, turnkey, mini-mall, or condo labs." *Id.* at 66315. CMS stated that it would continue to analyze the impact of the physician self referral regulations on Pod laboratory ventures, and would make additional changes in a rulemaking document if it determined that additional changes are necessary. *Id.* at 66316. ACLA remains concerned about these issues because these types of arrangements continue to proliferate. Furthermore, these ventures are expanding beyond the pathology setting into other medical specialties (*e.g.*, radiology, and medical imaging in particular). Thus, ACLA is interested in what actions CMS has taken to address the impact of the physician self-referral regulations on Pod laboratories and similar arrangements, which raise a whole host of issues under federal fraud and abuse laws.

In addition, ACLA is especially concerned about how CMS plans to address certain issues related to the in office ancillary services ("IOAS") exception to the Stark regulations. As ACLA pointed out in our comments on last year's physician fee schedule, it is inconsistent with the provisions of the Stark law for these Pods to utilize the "physician in the group" provision for its independent pathologists, because the clear intention of that provision was simply to permit the physician to *supervise* ancillary services furnished in the group. This change was designed to allow pathologists with minimal contacts with the group practice to *supervise* ancillary services under the IOAS exception where group practice members did not have the appropriate qualifications to do so. A review of the Preamble to the Phase I regulations makes clear that CMS intended this change only to permit the physician to supervise group practice services, *not to furnish separately billable physician services*. *See, e.g.*, 66 Fed. Reg. at 887 ("Many commenters also urged that independent contractor physicians be included as members of a group practice *for purposes of the direct supervision requirement* of the in-office ancillary services exception.") (emphasis added). These supervisory services otherwise permitted by the IOAS exception are not directly reimbursed by the Medicare Program, so there is no financial impact on the Program by allowing such supervision services to be furnished.

However, the exception is now being interpreted more broadly and is being used by group practices to cover services outside the group's sphere of medical practice, which are separately-billable to Medicare and performed by pathologists with minimal contacts with the group. This is a considerable, and unjustified, extension of the use of independent contractor physicians and is beyond the intention of the Stark law. Accordingly, ACLA recommends that CMS refine the Stark regulations to address this issue by specifying that the exception only applies to *medical direction/supervision* services, not to services that are *separately, directly* reimbursed by the Program.

Conclusion

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please do not hesitate to contact us should you have any questions about this information or need any further information.

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2005 SEP 30 P 1: 22

September 29, 2005

Dr. Mark McClellan
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

Re: **CMS-1502-P:** Comments from the Ohio Renal Association on the Physician Fee Schedule Proposed Rule

Dear Dr. McClellan:

I am writing on behalf of the Ohio Renal Association (ORA) to present our members' views about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year [CY] 2006 (Proposed Rule). 70 Fed. Reg. 45764. These comments focus on the End Stage Renal Disease Related Provisions. The ORA represents over 90% of the dialysis providers in Ohio.

There are numerous issues with the proposed rules however we feel that the NRAA and the KCP comments appropriately address them. The ORA is primarily concerned about the impact of modifying the wage index. In general we were supportive of modifying the index which hasn't been updated in 20 years however no one expected the horrific negative impact in Ohio. Using the existing wage index all facilities in Ohio were >1. Under the proposed Rule all of the areas in Ohio with the exception of the Columbus area, which is only slightly above 1, are <1. This probably occurred due to the elimination of the ceiling. For instance the Cleveland area went from a wage index of 1.19 down to .94. With the recognition that the labor component went from 40.65% to 53.711% of the composite rate, those facilities with an increase in their wage index received a much larger increase and those with a lower index had a more negative impact. If the proposed wage index is implemented the composite rate for Cleveland area providers will decrease by $13.95 per treatment!

As you know renal providers do not get an annual update and the dialysis industry is fighting to get legislation approved that will provide such an update. The proposed legislation, while a move in the right direction, was a compromise and limits the increase to only 1% per year until year 10 when the full market basket increase would be applied. Ohio providers are hoping for any increase to help deal with the rising salaries, health insurance,

medical malpractice insurance and non-routine drug costs, to name a few. Being hit with a 10% cut in reimbursement to the overwhelming percentage of our patients is unconscionable. Even thought the cuts are phased in over 2 years, the impact is unfathomable. Almost all providers in Ohio are experiencing huge cuts in reimbursement.

We are not sure how providers are going to be able to continue to survive in Ohio. Many of the providers in Ohio are independent and are extremely worried. Even though there are numerous facilities operated by national chains we do not believe that they will continue to subsidize facilities in the long run that lose money on every Medicare treatment. It is predicable that access to care is going to be a reality. Many Ohio providers especially the independent ones operate facilities with greater than 85% of their patients being funded by Medicare as their primary insurance. Access to care in the inner city and the rural areas are at the most risk. In spite of what the wage index might show, providers in the inner city have to pay higher salaries to attract qualified staff to work in these areas as compared to the suburbs. Likewise the rural providers also pay higher salaries because if they don't the staff will drive into the city to get jobs.

The basic problem is that the base composite rate is too low. Using a base rate of $128.35 20 years ago and today is absurd. In addition to the wage index issue this is compounded by the fact that the "drug add-on" is applied to the "wage adjusted" composite rate even though the cost of drugs has absolutely nothing to do with the variability of the wages. Therefore all facilities that receive an increase in their composite rate get a larger increase due to the drug add-on and providers with a loss get an even larger loss. Continuing with the Cleveland example, the drug add-on amounts to an addition loss of $.45 per treatment, which is very significant.

While we are very concerned about the impact on Ohio providers we know that there are numerous other states in the same or similar position. Under the budget neutral methodology, for every facility with an increase in their reimbursement another provider gets a loss. The implementation of the wage index might be the last straw for many providers especially the independent ones in the inner city and rural areas where the ability to cost shift to other third party payors is very limited.

Therefore the ORA offers the following recommendations for your serious consideration;

1) delay the implementation of the wage index until an impact analysis can be conducted
2) maintain the wage index floor of .9 – facilities at the lowest levels of reimbursement are in the worst position to be able to deal with on-going cuts in reimbursement just because other areas have larger increases
3) increase the ceiling from 1.3 to 1.4 but don't eliminate it as long as we are in a budget neutral environment
4) for facilities who will experience a decrease in their reimbursement due to the wage index extend the transition period from 2 years to 5 years or at least do this for providers with a loss of 3% or more

The ORA greatly appreciates the opportunity to comment on the proposed Rule and your review of our concerns. We are more than wiling to respond to any questions that you have and look forward to work with CMS on all matters affecting the dialysis community.

Please don't hesitate to contact me if you have any questions at (216) 295-7003 ext 252 or dpw@cdcare.org.

Sincerely,
Electronic Signature-Original on File

Diane Wish
Board Chair

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RENAL LEADERSHIP COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

September 30, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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200 Independence Avenue, SW
Washington, DC 20201

RECEIVED - CMS
2005 SEP 30 PM 3

Re: **CMS-1502-P:** Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006

Dear Administrator McClellan:

As indicated in the September 20, 2005, letter, I am writing on behalf of the Renal Leadership Council (RLC) to provide you with our members' additional comments about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year [CY] 2006 (Proposed Rule). 70 Fed. Reg. 45764. As you are aware, the RLC is a coalition representing the four largest entities providing dialysis care and services to Medicare beneficiaries: DaVita, Inc.; Fresenius Medical Care North America; Gambro Healthcare/USA; and Renal Care Group. Collectively, these suppliers operate more than 2,700 dialysis facilities in 42 states that provide dialysis care to approximately 200,000 patients.

In our previous letter, we expressed our gratitude for the Agency's quick response to concerns about the accounting of three J-codes and the weight for EPO including expenditures by hospital-based providers. In addition, we described our remaining concerns with the Agency's calculation of the drug add-on adjustment. Specifically, the letter urges the Agency to fix the drug add-on adjustment by (1) adjusting the trend factor used to calculate the add-on adjustment to reflect the historical trend for ESRD drugs; (2) estimating appropriately the 2006 ASP+6 percent for calculation of the drug add-on adjustment; (3) ensuring that the Agency has correctly estimated the amount of spending on syringes used to administer EPO, which is directly related to the actual number of EPO administrations; and (4) calculating separate drug add-on adjustments for hospital-based providers and independent facilities to reflect the intent of Congress. We have attached a copy of our previous letter for your convenience, along with a copy of The Moran Company (TMC) analysis and a legal opinion we provided to the General Counsel's Office on September 27, 2005.

In addition to the concerns about the calculation of the drug add-on adjustment, our members have these additional comments:

- Even though the RLC agrees that it is appropriate for CMS to adopt an Average Sales Price (ASP) drug reimbursement methodology for CY 2006, the Agency should also recognize and address the unique operational difficulties dialysis facilities face related to the lag time inherent in this methodology.

- CMS should follow MedPAC's recommendations and establish reimbursement parity among hospital-based providers and independent facilities.

- Even though we applaud the effort to revise the geographic wage index, CMS should implement these changes in a manner that does not result in significant reductions in reimbursement to facilities that are already experiencing negative Medicare payment to cost ratios and that have no annual update mechanism to their payment rate.

- CMS should clarify that the revisions to the exceptions process do not eliminate the current home training exception rate status of those facilities that have them, consistent with the congressional mandate.

- CMS should identify renal dialysis facilities as "originating sites" for providing telehealth services.

I. ESRD—PRICING METHODOLOGY/PAYMENT FOR ESRD DRUGS: Even though the RLC agrees that it is appropriate for CMS to adopt an Average Sales Price (ASP) drug reimbursement methodology for CY 2006, the agency should also recognize and address the unique operational difficulties dialysis facilities face related to the lag time inherent in this methodology.

Consistent with the MedPAC recommendation, the RLC supports the Agency's efforts to adopt a drug reimbursement methodology that allows for more frequent updating that reflects actual pricing. However, our members remain concerned that without broader reforms, the growth of Medicare reimbursement for pharmaceuticals will significantly outpace Medicare reimbursement for those services.

Even though we agree that, given a choice between ASP and Average Acquisition Payment (AAP), an ASP methodology is a better solution for CY 2006, the RLC is uncomfortable endorsing an overall reimbursement structure that encourages continuing price

increases in pharmaceuticals at the expense of dialysis facilities that already have negative Medicare payment to cost ratios. Given the current state of Medicare reimbursement to dialysis facilities, we are concerned that a price increase in the single drug that dominates the therapy of dialysis patients (EPO) will decrease the amount that can be spent on other types of patient care and services. Such a model is not sustainable. Therefore, it is critically important that the government establish an appropriate balance between the reimbursements for drugs and patient care services. The inherent limitation of the ASP methodology is that it favors and provides an incentive for manufacturers to raise their prices on a regular basis, while providers experience a lag time in the recognition of these price increases in their reimbursement.

Although we believe these concerns should be addressed quickly, the RLC recognizes that CMS must adopt a less-than-perfect system for CY 2006. In this regard, we support shifting from the AAP to an ASP methodology. We agree with MedPAC's assessment that an ASP methodology is a more sustainable and predictable system and allows for more timely incorporation of manufacturer price increases into the payment methodology. Of course, minimizing the lag time requires that CMS use the most current ASP data when calculating the reimbursement amounts. We also recognize that adopting an ASP methodology meets the Agency's goal to establish a consistent drug reimbursement methodology across treatment settings.

To further minimize the negative impact of the lag time, the RLC encourages CMS to provide retrospective payments that eliminate the loss facilities will experience because of it. Although we appreciate that other Medicare providers reimbursed for drugs also experience the negative consequences of a lag time, the ESRD program's unique situation makes it appropriate for CMS to protect dialysis facilities from incurring these significant losses. First, MedPAC has recognized that facilities continue to experience negative Medicare payment to cost ratios. Thus, unlike other providers that have an annual update mechanism, dialysis facilities do not have such a mechanism that would better enable them to bear the risk. The losses also represent a significant portion of dialysis facility revenues. Given the central role that drugs play in the provision of dialysis therapy to beneficiaries, pharmaceuticals account for approximately 40 percent of revenues, with EPO constituting 70 percent of that amount. In addition unlike other providers, dialysis facilities cannot report and recover bad debt that results from patients not meeting their deductible and copayment obligations for separately billed drugs. For these reasons, it is appropriate for CMS to provide retrospective payments to dialysis facilities so they do not have to bear the burden that results from a significant lag time between the increase in drug prices and an increase in the ASP.

II. ESRD—DRUGS AND BIOLOGICALS: CMS should follow MedPAC's recommendations and establish reimbursement parity among hospital-based providers and independent facilities.

The RLC supports MedPAC's recommendations[1] to reimburse hospital-based providers for separately billable drugs using the same drug methodology that it does for independent dialysis facilities and to eliminate the approximately $4 per treatment difference in composite rates.

There is no longer any reason to pay hospital-based providers using a more favorable drug reimbursement methodology. The agency first codified without explanation the different payment methodologies for separately billed drugs in the Nov. 25, 1991, Physician Services Fee Schedule. 56 Fed. Reg. 59502, 59507; *see also* 42 CFR § 413.170(a); 42 CFR § 413.174(g). Presumably, the distinction grew out of CMS's interpretation that Congress required the Agency to adopt different payment methodologies for hospital-based providers and independent facilities. 42 USC § 1395rr(b)(7). Under this authority and 42 USC § 1395rr(b)(2)(B), CMS decided to reimburse hospital-based providers based on reasonable costs and independent facilities based upon the AWP. 42 CFR § 413.174(g). Because Congress established the reimbursement rate for erythropoietin in statute, CMS has always paid hospital-based providers and independent facilities the same amount for this biological.

The change is warranted because hospital-based providers experience significant profits from separately billable drugs under the cost-based drug reimbursement methodology. In a study commissioned by the Kidney Care Partners, The Moran Company (TMC) evaluated how the cost-based reimbursement for non-EPO drugs provided by hospital-based providers affects the economics of the dialysis treatments they provide. Using data from the 2003 Five-Percent Sample Outpatient Standard Analytical File, TMC found that hospital-based providers' drug margins ranged from 108 percent to 384 percent above those of independent facilities.[2] Given that independent facilities are providing the same drugs for less reimbursement, it is difficult to understand why hospital-based providers should continue to receive such large profit margins for separately billable drugs under the ESRD program.

For purposes of establishing parity, the RLC agrees with the proposal that CMS could estimate the costs of separately billable drugs for hospital-based providers from cost data

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[1]MedPAC, "Report to the Congress: Issues in a Modernized Medicare Program" 91 (June 2005).

[2]The Moran Company, "Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System" 10 (September 2005).

provided by independent facilities. CMS should also follow MedPAC's recommendation to collect acquisition cost and data on drug payment per unit from hospital-based providers.[3]

The RLC also agrees with MedPAC[4] that CMS should eliminate the differences in paying for composite rate services between hospital-based providers and independent facilities. CMS should pay the same rates for the same services, regardless of the treatment setting. In addition, payments should reflect the costs of efficient providers and be adjusted for costs that are beyond the providers' control, rather than allow inefficiencies to continue.

If CMS were to maintain different composite rates and different drug reimbursement methodologies, hospital-based providers would inappropriately continue to receive higher payments and higher drug reimbursement amounts for providing the same services that independent facilities do. Therefore, CMS should adopt MedPAC's recommendation and eliminate these differences.

III. ESRD—COMPOSITE RATE PAYMENT WAGE INDEX: Even though we applaud the effort to revise the geographic wage index, CMS should implement these changes in a manner that does not result in significant reductions in reimbursement to facilities that are already experiencing negative Medicare payment to cost ratios and that have no annual update mechanism to their payment rate.

The RLC applauds CMS for moving forward with revisions to the wage index, increasing the labor share component of the market basket, and indicating that the index will be updated annually. These revisions are long overdue. However, the lack of transparency in terms of the data and methodology make it difficult to assess the accuracy of the revisions, especially the budget neutrality provision. In addition to providing this clarity, CMS should also establish an adequate transition to reduce the hardship the new geographic wage index will create for some facilities.

First, the RLC strongly urges CMS to provide the data and methodology it is using to calculate the wage index generally and the budget neutrality factor specifically. The Proposed Rule does not contain the underlying data or explain the Agency's methodology. In particular, the lack of transparency of the budget neutrality calculation makes it impossible for any facility to

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[3] *Supra*, note 1 at 96.

[4] *Id.* at 89.

evaluate the long-term effect of the proposal. Therefore, the Agency should provide in the Final Rule the data and methodology it is using to establish the new geographic wage index.

In addition, it remains critically important that CMS implement the geographic wage index in a manner that does not lead to financial instability within the industry. The fact that the current Medicare composite rate does not cover the cost of providing care, coupled with the lack of an annual inflationary update mechanism, provides little cushion with which facilities can absorb dramatic changes in their payments. The proposed modifications to the geographic wage index will amplify these problems because they are only redistributing payments of an already under-funded system.

To accomplish the goal of a smooth transition, CMS should maintain its commitment to eliminating the ceiling. Because the Agency has not updated the geographic wage index since the early 1980s, many facilities have suffered under a system that has not recognized the increases in labor cost. Eliminating the ceiling allows these facilities to recognize the revisions immediately.

However, CMS's proposed phase-out of the floor is problematic. Without a floor, the payments to many facilities will decrease dramatically. Although the need to recognize the change in wage rates is important, it is equally important to maintain the financial stability of the ESRD provider community. We recognize that maintaining the floor at 0.9 percent may result in a short-term negative impact on those providers who have been underpaid because of the inappropriate wage index. However, the RLC strongly believes it is better for the ESRD provider community as a whole if CMS implements the modifications more slowly by maintaining the current level of the floor.

Another important component of transitioning the ESRD community to a new geographic wage index is implementing an appropriate transition period. The RLC applauds CMS's general approach to the transition period for facilities that will have a lower composite rate under the new wage adjustment system that will allow them to receive the <u>higher</u> of (1) the new wage-adjusted composite rate or (2) a 50-50 blend of the current rate and the new rate. To help facilities adjust under the new wage index, the RLC suggests extending the proposed transition period to <u>three years</u>. This extension will allow facilities the additional time they need to adjust to the new payment structure.

IV. ESRD—EXCEPTIONS PROCESS: CMS should clarify that the revisions to the exceptions process do not eliminate the current home training exception rate status of those facilities that have them, consistent with the congressional mandate.

The RLC strongly encourages CMS to clarify that facilities permitted to retain their exception rate status may continue to do so consistent with congressional intent. The preamble presents conflicting statements about the continued validity of the status of these facilities. 70 Fed. Reg. at 45841. In addition, the regulatory text no longer contains language that acknowledges that Congress permitted facilities already paid through the exceptions process to maintain their exceptions status until they notify CMS in writing that they no longer wish to receive exceptions payments. *See* Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) § 422; the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) § 623(b). To comply with these requirements, we urge CMS to modify the preamble and regulatory text to meet the statutory mandate.

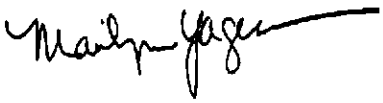
V. TELEHEALTH: CMS should identify renal dialysis facilities as "originating sites" for providing telehealth services.

The RLC encourages CMS to include dialysis facilities within the definition of originating sites for providing telehealth services. Patients with chronic kidney disease would benefit enormously from such services. Telehealth could prove particularly useful in rural or underserved areas by allowing patients to receive counseling or other services from physicians, nutritionists, or other health care professionals, even if each is located in different parts of the state. In addition, even though Medicare does not cover medical nutritional therapy through the ESRD program, the RLC applauds CMS for recognizing the importance of nutritional therapy in patient care. We look forward to working with the Agency to ensure that patients with kidney failure receive appropriate nutritional services.

VI. Conclusion

The RLC members sincerely appreciate your thoughtful consideration of our concerns and suggestions. We appreciate the opportunity to discuss our concerns about the drug add-on adjustment earlier this month and would be pleased to discuss these comments with you as well. In the meantime, please do not hesitate to contact Kathy Means at 202-457-6328 if you have questions regarding these comments.

Sincerely,



Marilyn Yager
Executive Director

RENAL LEADERSHIP COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

September 20, 2005

Dr. Mark McClellan
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

Re: **CMS-1502-P:** Preliminary Comments of the Renal Leadership Council on the Physician Fee Schedule Proposed Rule

Dear Administrator McClellan:

I am writing on behalf of the Renal Leadership Council (RLC) to present our members' preliminary views about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year [CY] 2006 (Proposed Rule). 70 Fed. Reg. 45764. The RLC is a coalition representing the four largest entities providing dialysis care and services to Medicare beneficiaries: DaVita, Inc.; Fresenius Medical Care North America; Gambro Healthcare/USA; and Renal Care Group. Collectively, these suppliers operate more than 2,700 dialysis facilities in 42 states that provide dialysis care to approximately 200,000 patients. In addition to this letter, the RLC plans to submit more detailed comments on the Proposed Rule.

The RLC is pleased that CMS published a correction to the proposed End Stage Renal Disease (ESRD) drug add-on adjustment. As the Agency has recognized, the Proposed Rule did not account for three "J"-code changes implemented in 2003 and incorrectly calculated the weight for EPO by including expenditures for hospital-based facilities. Without this correction, the drug add-on adjustment would have inappropriately taken dollars out of the ESRD program in contrast to congressional intent that the changes be budget neutral. The RLC appreciates the opportunity members had to raise our concerns with the Agency so early in the comment period and the Agency's prompt review and response to them.

As noted in our discussions with CMS, our members are also concerned about several critical issues related to the calculation of the drug add-on payment that are not addressed in the correction notice. Specifically, the RLC urges CMS to:

- Fix the drug add-on adjustment by (1) adjusting the trend factor used to calculate the add-on to reflect the historical trend for ESRD drugs; (2) estimating appropriately the 2006 ASP+6 percent for calculation of the add-on; (3) ensuring that the Agency has correctly estimated the amount of spending on syringes used to administer EPO, which is directly related to the actual number of EPO administrations; and (4) calculating separate add-on adjustments for hospital-based and independent facilities to reflect the intent of Congress.

- Provide an appropriate, stable methodology for the reimbursement of ESRD drugs by (1) ensuring the timeliness of updates; (2) protecting small independent facilities that are disadvantaged by a methodology that relies upon averages rather than on the most current data; and (3) recognizing the impact a single, dominant product – EPO – has on prices.

I. Calculating the drug add-on adjustment

A. Calculating the correct growth factor

CMS should correct its calculation of the trend factor used to determine the drug add-on adjustment to reflect the historical growth rate of ESRD drugs. CMS has proposed to use an EPO-based growth estimation of 9 percent to determine the amount at which total ESRD drug expenditures will grow in CY 2006. This percentage does not reflect the historical trend factor. MedPAC has consistently indicated an historical trend factor significantly higher than 9 percent. For example, in the March 2005 report, MedPAC calculated the increase in spending for separately billed drugs other than EPO as 17 percent per year between 1996 and 2003 and 14 percent per year for EPO alone during the same period.[1] In a report commissioned by the Kidney Care Partners (KCP), The Moran Company (TMC) also indicated that CMS's proposed estimate is "materially lower than the drug trend observed in the last few years for which ESRD drug claims data are publicly available."[2] TMC's analysis of the publicly available 5 percent

[1]MedPAC, "Report to the Congress: Medicare Payment Policy," 123 (March 2005).

[2]The Moran Company, "Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System" 6 (September 2005).

sample data indicates a growth trend of approximately 11.2 percent from 2001-2003.[3] Although it may be true that there is no clear and consistent pattern of year-to-year changes in drug spending, using the aggregate trend rather than an artificial annual trend will produce meaningful differences in the drug add-on adjustment.[4] When comparing these different approaches, TMC calculated that within 3 years, the use of a 9 percent growth rate rather than an 11.2 percent growth rate would result in a 6.18 percent difference, assuming a stable base.[5] Because the calculation of the growth factor significantly affects the overall add-on percentage, it is critical that CMS use the more accurate historical trend data.

In addition, the RLC disagrees with the Agency's assessment that it is "reasonable to correlate the growth of Epogen and separately billable drugs in an independent facility, since Epogen constitute[s] the largest amount of drugs dispensed in an independent facility." 70 Fed. Reg. at 45791. Even though it is true that independent facilities dispense more EPO than the other separately billable drugs, there is no evidence that this fact necessarily leads to the conclusion that the growth rate for other separately billable drugs matches that of EPO. The RLC members' experience indicates that the growth of several of the other separately billable drugs historically has exceeded the growth rate of EPO. As already noted, MedPAC also recognizes this difference in trends. In its March 2005 report and contrary to the assumption in the Proposed Rule, MedPAC estimated a difference three-percentage points in the growth trends of EPO and the other separately billable drugs.[6]

Given the calculations of significantly higher percentage increases in the growth trend by MedPAC and TMC, as well as MedPAC's ability to estimate different growth rates for EPO and other separately billable drugs, it seems clear that CMS has miscalculated the trend factor and applied an incorrect assumption. Thus, the RLC urges CMS to develop separate trend factors for EPO and other separately billable drugs and to use historical data that are also available to the public for verification.

B. Estimating the 2006 ASP+6 percent

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[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *See supra*, note 1.

The RLC is concerned that the proposed methodology for calculating the 2006 ASP+6 percent for purposes of determining the drug add-on adjustment will result in an understatement of reimbursement and will not be budget neutral. Any methodology adopted should be based upon the most recent manufacturer pricing data available – rather than a four-quarters average – to more accurately reflect price changes in the payments.

CMS should include an inflation factor that represents historical trends of ESRD drugs only, not all drugs in the aggregate. The proposed inflation factor of 5.7 percent, which is the forecast of the Producer Price Index (PPI) for all prescription drugs, does not reflect the actual ESRD drug trends. The table below shows the recent ASP+6 percent trends for ESRD drugs, the actual trend shows declining prices of 1.2 percent overall and 6.3 percent for the non-EPO drugs.

Drug	**Jan'05 Payment Limit**	**Apr'05 Payment Limit**	**Jul'05 Payment Limit**	**Jul'05 vs. Jan'05**
Epogen	$9.317	$9.250	$9.307	(0.1%)
Zemplar	$4.017	$3.971	$3.871	(3.6%)
Venofer	$0.362	$0.365	$0.365	0.8%
Hectorol	$2.797	$2.784	$1.501	(46.3%)
Ferrlecit	$4.829	$4.726	$4.713	(2.4%)
Infed	$11.060	$11.218	$11.223	1.5%
Carnitor	$14.649	$11.122	$12.174	(16.9%)
Alteplase	$30.152	$30.089	$30.772	2.1%
Calcitriol	$0.710	$0.859	$0.623	(12.3%)
Vancomycin	$2.419	$3.188	$2.983	23.3%
Weighted Avg ASP+6%				
Total	$ 7.69	$ 7.58	$ 7.60	(1.2%)
Non-Epogen	$ 4.27	$ 4.06	$ 4.00	(6.3%)

A broad industry update trend of 5.7 percent is not an appropriate estimate for ESRD.

C. Estimating of the number of EPO administrations

Additionally, the RLC is concerned that CMS has overstated the number of administrations of EPO in its calculation of the drug add-on adjustment. In the Proposed Rule, CMS estimates the number of administrations of EPO to deduct the 50 cents included in EPO payments for syringes from the total 2005 spending for this drug. CMS calculated the aggregate syringe value to be $1.6 million for hospital-based facilities and $26.8 million for independent facilities. 70 Fed. Reg. at 45791. According to TMC analysis, even if facilities administered EPO in conjunction with each of the 34.5 million projected dialysis treatments, the total amount of payments attributable to syringes would be $0.50 * 34.5 million = $17.25 million in the aggregate.[7] Because not all patients receive EPO during each treatment, that estimate also overstates the true cost of syringes. It is more likely that the amount would be $15 – 16 million. The RLC strongly encourages CMS to modify its estimation of the amount attributable to syringes for purposes of calculating the drug add-on adjustment.

D. Establishing two drug add-on adjustments

If CMS maintains distinct drug reimbursement methodologies for hospital-based and independent facilities, it should establish distinct drug add-on adjustments. CMS has incorrectly interpreted Section 623(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to require it to adopt a single add-on adjustment for both hospital-based and independent facilities. This interpretation ignores statutory rules of construction and the legislative history. It is also inconsistent with CMS precedent and public policy. Therefore, the RLC urges CMS to revise its interpretation of this section and to implement two separate drug add-on adjustments.[8]

The plain language and legislative history of Section 623 requires the creation of separate add-on adjustments because both demonstrate that Congress did not seek to upset the existing balance between hospital-based and independent facilities. Congress did not require CMS to adopt a single reimbursement methodology for separately billable drugs. *See* 42 U.S.C. § 1395rr(b)(13)(A); H. Rep. No. 108-391 at 683-87. The text and Conference Report indicate that Congress intended to modify only the payments for erythropoietin and drugs billed separately by independent facilities. If Congress had intended to establish a single reimbursement methodology for all drugs billed separately by hospital-based and independent facilities, it would have expressly eliminated the authority upon which CMS relies to use a cost-based methodology

[7] *See supra*, note 2 at 8.

[8] In addition to this brief analysis, the RLC has prepared a detailed legal analysis to present to the CMS Office of the General Counsel in the coming days.

to reimburse hospital-based facilities for separately billable drugs. It did not. *See* Social Security Act § 1861(v). The only changes Congress made were to the methodology the Agency employs to reimburse independent facilities for all separately billable drugs and hospital-based facilities for EPO.

Because Congress maintained the distinction in the reimbursement methodology, it would be inconsistent for the Agency to adopt a single drug add-on adjustment to apply across the different methodologies. The clear intent of Congress was for the Agency to establish separate drug add-on adjustments. In addition to the text and legislative history, the bill's managers – Sens. Grassley, Baucus, Santorum, and Conrad – have indicated in a letter to CMS that they envisioned two distinct add-on adjustments as well. Other agencies also support this interpretation. For example, when the Office of the Inspector General (OIG) conducted its congressionally mandated study to determine the cost of separately billable drugs, it expressly excluded the hospital-based facilities from its analysis, consistent with the mandates of the MMA.[9]

CMS incorrectly asserted in the CY 2005 Final Rule that the use of the word "difference" in the singular form requires the Agency to establish a single, integrated add-on percentage. In addition to being inconsistent with the Agency's initial interpretation of the statute, it also fails to comply with the statutory rule that states that legislative terms that are singular in form may apply to multiple subjects or objects. *See Smith v. Zachary*, 255 F.3d 446 (7th Cir. 2001); *Johnson v. Penrod Drilling Co.*, 803 F.2d 867 (5th Cir. 1986); *see also*, 1 U.S.C. § 1 ("[i]n determining the meaning of any Act of Congress ... words importing the singular number include and apply to several persons, parties, or things). Thus, CMS's assertion that it must interpret the term "difference" as requiring only one add-on adjustment is incorrect.[10]

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[9]OIG, "Medicare Reimbursement for Existing End Stage Renal Disease Drugs" (May 2004).

[10]In addition, CMS incorrectly asserts that 42 U.S.C. § 1395rr(b)(7) requires it to adopt a single add-on adjustment to allow it to maintain higher payments to hospital-based facilities. 69 Fed. Reg. at 66320. This interpretation is incorrect because 42 U.S.C. § 1395rr(b)(7) requires only that the rates between the types of facilities be different; the statute does not specify that the hospital-based rate must be higher. 42 U.S.C. § 1395rr(b)(7).

CMS also incorrectly implies that it must adopt a single add-on adjustment because to do otherwise would require different calculations for budget neutrality and the case-mix adjustors based upon facility type. Nothing in the statute requires the calculation of the add-on adjustment to be implemented in the same manner as the case-mix adjustors or the budget neutrality requirement. In addition, it is not appropriate to compare the case-mix adjustors to the drug payment add-on because they are based on different underlying payment methodologies. Providing separate add-on adjustments would result in different payment rates to independent and hospital-based facilities, but would not run afoul of the budget neutrality requirement, as CMS itself implied in the preamble to last year's Notice

A single drug add-on adjustment also thwarts Congressional intent by providing a windfall to hospital-based facilities and reducing the overall reimbursement amount independent facilities receive. According to TMC's analysis, the windfall problem would continue under the Proposed Rule if adopted by increasing hospital-based facility reimbursement approximately $54 million and lowering the reimbursement to independent facilities by the same amount in 2006 alone.[11] The two-year combined effect would result in a decrease of $82 million to independent facilities.[12] The single add-on adjustment would lead to a loss of approximately $2.00 per treatment for independent facilities, while hospital-based facilities will receive a windfall of approximately $11 per treatment in addition to their profits on separately billable drugs. Independent facilities provide the majority of care to individual with kidney failure. The continued extraction of funding from their reimbursement will negatively affect access to care and drive patients to higher cost settings. Allowing this windfall inappropriately rewards hospital-based facilities for providing the same care that independent facilities do. In addition to being bad policy and inconsistent with Congress's mandate, it also contradicts the statutory requirement to establish payment methodologies that encourage efficient care. *See* 42 U.S.C. § 1395rr(b)(7).

To comply with Congressional intent, CMS should ensure that the drug add-on adjustment provides an appropriate offset to the legislated changes in the drug reimbursement methodology. This means that hospital-based facilities must have an add-on adjustment that accounts for changes in EPO payments and that independent facilities must receive an add-on adjustment that accounts for changes in the reimbursement for <u>all</u> separately billed drugs, including EPO.

II. Determining the appropriate methodology for reimbursing separately billable drugs

Establishing a new methodology for reimbursing all separately billable drugs provided by independent facilities and EPO provided by hospital-based facilities will dramatically affect the overall reimbursement to dialysis facilities, as well as the ability of these facilities to provide high quality care to patients. The RLC strongly urges CMS to consider the economic hardship inherent in a system in which reimbursement lags real provider payments particularly in an

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of Proposed Rulemaking for CY 2005 by stating that providing separate add-on adjustments was a legitimate alternative to a single add-on adjustment.

[11] *See supra*, note 2 at 9.

[12] *Id.*

environment where drugs are a major component of the therapy provided, and a single, dominant product (EPO) can materially impact this equation.

The ESRD program presents unique challenges when establishing a reimbursement methodology for drugs. More than in any other aspect of outpatient care, drug therapy is a significant component of the life-sustaining services delivered to dialysis patients. Patients receive one or more of these drugs during each of their thrice-weekly dialysis sessions. Drugs account for approximately 40 percent of revenues, with EPO accounting for 70 percent of this amount. Another challenge is that the drug that has had the greatest impact on improving patient care and quality of life and is administered to most patients – EPO – is provided by a single manufacturer. This manufacturer dominates the market.

Because of these factors, facilities are particularly sensitive to the lag time between a manufacturer's increase in price and its inclusion in the reimbursement rate. Using a system that relies upon annual averages rather than the most current data means that facilities will receive payments that do not cover the current cost of the drugs they provide. Given the already negative Medicare margins, as recognized by MedPAC,[13] and the lack of an annual update mechanism, facilities simply do not have the financial flexibility to make up such differences.

In addition to being disadvantaged by a methodology with a lag time between payment rates and actual costs, small, independent facilities would also suffer under a system that relies upon industry averages. These facilities are most often located in underserved, low-population, rural areas. They do not have the same buying power or economies of scale that larger facilities do. This difference usually results in such facilities paying higher prices for drugs. If they are reimbursed at an average amount that includes the significantly lower prices negotiated by large dialysis organizations, it is unlikely that they could cover the true cost of their drugs with Medicare payments.

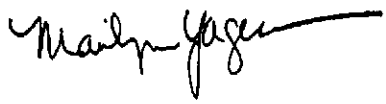
In addition to these comments, the RLC may respond more extensively under separate cover to the proposal to shift to an Average Sales Price methodology. The RLC is currently working with TMC to evaluate the effect of this change and will provide CMS with comments based upon this work before the end of the comment period. Consistent with recommendations from CMS personnel during a recent meeting, the RLC is scheduling a meeting with Liz Richter and Amy Bassano to discuss alternatives and develop a workable solution to this issue.

V. Conclusion

[13] *See supra*, note 1 at 129.

The RLC members sincerely appreciate your review of our concerns and look forward to working with the Agency to resolve them. Again, the RLC is extremely pleased that the Agency issued a correction acknowledging the errors related to the "J"-codes and the resultant weighting changes for the top ten ESRD drugs, including EPO. We look forward to having the opportunity to discuss these, as well as our subsequent, comments with you in person. In the meantime, please do not hesitate to contact Kathy Means at 202-457-6328 if you have questions regarding these comments.

Sincerely,



Marilyn Yager
Executive Director

Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System

September, 2005

THE MORAN COMPANY

Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System

On Monday, August 8, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule setting forth policy and methodology changes for 2006 in the prospective payment system for End Stage Renal Disease (ESRD) services under Medicare. On August 26, CMS posted a correction notice on its Web site revising some of the data used to calculate the 2006 payment amounts, and providing corrected update adjustment factors. The Moran Company was commissioned by Kidney Care Partners (KCP) to conduct an analysis of the data and methodology used by CMS to determine its proposed payment policy, in order to identify methodology and data issues that might warrant comments on the proposed rule. This report presents our findings regarding issues of potential technical concern that KCP may wish to address in communications with the agency going forward. Our analysis is directed toward the CMS data and methodology *as amended* by the correction notice.

Policy Summary

In the Medicare Modernization Act (MMA), Congress mandated a number of important policy changes to reimbursement for treatment of dialysis patients. Prior to 2005, Medicare made two types of payments to ESRD providers:

- They were paid a flat dollar "composite rate" payment per dialysis treatment.
- They were separately reimbursed for drugs under the then-prevailing payment methodology under §1842(o) of the Social Security Act[1], which provided for reimbursement of drugs at Average Wholesale Price (AWP) minus 5% (although erythropoietin (EPO) for ESRD use was reimbursed at a separate statutory rate of $10.00 per 1,000 units.)

In the MMA:

- The Congress provided a uniform 1.6% update to the base composite rate for both hospitals and free-standing facilities.
- The Congress directed that, in lieu of prior payment methodologies, ESRD providers would be reimbursed for the actual acquisition cost of drugs.
- The statute provided a prospective adjustment to the basic composite rate, commonly called the "drug spread add-on", to reflect compensation to ESRD providers for the loss of the "spread" between prior payments and acquisition cost.

[1] Statutory references in this paper, unless otherwise noted, are to the Social Security Act, as amended by MMA.

- The statute authorized the Secretary to make case mix adjustments for ESRD patients, and to adjust the wage indexing methodology applied to ESRD payments.

CMS implemented these payment changes for 2005 by rulemaking in calendar year 2004. In that process, CMS made a number of significant policy choices:

- It elected to use pricing information collected by the Health and Human Services Office of Inspector General (OIG) to set "average acquisition cost" payments for ESRD drugs.
- It elected to implement the drug spread add-on as a percentage adjustment (8.7% in the Final Rule) applied uniformly to both the hospital and free-standing facility rates.
- It implemented a limited system of case mix adjustment.
- It deferred implementation of wage index adjustments.

For 2006, CMS is proposing to revisit some, but not all, of these policy choices. Highlights of the proposed rule include the following:

- For 2006 and later years, CMS proposes to move ESRD drug reimbursement from the current schedule based on acquisition costs to payment under §1847A, which provides for reimbursement of all ESRD drugs at average sales price (ASP) plus 6%. Beginning 1/1/06, these payment rates will be updated quarterly.

- CMS will update the drug spread add-on required by the statute in 2006 to reflect this change, and to incorporate later data.

- CMS will implement a transition to a new wage index policy based on the recently-revised structure for wage area classification implemented for other payment systems.

- CMS is proposing no changes in the case mix adjustment system implemented in the 2005 Final Rule.

Based on our review of these policy changes, and the data and methodological issues that underlie them, we believe that the primary issues of concern to the KCP members are likely to flow from the way in which CMS elected to update the drug spread add-on adjustment, which it is proposing to increase from the 8.7% adjustment provided in the 2005 rates to an 11.3% adjustment for 2006.[2]

The Drug Spread Add-On Methodology

While CMS draws on data from a variety of sources to determine the amount it proposes for the drug spread add-on adjustment, the critical variables are presented in Figure One.

[2] This amount was corrected, in the Web site notice, from the published value of 8.9%.

Figure One

$$\% \text{ ADD-ON} = \frac{\text{WTD \% CHANGE * PRIOR LAW DRUG \$\$\$}}{\text{TREATMENTS * WTD COMPOSITE RATE}}$$

As indicated in that figure, there are four key variables that drive calculation of the adjustment:

- The percentage change in payment rates for ESRD drugs between prior policy and the proposed payment methodology, weighted by volume across the drugs actually used by ESRD providers.
- CMS's estimate of the volume of drug spending that would have occurred under prior law.

These two values are multiplied together to obtain an estimate of the aggregate dollar value of the difference between prior payment policy and the proposed policy. This value is then related to the composite rate via two additional variables.

- The estimated number of dialysis treatments to be performed in the adjustment year; and
- The weighted average value of the composite rate (which we estimate, using CMS data, to be $128.81 in 2005 and later years).

First, the estimated dollar difference between prior and proposed drug payment policy is divided by the estimated treatments to convert it into a per treatment value. This value is than divided by the $128.81/treatment weighted composite rate to determine the add-on percentage.

As indicated in Figure One, this methodology creates a linear relationship between the estimate of the add-on percentage, and changes in any of these four variables. Holding the other three variables constant, a ten percent increase in the value of a variable in the numerator will increase the add-on percentage by ten percent, e.g., from 11.3% to 12.4%. Conversely, a ten percent increase in the estimated number of treatments would reduce the value of the add-on percentage by a factor of 1/1.1, or by 9.09% percent.

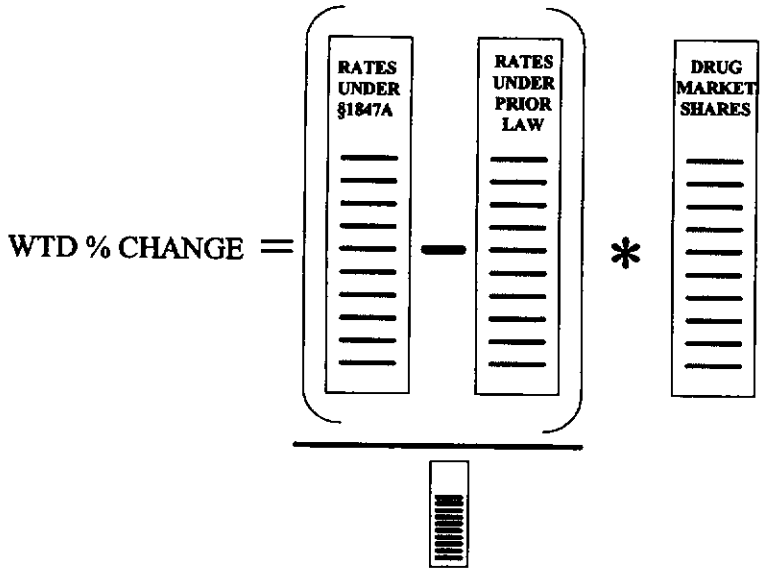
Based on our analysis, we do not believe that the variables in the denominator of this calculation have a meaningful effect on the accuracy of the CMS add-on estimate. With respect to the composite rate, this is true tautologically, since the composite rate values are fixed in statute and hence invariant. While CMS slightly reduced the estimate of treatments from the 35.8 million estimate in the 2005 Final Rule to the 35.4 million value used in the proposed rule, this change of slightly more than 1% in the numerator would cause only a comparably small change in the add-on percentage.

Variations in the data CMS uses in the numerator of this calculation, however, could have a more material effect, since our analysis suggests the potential for greater uncertainty over the appropriate values to use for each of these variables. In the sections that follow, we discuss each of these values in turn.

The Weighted Percentage Change Calculation

The methodology CMS has employed in all three rulemakings related to the ESRD prospective payment system is summarized in the graphic in Figure Two.

Figure Two



Under this methodology, CMS determines three sets of values for each of the top ten (volume) ESRD drugs:

- The dollar per unit value of the post-MMA drug payment policy (in this case, ASP + 6%) for each drug.
- The dollar per unit value of the pre-MMA drug payment policy ($10/1,000 for EPO, AWP-5% for the others); and
- The respective market share of the drug among the top ten, weighted by payment volume.

Using these variables, CMS calculates a percentage change from pre- to post-policy prices for each of the ten drugs, and then produces a composite percentage change weighted by payment market share. Table One shows the data CMS is using in this proposed rule as amended by the correction notice, to make this calculation.

Table One

Calculation of Weighted Percentage Change Due to Payment Policy Change

Drugs	Table 20 ASP+6 2Q 05	Table 21 AWP 2Q 05	Table 22 % of Top Ten	Table 23 % Change	Weighted Impact
EPO	$ 9.25	$ 10.00	69.33%	7.50%	-5.20%
Calcitriol	$ 0.86	$ 1.40	0.84%	38.70%	-0.33%
Doxecalciferol	$ 2.78	$ 3.11	1.48%	10.60%	-0.16%
Iron dextran	$ 11.22	$ 18.04	0.23%	37.80%	-0.09%
Iron sucrose	$ 0.37	$ 0.66	7.03%	45.10%	-3.17%
Levocarnitine	$ 11.12	$ 36.75	0.77%	69.70%	-0.54%
Paracalcitol	$ 3.97	$ 5.37	14.61%	26.00%	-3.80%
Sodium ferric glut	$ 4.73	$ 8.23	4.96%	42.60%	-2.11%
Alteplase, recomb	$ 30.09	$ 38.82	0.56%	22.50%	-0.13%
Vancomycin	$ 3.19	$ 5.55	0.19%	42.60%	-0.08%
					-15.59%

The data values for the pre- and post-policy prices are based on administrative data. The ASP-based payment values are derived from manufacturer ASP reports for the second calendar quarter of 2005; the values published track to the values presently reported for this period on the CMS Web site. The prior law payment values are derived from published AWP prices for the first quarter of 2005; these have been updated to the second quarter using an increase percentage that annualizes to 3.0%.

As the data suggest, the percentage change calculated using this methodology is highly sensitive to the market share assumptions, particularly that for EPO. In contrast to all other drugs, the pre- to post-policy payment change for EPO is only 7.5%, in comparison to the 10-70% changes for the other products. Since EPO is the dominant product, relatively small changes in the market share attributed to EPO can produce large changes in the reported composite percentage change – which as noted above produces a proportional increase (or decrease) in the add-on percentage.

- CMS indicates in the proposed rule that the market share values it is using are derived from 2004 claims data. Since these data were not available in time for this analysis, it is impossible, at this point, to verify this calculation.
- These data, however, were completely revised by the correction notice.
- In the proposed rule, CMS indicated that it would use full year market share data from 2004 – a period prior to the change in payment methodology – to weight this calculation. We believe that this is the correct methodology choice.
- Absent evidence that the revised data reflect errors, we believe that this calculation, as corrected, has been properly done.

Estimating Pre-Policy ESRD Drug Spending

As suggested above, the other major determinant of the accuracy of the drug spread add-on adjustment percentage is the accuracy of CMS's estimates of pre-policy drug spending. A formal statement of CMS's approach to estimate these values would be the following:

Figure Three

$$\text{PRIOR LAW DRUG } \$\$\$_{YEAR} = \text{ACTUAL } \$\$\$_{2003} * (1 + \text{TREND})^{(YEAR-2003)}$$

In its methodology description, CMS indicates that it bases its projections on actual claims data for drugs billed by ESRD providers in 2003. After conversations with CMS analysts involved in generating these estimates, we have checked their 2003 EPO spending estimates against publicly-available data from the 2003 5% Outpatient Standard Analytical File (SAF), and believe that the base values they are using are consistent with the data we see in the SAF.

To index these values forward to 2005 (and subsequently to 2006), CMS indicates that it performed an analysis involving 2005 claims data, in which they derived a year over year growth trend of 9% for EPO, and then applied that trend to update both EPO and non-EPO drug spending to 2005 (and then to 2006).

Since the 2005 claims data CMS employed in this analysis are not available to the public, we cannot verify the accuracy of this estimate, or test the applicability of this EPO-based trend to other products.

This value, however, is materially lower than the drug trend observed in the last few years for which ESRD drug claims data are publicly available. As CMS indicates in its discussion of this issue in the preamble to the proposed rule, there is no clear and consistent pattern of year-to-year changes in drug spending. In the aggregate, however, the trend is clearly upward: the 2003 drug spending totals for all ESRD drugs reflect an 11.2% compound annual increase over the level of ESRD drug spending in 2001.

Since, as noted above, the drug spread add-on percentage varies in direct proportion to changes in estimated prior law drug spending, even relatively small differences in assumed growth rates, when compounded over a 2-3 period, can produce meaningful differences in the drug spread add-on percentage. This reality is demonstrated in Table Two.

Table Two

Effect of Alternative Drug Spending Growth Assumptions

	9% Growth Rate	11.2% Growth Rate
2003 Base	100.00	100.00
2006 Estimate	129.50	137.50
% Difference		6.18%

As shown in this table, a 2.2% difference in the annual trend assumption employed in the CMS methodology would, compounded over the three year period between 2003 and 2006, result in a 6.18% difference in the value of prior law ESRD drug spending 2006, which, holding everything else constant, could increase the calculated drug spread add-on percentage from 11.3% to 12.0%%.

The exact effect of disparities in trend assumptions, over time, will depend on whether and how CMS makes future adjustments to reflect variance between forecast trends and actual changes in ESRD drug spending. The presentation in the proposed rule suggests that CMS intends to anchor its future calculations in historical drug spending data for CY 2004, and then to continually rebase the calculation to historical actuals before estimating a new prospective adjustment.

If this methodology is followed, the impact will depend on whether the variance between projected trends and actuals is random over time. If CMS overestimates trend in some years while under-estimating trend in other years, the cumulative effect of prospective adjustments would be neutral relative to the statutory intent to make budget-neutral adjustments to the drug spread add-on adjustment going forward.

If, however, there is a bias (even if inadvertent) in the relationship between forecast trends and subsequent actuals, errors relative to pure budget neutrality could accumulate over time. Table Three shows the potential magnitude of such effects.

Table Three

Effects of Lags in Adjustments to Drug Spread Add-On Calculations

	Base Year 2005	Year 1	Year 2	Year 3
Hypothetical CMS Projected Trend		9%	9%	9%
Hypothetical "Actual" Trend		12%	12%	12%
Drug Spend Add-On Units	100.00			
Contemporaneous Estimates w. Retro Adjustment		109.00	122.08	136.73
Actual Drug Spend		112.00	125.44	140.49
Disparity		(3.00)	(3.36)	(3.76)

In this table, we have applied the stated CMS estimating methodology in a scenario in which drug trend was consistently estimated at 9%, but actual trend was retrospectively determined to be 12%. In each year, we have retrospectively adjusted the prior year's drug trend to the actual before applying the 9% forecast trend off that adjusted base. As the data presented in the table indicate, a consistent downward bias in the prospective estimate would mean that, even after reconciliation to known actuals, the drug spread add-on percentage calculation would accumulate errors.[3] Since payments to providers would not be retrospectively adjusted to offset the prior underestimate, there would be a widening disparity between actual payments and true budget neutrality.

The Adjustment for EPO Syringes

In its projections of pre-policy drug spending, CMS correctly adjusts the values used to reflect the fact that, beginning in 2005, Medicare makes separate payment at $0.50 per unit for syringes used to administer EPO for ESRD use. In the proposed rule, CMS indicates that the amounts of the adjustments made were $1.6 million for hospital-based facilities and $26.8 million for free-standing facilities. While claims data for 2005 are not yet available to directly check these values, there is reason to believe that these amounts may be overstated, resulting in a corresponding understatement of pre-policy drug spending in 2005 and 2006. The reason for this conclusion is that, even were it assumed that Medicare would pay for an EPO syringe in 100% of the estimated 34.5 million dialysis treatments, total spending on syringes would be only $17.25 million across both settings of care. It is our understanding that intermediaries will reimburse only one syringe per dialysis treatment. We believe, therefore, that CMS should recheck the source of the data being used to make these adjustments.

Measuring the Effects of Uniform Adjustments on Free-standing Providers

Whatever judgment KCP members may reach about the accuracy of the drug spread add-on adjustment percentage, CMS's decision to continue to make uniform adjustments to

[3] If the prospective trend estimate reflected a consistent over-estimate, of course, the bias would work in the opposite direction.

both the hospital and free-standing rates means that a proportionate share of the adjustment will be paid to hospital-based providers in 2006, even though they will continue to be paid on a cost basis for drugs other than EPO. KCP members requested that we update our prior estimates of the magnitude of this effect to be consistent with the CMS proposed add-on percentage of 11.3%. Our findings from this analysis are presented in Table Four.

Table Four

Impact of Uniform Adjustment Policy on Free-Standing Providers

Estimates of Dollar Value of Reimbursement Policy Change

	2005 Base	2006 Increment	2006 Implied	Treatments	Base Rate	Adjustment Value	Variance
		(millions of dollars)				(millions of dollars)	
Hospital EPO	$18	$2	$20	4,946,302	$132.41	$74	+$54
Freestanding Total	$445	$50	$495	30,453,698	$128.35	$442	-$54
	$463	$52	$516	35,400,000		$516	

As these data indicate, the corrected CMS add-on percentage is consistent with an estimate that the MMA reimbursement policy change will lower EPO reimbursements to hospitals by approximately $20 million in 2006, while drug reimbursements to free-standing providers would be lower by $495 million. By applying a uniform percentage adjustment to both the hospital and free-standing rates, however, the CMS methodology weights the value of the adjustment toward hospital providers. We estimate that an 11.3% adjustment would increase hospital reimbursements by approximately $54 million in 2006. This $54 million gain relative to CMS's estimates of the reimbursement policy shortfall would be offset, however, by lowering reimbursements to freestanding providers by the same amount, or $1.53 per treatment ($54 million divided by 35.4 million projected treatments). If a uniform add-on policy is implemented in the Final Rule for 2006, the cumulative effect of this reallocation of the drug spread add-on would reduce payments to free-standing providers in 2005-2006 by $82 million.

In evaluating the appropriateness of the uniform adjustment policy, KCP members asked us to evaluate how cost-based reimbursement for non-EPO drugs in the hospital setting affects the economics of dialysis treatment by hospital-based providers. To evaluate this question, we tabulated payments to hospital-based ESRD providers for non-EPO drugs as reported in the 2003 5% Sample Outpatient Standard Analytical File. Our findings are as follows:

Table Five

Non-EPO Drug Reimbursements by Provider Type

Drug	Average Payment Per Unit, 2003		
	Free-Standing	Hospital-Based	Hospital/Free-Standing
Alteplase	$ 27.39	$ 52.03	190%
Calcitriol	$ 1.20	$ 4.62	384%
Doxercalciferol	$ 4.14	$ 9.50	229%
Iron Dextran	$ 13.98	$ 30.46	218%
Iron Sucrose	$ 0.58	$ 1.19	206%
Levocarnitine	$ 26.66	$ 28.72	108%
Paricalcitol	$ 4.34	$ 11.70	270%
Sodium ferric glut	$ 7.08	$ 18.26	258%
Vancomycin HCL	$ 5.45	$ 13.28	243%

These data are preliminary, and should be interpreted with considerable caution. This table reports the payment values, recorded at the level of individual claims, for dialysis provider bill types presented by both hospitals and free-standing providers. It is our understanding that, in paying ESRD claims from hospital-based providers, fiscal intermediaries annually establish prospective payment rates for ESRD drugs other than EPO based on hospital billed charge amounts for each drug, and the cost-to-charge ratio information presented on cost reports. This practice is consistent with the statutory payment policy of cost-based reimbursement for these drugs. We have confirmed that, in the underlying data, the drug-specific payment amounts do vary by hospital. Absent far more detailed analysis of these data, however, we cannot tell whether the significant observed disparities in reimbursement for these drugs between hospital-based and free-standing providers reflect actual reimbursement differences, rather than being artifacts of anomalies in unit coding of these drugs by hospital-based providers.[4]

Summary Conclusions

As the discussion in the preceding sections makes clear, our analysis suggests that CMS's calculation of an 11.3% drug spread add-on, while materially corrected from the calculations presented in the proposed rule, may still be subject to some degree of uncertainty. Although CMS's estimate of dialysis treatments in either 2005 or 2006 could be a potential source of error, we do not believe such an error, if any, is likely to be material. By contrast, potential errors in either the policy change percentage, or the

[4] In prior work, we have noted that unit coding errors in hospital outpatient departments for separately-reimbursed prescription drugs can be frequent. In the hospital OPPS, errors in coding translate directly into errors in payment, since the payment methodology works on a per-unit basis. In the instant case, however, if intermediaries are paying for drugs based on charge information rather than the unit count, payments for the drugs could accurately reflect the Medicare concept of reasonable cost even if the cost per observed unit appear inflated relative to the AWP-based payment policy applicable to freestanding centers in 2003.

estimate of prior law drug spending in 2005 and 2006, could be material. Though CMS has made a substantial effort to correct its calculation of the weighted change in payment rates between prior policy and current law, subsequent experience may show that CMS's estimate of a 9% drug growth trend may be understated. As noted above, consistent underestimates, if accumulated over time, could lower payments to ESRD providers relative to budget neutrality.[5]

[5] In evaluating the accuracy of compensation for policy changes in drug reimbursement, it is also important to understand that, under the ESRD prospective payment methodology CMS has implemented, the portion of the payment intended to compensate providers for changes in drug reimbursement is subject to wage indexation. While this payment policy is clearly implied by the language of §623 of MMA, it has the effect redistributing the add-on value relative to the drug costs experienced by providers, which are generally based on uniform national market prices.

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September 27, 2005

Mr. Thomas Barker
Deputy General Counsel
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Barker:

We are writing on behalf of the Renal Leadership Council (RLC) to present our understanding of the Medicare Modernization, Prescription Drug, and Improvement Act of 2003 (MMA) provision that establishes an adjustment payment to the End Stage Renal Disease (ESRD) composite rate. The RLC requests that the Centers for Medicare and Medicaid Services (CMS) adopt two distinct drug add-on adjustments that distinguish between hospital-based renal dialysis providers and independent renal dialysis facilities to comply with federal statutory requirements.

As set out below, CMS misinterpreted Section 1395rr(b)(12)(B) by adopting a single, blended drug add-on adjustment for both hospital-based providers and independent facilities. Added by MMA section 623(d), this provision (42 U.S.C. § 1395rr(b)(12)(B)) requires the new basic case-mix adjusted prospective payment system for dialysis services to include "the difference between payment amounts under this title for separately billed drugs and biologicals (including erythropoietin) and the acquisition costs of such drugs and biologicals, as determined by the Inspector General..." which is commonly referred to as the drug "add-on" adjustment.

While the statutory text, structure, and supporting legislative history call for distinct drug add-on adjustments for hospital-based providers and independent facilities, CMS blended the two in its Physician Fee Schedule for CY 2005 Final Rule (CY 2005 Final Rule), 69 Fed. Reg. 66236 (Nov. 15, 2004), and again in the CY 2006 Physician Fee Schedule Notice of Proposed Rulemaking (CY 2006 NPRM), 70 Fed. Reg. 45764 (Aug. 8, 2005). Contrary to law, CMS implemented Section 1395rr(b)(12)(B) by interpreting the language to require the agency to establish a single add-on adjustment that combines the difference in payment amounts for hospital-based providers and independent facilities. *See* 69 Fed. Reg. at 47526; 70 Fed. Reg. at 47527-29. The RLC urges CMS to revise its legal interpretation of this section and to implement two separate drug add-on adjustments.

I. The text and legislative history indicate that CMS should establish different drug add-on adjustments based on facility type.

Congress established the drug add-on adjustments to ensure that dialysis facilities receive the same aggregate payments post-MMA as they had prior to the MMA changes in the reimbursement methodology for separately billed drugs. CMS reimburses hospital-based providers and independent facilities using different methodologies. In the MMA, Congress changed the reimbursement methodologies for all drugs billed separately by independent facilities and changed the reimbursement for erythropoietin billed in both settings. It did not change the reimbursement methodology for non-erythropoietin drugs billed separately by hospital-based providers. Congress called on CMS to ensure that payments for dialysis did not decrease because of these changes. Therefore, because Congress expressly changed the drug reimbursement methodology for independent facilities in a way that differs from the way it altered the reimbursement methodology for hospital-based providers, it is appropriate to interpret Congress's intent as requiring separate drug add-on adjustments.

A. The statute's plain language requires separate drug add-on adjustments to be calculated for independent dialysis facilities and hospital-based providers to offset the changes made in the drug reimbursement methodologies.

The plain language of MMA Section 623 requires the creation of separate drug add-on adjustments. Further, the statute as a whole demonstrates that Congress intended to maintain the distinction between hospital-based providers and independent facilities and sought to establish separate drug add-on adjustments for each setting. This is true for several reasons.

First, Congress did not substitute a new structure for calculating the distinct reimbursement methodology for independent facilities, but went out of its way to preserve the pre-existing statutory regime that even CMS understood required separate calculations. For example, rather than overwrite 42 U.S.C. § 1395rr(b)(7), Congress preserved that provision and simply enhanced it by adding Paragraphs 12 and 13 to accommodate other changes to the reimbursement methodologies embodied in Paragraph 12. Stated differently, the text makes clear that Congress modified only the payments for erythropoietin and drugs billed separately by independent facilities, in that 42 U.S.C. § 1395rr(b)(13)(A) calls for a limited series of payment changes. It begins by retaining the 95 percent Average Wholesale Price (AWP) methodology, which applied only to independent facilities, for separately billed drugs in 2004. 42 U.S.C. § 1395rr(b)(13)(A). For 2005, Congress modified the reimbursement structure for independent facilities to acquisition cost for separately billed drugs and erythropoietin. *Id.* When it selected the 95 percent AWP methodology as the starting point, Congress focused solely on independent facilities and the erythropoietin payments. If Congress had

intended to include all drugs billed separately by hospital-based providers, it would have referenced the section of the Social Security Act (§ 1861(v)) under which CMS reimburses hospital-based providers as well. Congress, however, only modified all drug reimbursement for independent facilities and only erythropoietin reimbursement for hospital-based providers. Therefore, the Congressional add-on adjustment must also distinguish between the two drug reimbursement methodologies to maintain the current reimbursement levels for each type of dialysis setting.

Second, the language in the MMA related to the Inspector General study supports this conclusion as well. When Congress mandated that the Inspector General conduct the study referred to in the provision establishing the drug add-on adjustment, it expressly required the examination of independent facilities only; it did not include hospital-based providers. Specifically, Congress instructed the Inspector General to:

> determine the difference between the amount of payment made to end stage renal disease facilities under title XVIII of the Social Security Act for such drugs and biologicals and the acquisition costs of such facilities for such drugs and biologicals and which are separately billed by end stage renal disease facilities, and . . . estimate the rates of growth of expenditures for such drugs and biologicals billed by such facilities.

MMA § 623(c). In the Social Security Act, Congress uses the terms "renal dialysis facilities" and "facilities" to describe non-hospital-based dialysis centers, while the term "providers of services" refers to dialysis centers located in hospitals (*i.e.*, hospital-based providers). *See* 42 U.S.C. 1395x(u); *see generally*, 42 U.S.C. § 1395rr. Thus, the words chosen by Congress when instructing the Inspector General to focus on "facilities" demonstrates that Congress had a clear understanding of the particular entities it was addressing when establishing the drug reimbursement methodology (and the corresponding unique add-on adjustments) for all separately billable drugs provided by independent facilities only.

Third, the budget neutrality requirement of MMA Section 623 requires that the modifications to the drug reimbursement methodology do not change the overall reimbursement for dialysis. *See* 42 U.S.C. § 1395rr(b)(12)(D). Congress directed CMS to ensure that drug reimbursement changes were offset by drug add-on adjustments by requiring CMS to calculate the difference between the previous drug reimbursement methodologies and the new drug reimbursement methodologies. 42 U.S.C. § 1395rr(b)(12)(B).[1] Coupled with the requirement to

[1]The text does not expressly state whether the budget neutrality calculation is determined overall to the ESRD Program or to the type of facilities. To determine exactly what Congress intended, it is necessary to consider this provision in the context of the rest of the text and the legislative history. *See infra*, Section II.B.

include drug add-on adjustments to the composite rate, the budget neutrality provision demonstrates a Congressional desire to ensure that payments for dialysis did not change, even though it changed the drug reimbursement methodologies in the MMA. Congress did not seek to upset the existing balance between hospital-based providers and independent facilities. Nothing in this provision indicates that CMS has the authority to shift dollars from independent facilities to hospital-based providers, which is the effect of the CMS blended drug add-on adjustment methodology.

Fourth, Congress could have, but did not, require CMS to adopt only a single methodology for the reimbursement of separately billed drugs in the dialysis setting. Nothing in the legislative changes altered the existing statutory regime requiring separate calculations for hospital-based providers and independent facilities. "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lorillard v. Pons,* 434 U.S. 575, 580 (1978); *Johns-Manville Corp. v. U.S.,* 855 F.2d 1556, 1559 (Fed. Cir. 1988). Congress did not expressly modify the reimbursement methodology for hospital-based providers. Thus, Congress preserved the separate add-on calculation for independent facilities in statute.

As you are aware, "[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)(internal quotation marks and citations omitted); *Smith v. Zachary,* 255 F.3d 446, 448 (7th Cir. 2001); *see also Dersch Energies, Inc. v. Shell Oil Co.*, 314 F.3d 846, 856 (7th Cir. 2002). Given that Congress sought to hold facilities harmless from the MMA drug reimbursement changes by creating the drug add-on adjustments and the fact that it did not change the reimbursement methodology for all drugs billed separately by hospital-based providers, it is clear that Congress sought to adopt separately constructed drug add-on adjustments based upon the distinctions CMS has established between hospital-based providers and independent facilities.

B. The legislative history indicates that Congress intended to protect independent facilities and hospital-based providers from changes in the drug reimbursement rate through separate drug add-on adjustments.

The MMA Conference Report also indicates that Congress sought to maintain the existing methodological distinction between independent facilities and hospital-based providers, which supports separate drug add-on adjustments. Consistent with the text of section 1395rr(b)(13)(A), the Report envisions a change in the separately billed drugs reimbursement methodology for independent dialysis facilities because it references only the 95 percent AWP methodology, which pre-MMA applied to independent facilities only. *See* H. Rep. No. 108-391 at 683-87. If Congress

had meant to include hospital-based providers, it would have mentioned the reasonable cost methodology under which they are reimbursed. *See, Johns-Manville Corp.*, 855 F.2d at 1559. It did not. Therefore, it is appropriate to conclude that Congress sought to maintain the distinction between the drug reimbursement methodologies for hospital-based providers and independent facilities.

Maintaining the drug reimbursement methodology distinction between hospital-based providers and independent facilities implies that Congress intended the drug add-on adjustments to be calculated based upon the existing methodologies. The managers have indicated that they envisioned two distinct drug add-on adjustments as well. Sens. Grassley, Baucus, Santorum, and Conrad expressly endorsed the separate drug add-on adjustments interpretation in a letter to CMS. Rep. McDermott sent a similar letter as well.[2] These letters to CMS support the need for separate drug add-on adjustments based upon facility type; they expressly reject a single average drug add-on adjustment.[3]

C. The only way to offset the changes required by the MMA is to establish separate drug add-on adjustments.

There is also little question that to comply with Congressional intent, CMS must implement a policy that maintains aggregate reimbursement in both dialysis treatment settings following the changes to the drug reimbursement methodology enacted in the MMA. This means that hospital-based providers need a drug add-on adjustment that accounts for changes in their erythropoietin payments and that independent facilities receive an add-on adjustment that accounts for changes in reimbursement for <u>all</u> separately billed drugs, including erythropoietin.

To accomplish this goal, there must be separate drug add-on adjustments. CMS recognized in the CY 2005 NPRM that a single drug add-on adjustment would not offset the changes resulting from modifying the drug reimbursement methodologies. In fact, a single drug add-on adjustment provides a windfall to hospital-based providers and reduces the overall reimbursement to independent facilities. For example, if in CY 2005 CMS had adopted separate drug add-on adjustments, hospital-based providers would have received an add-on of 2.7 percent; independent facilities would have received an add-on of 12.8 percent. 69 Fed. Reg. at 47529. Even though the calculation changed slightly in the Final Rule, hospital-based providers still received a substantial

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[2]See attachment.

[3]In addition, the Office of the Inspector General (OIG) also interpreted these provisions to maintain the distinction between hospital-based providers and independent facilities. When implementing its mandated analysis of the cost of ESRD drugs, the OIG examined data only from independent facilities for separately billed drugs.

windfall of 6.6 percent. 69 Fed. Reg. at 66320. The single drug add-on adjustment amount in the CY 2005 Final Rule reduced the reimbursement rate for independent facilities by $1.41 per treatment, according to the agency's own calculations, by shifting that amount to hospital-based providers. *Id.* In 2005, this meant that CMS transferred approximately $44 million to hospital-based providers without Congressional approval. According to The Moran Company, the windfall problem would continue under the CY 2006 Proposed Rule, if adopted, by increasing hospital-based provider reimbursement approximately $54 million in 2006, lowering the reimbursement to independent facilities by the same amount.[4] The single add-on means that independent facilities will lose approximately $2.00 per treatment, while hospital-based providers will receive a windfall of approximately $11 per treatment.

This windfall to hospital-based providers is inconsistent with Congressional intent. Because Congress recognized a difference in the drug reimbursement methodologies based on facility type and provided the add-on adjustments to ensure that overall Medicare payments for dialysis did not decrease because of the changes to the drug reimbursement methodologies, the add-on provision should be read to require CMS to adopt an add-on adjustment methodology that maintains the pre-MMA payment levels to hospital-based providers and independent facilities. Therefore, the best interpretation of 42 U.S.C. § 1395rr(b)(12)(B) requires CMS to adopt separate drug add-on adjustments for hospital-based providers and independent facilities.

II. CMS's justification for ignoring the statutory requirements for separate add-on adjustments is incorrect.

CMS incorrectly asserts that the plain text of the statute requires the agency to establish a single, integrated add-on adjustment. In the CY 2005 Final Rule, CMS states:

> [W]e believe that the statutory language supports one uniform drug add-on adjustment to composite payment rates set forth in section 1881(b)(7) of the Act after updating by 1.6 percent. The provision speaks of one "difference between payment amounts" and "acquisition cost * * * as determined by the Inspector General." It is reasonable to infer that the Congress intended us to compute one "difference" based only on the payment amounts under sections 1842(o) and 1881(b)(11) of the Act.

[4]The Moran Company, "Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System" 11 (September 2005).

69 Fed. Reg. at 66320. In the agency's view, because Congress used the singular of the term "difference", it clearly meant a single drug add-on adjustment.

This interpretation, however, is inconsistent with the agency's initial reading of the requirement. In the CY 2005 NPRM, the agency expressly indicated that it interpreted the statute to provide it with the authority to establish different drug add-on adjustments for independent facilities and hospital-based providers. 69 FR at 47529. Yet, it chose to implement only a single drug add-on adjustment in the CY 2005 Final Rule, ignoring its previous interpretation by claiming the statute supports only a single drug add-on adjustment based upon a narrow reading of the word "difference." 69 Fed. Reg. at 66320.

The CY 2005 Final Rule interpretation ignores the fact that legislative terms that are singular in form may apply to multiple subjects or objects. *See Smith v. Zachary*, 255 F.3d 446 (7th Cir. 2001); *Johnson v. Penrod Drilling Co.*, 803 F.2d 867 (5th Cir. 1986); *see also* 1 U.S.C. § 1 ("[i]n determining the meaning of any Act of Congress . . . words importing the singular number include and apply to several persons, parties, or things). CMS applied this theory itself when reading the provision directly preceding the drug add-on adjustment language as applying to both the hospital-based provider and independent facility composite rates, not just one of them. 42 U.S.C. § 1395rr(b)(12)(B)(i). Thus, CMS's assertion that it must interpret the term "difference" as requiring only one add-on adjustment is incorrect. The legislative text and history, as well as CMS's past practices and public policy, support implementing 42 U.S.C. § 1305rr(b)(12)(B) to provide separate drug add-on adjustments for hospital-based providers and independent facilities.[5]

In addition, CMS incorrectly asserts that 42 U.S.C. § 1395rr(b)(7) requires it to maintain these higher payments to hospital-based providers. 69 Fed. Reg. at 66320. This interpretation is incorrect because 42 U.S.C. § 1395rr(b)(7) requires only that the rates between the types of facilities be different; it does not specify that one should be higher. 42 U.S.C. § 1395rr(b)(7).[6] In addition,

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[5]In the CY 2005 Final Rule, CMS also indicated as a justification for a single, add-on adjustment the idea that if it established two drug add-on adjustments, it would also be required to calculate separate budget neutrality calculations and case-mix adjustors for each type of facility. 69 Fed. Reg. at 66320. Whether or not CMS has to make one calculation or two is irrelevant, however, to what 42 U.S.C. § 1395rr(b)(12)(B) requires. Moreover, CMS is surely able to make both calculations within an overall budget neutrality evaluation.

[6]CMS also incorrectly implies that it must adopt a single drug add-on adjustment because to do otherwise would require different calculations for budget neutrality and the case-mix adjustors based upon facility type. Nothing in the statute requires that the calculation of the add-on adjustments be implemented in the same manner as the case-mix adjustors or the budget neutrality requirement. In addition, it is not appropriate to compare the case-mix adjustors to the drug add-on adjustments because they are based on different underlying reimbursement methodologies. In terms of the budget neutrality requirements, providing separate add-on adjustments would result in different payment rates to independent

nothing in the MMA indicates that Congress sought to maintain a higher overall payment to hospital-based providers through the drug add-on adjustments.

III. Separate single drug add-on adjustments for both independent facilities and hospital-based providers is inconsistent with CMS's past practices of treating these dialysis settings differently.

Establishing separate drug add-on adjustments for hospital-based providers and independent facilities is consistent with CMS's historical interpretation of 42 U.S.C. § 1395rr as requiring different methodologies for calculating reimbursement for separately billed drug to hospital-based providers and independent facilities. CMS consistently has reimbursed hospital-based providers using a different methodology than independent facilities. Both pre- and post-MMA, CMS interprets 42 U.S.C. § 1395rr(b)(7) to require the Secretary to "differentiate between hospital-based facilities and other renal dialysis facilities" by adopting a separate composite weighted formula or through some other method. Sections 1395rr(b)(7) and (b)(2)(B) allow the Secretary to determine the services covered by the composite rate and to determine the cost of providing these services. Based upon this authority, the agency first codified the different methodologies for separately billed drugs in the Nov. 25, 1991 Physician Services Fee Schedule. 56 Fed. Reg. 59502, 59507; *see also* 42 CFR § 413.170(a); 42 CFR § 413.174(g). CMS proposes to maintain this distinction in the CY 2006 NPRM. [7] 70 Fed. Reg. at 45790-93. CMS reimburses hospital-based providers and independent facilities at the same rate only for erythropoietin, which Congress expressly established at 42 U.S.C. § 1395rr(b)(11)(B). To be consistent, CMS should maintain the same distinction when establishing the drug add-on adjustments.

IV. Applying separate add-on adjustments for hospital-based providers and independent facilities is the appropriate public policy.

As described above, if CMS does not change the reimbursement methodology for hospital-based providers, they will continue to receive an inappropriate windfall of $54 million in 2006 and a cumulative windfall of $82 million (2005 – 2006) that unfairly disadvantages 85 percent of the dialysis population that receive their care in independent facilities. The current interpretation inappropriately rewards hospital-based providers for providing the same care at a higher cost and, as

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facilities and hospital-based providers, but would not run afoul of the budget neutrality requirement, as CMS implies in the CY 2005 NPRM through its suggested alternative of providing separate add-on adjustments.

[7]Even though CMS asserts that it agrees with MedPAC that it would be better public policy to use the same reimbursement methodology across treatment settings, it has not proposed to make such a change for CY 2006.

such, is inconsistent with the Congressional mandate for CMS to establish reimbursement methodologies that encourage efficient care. *See* 42 U.S.C. § 1395rr(b)(7).

V. Conclusion

RLC urges CMS to adopt separate drug add-on adjustments for hospital-based providers and independent facilities. This distinction is consistent with the statute as a whole and the legislative history. Separate drug add-on adjustments are also more consistent with the agency's historic interpretation of 42 U.S.C. § 1395rr. Most importantly, sound public policy supports separate drug add-on adjustments because hospital-based providers should not receive windfall payments for providing the exact same services.

Sincerely,

David Farber and Kathy Lester
Patton Boggs LLP

COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON HEALTH
SUBCOMMITTEE ON HUMAN RESOURCES

JIM McDERMOTT
7TH DISTRICT, WASHINGTON

CHAIRMAN
CONGRESSIONAL TASK FORCE ON
INTERNATIONAL HIV/AIDS

Congress of the United States
House of Representatives
Washington, DC 20515

October 26, 2004

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Room 445-0
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

As the co-chair of the Congressional Kidney Caucus, I am writing to express my concern about proposed changes to the add-on adjustment for independent and hospital-based dialysis facilities. I believe the proposed single, average add-on adjustment for both independent and hospital-based facilities will result in a net loss for independent facilities, and that this violates the intent of the Congress.

Through Section 623 of the MMA, the Congress sought to eliminate the negative impact of changes to the Part B drug reimbursement methodology on independent facilities. I am concerned that if CMS were to implement the add-on adjustment as proposed, independent facilities would not receive the full amount they received prior to the changes in Part B reimbursement for drugs. As proposed, the add-on would be 11.3 percent, even though CMS calculated the amount for independent facilities to be 12.8 percent. The lower percentage is due to CMS's decision to average the much lower hospital percentage with the higher independent facility amount to create a single add-on adjustment.

The add-on provision in the MMA was meant to address the concern that without the budget neutral add-on payment, the changes in Part B reimbursement for separately billed drugs would result in a loss of revenue to dialysis facilities. I am concerned that without a proper add-on payment the drug reimbursement changes would destabilize these facilities and could jeopardize the care of many of the more than 300,000 Americans diagnosed with kidney failure.

I urge you to consider these issues as you finalize your proposal. Specifically, I want to ensure that independent facilities receive an add-on adjustment equal to the difference between the 2004 payments to independent facilities for separately billed drugs, including erythropoietin, and the 2005 acquisition cost for those drugs. Similarly, hospital-based facilities should receive a separately calculated add-on adjustment that equals the difference between the 2004 payments to them for erythropoietin and their 2005

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acquisition cost for the drug. These amounts should not be averaged into a blended rate, as suggested in the proposed rule.

Thank you for considering these concerns and I look forward to working with you prior to release of the final rule.

Sincerely,

Jim McDermott

Jim McDermott
Member of Congress

United States Senate

WASHINGTON, DC 20510

October 14, 2004

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

Dear Dr. McClellan:

As the Centers for Medicare and Medicaid Services (CMS) works toward finalizing the regulations implementing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), it is essential that the agency provide a fair add-on adjustment for independent End Stage Renal Dialysis (ESRD) facilities. The proposed add-on adjustment fails to do this by establishing a single, average add-on adjustment for both independent and hospital-based facilities that leads to a lower add-on for independent facilities.

Through Section 623 of the MMA, we sought to eliminate the negative impact of the changes to the Part B drug reimbursement methodology on independent facilities. We are concerned that if CMS were to implement the add-on adjustment as proposed, independent facilities would not receive the full amount they received prior to the changes in Part B reimbursement for drugs. As proposed, the add-on would be 11.3 percent, even though CMS calculated the amount for independent facilities to be 12.8 percent. The lower percentage is due to CMS's decision to average the much lower hospital percentage with the higher independent facility amount to create a single add-on adjustment.

We included the add-on provision in the MMA to address the concern that without the budget neutral add-on payment, the changes in Part B reimbursement for separately billed drugs would result in a loss of revenue to these independent facilities. As you know, MedPAC has consistently noted that the composite rate component of Medicare reimbursements to these facilities does not cover their costs. They break even only because of the cross-subsidization of payments for separately billed drugs. We were concerned that without a proper add-on payment the drug reimbursement changes would destabilize these facilities and jeopardize the care of many of the more than 300,000 Americans diagnosed with kidney failure.

Accordingly, we urge you to consider these issues as you finalize your proposal. More specifically, we want to ensure that independent facilities receive an add-on adjustment equal to the difference between the 2004 payments to independent facilities for separately billed drugs (including erythropoietin) and the 2005 acquisition cost for those drugs. Similarly, hospital-based facilities should receive a separately calculated add-on adjustment that equals the difference between the 2004 payments to them for erythropoietin (the only drug for which their reimbursement methodology will change) and their 2005 acquisition cost for the drug. These amounts should not be averaged into a blended rate, as suggested in the proposed rule. Thank you for considering these concerns and we look forward to working with you prior to release of the final rule.

Sincerely,

Rick Santorum

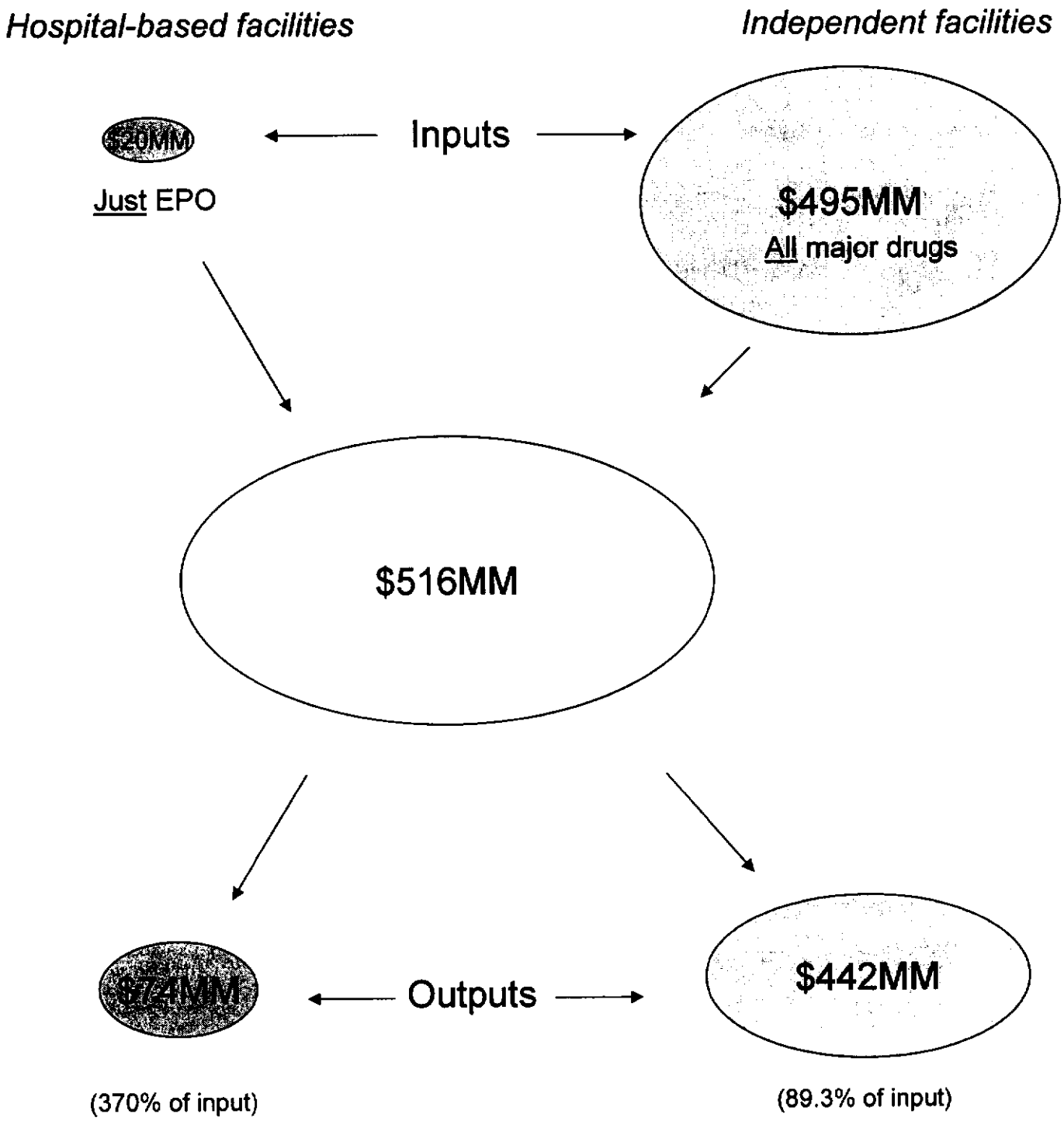
Kent Conrad

Charles Grassley

Max Baucus

3809436v3

In 2005 NPRM: What comprises the 2006 add-on pool, and how will it be distributed?



Source: The Moran Company, Analysis of the Proposed 2006 Update to the ESRD Prospective Payment System

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September 29, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Bldg.
200 Independence Ave., SW
Washington, DC 20201

Attn: CMS-1502-P

RE: Comments on Medicare Program; Revisions to Payment Policies Under Physician Fee Schedule for Calendar Year 2005; Proposed Rule. (70 Fed. Reg. 45764, August 8, 2005)

1) **SUSTAINABLE GROWTH RATE (SGR) Formula - Need to Develop a SGR and Related Methodologies that Produce Realistic Results**
2) **TEACHING ANESTHESIOLOGISTS - Payment Policies for Anesthesia Teaching Services**

Dear Sir/Madam:

The American Association of Nurse Anesthetists (AANA) appreciates this opportunity to comment on the proposed revisions to payment policies under physician fee schedule for calendar year 2006. (70 Fed. Reg. 45764, August 8, 2005) The AANA is submitting comments in two areas relevant to providing anesthesia services. These two areas are: (1) Sustainable Growth Rate (SGR) Formula, and (2) Teaching Anesthesiologists - Payment Policies for Anesthesia Teaching Services.

The AANA is the professional association for more than 30,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. Today, CRNAs are directly involved in approximately 65 percent of all anesthetics given to patients each year. CRNA services

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include administering the anesthetic, monitoring the patient's vital signs, staying with the patient throughout the surgery, as well as providing acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost 70 percent of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists and plastic surgeons.

Comment No. 1: SUSTAINABLE GROWTH RATE (SGR) Formula
Need to Develop a SGR Formula and Related Methodologies that Produce Realistic Results

Need to Reform Current SGR Formula

We commend CMS in soliciting comments on the methodology for calculating the Sustainable Growth Rate (SGR). We echo the comments made by medical and other professional societies in regards to establishing a better methodology for calculating the SGR. We understand that the intent of the Balanced Budget Act (BBA) in replacing the Medicare Volume Performance Standard (MVPS) calculation with the SGR methodology was to curb Medicare expenditures. We also understand that Section 1848(f)(2) of the Act specifies the formula for establishing yearly SGR targets for physicians' services under Medicare and that it is up to Congress whether to change the SGR formula.

We also understand that the following factors are used in calculating the SGR; (1) Estimated percentage change in fees for physicians' services (before any performance adjustment), (2) Estimated change in the average number of Medicare fee-for-service beneficiaries, (3) Estimated growth in real gross domestic product (GDP) per capita, and (4) Estimated change in expenditures due to changes in laws and regulations. CMS has noted that two of the most volatile factors in the above estimates are the fee-for-service enrollments and GDP. Linking Medicare expenditures to GDP growth burdens both the healthcare community and Medicare patients for any economic slowdown.

Further, the SGR as it is calculated does not use the most current figures related to the rising costs of drugs and new technology, the increases in malpractice premiums, and the growth in Medicare utilization over projected amounts. Therefore, the SGR calculated minus 4.3 percent estimate for the 2006 physician fee schedule update does not accurately account for these actual increases in health care provider costs for quality services. For this reason, the AANA supported final passage of the Medicare Modernization Act which called for a plus 1.5 percent payment increase for physician services in 2004 and 2005 rather than the projected cuts as well as an increase in the anesthesia conversion factor. We sincerely appreciate CMS' efforts in implementing the 1.5 percent payment increases as well as an increase of the mean anesthesia conversion factor.

Administrative Reforms to the SGR are Possible

Together with some 90 healthcare associations, AANA wrote CMS Director Mark McClellan, M.D., Ph.D., July 16, 2004, acknowledging that major change in the Part B sustainable growth rate (SGR) formula demands congressional action. However, the letter also highlighted that some adjustments could be made administratively. For instance, CMS could remove drug costs from the SGR calculation. Congress intended the SGR to account for Medicare spending on physician/practitioner services. However, even though drugs are products and not "physician services" as defined in the law, CMS includes the cost of drugs in the SGR. Due to increasing technology and growing demand, spending on these drugs is rising far more rapidly than spending on physicians' and other practitioners' services. Combining the two creates an inaccurate picture of growth in services. Removing drugs from the SGR formula thus is a logical step towards improving the accuracy of the current formula to account for actual practitioner costs.

Further, the current SGR calculation fails to adequately capture the impact of changes to laws and regulations. For example, although Medicare has new screening benefits, the SGR targets do not appear to account for the downstream services that result when screenings reveal health problems. The same is true of the Medicare prescription drug benefit, which will unquestionably lead to more medical visits, thus generating additional

tests and care. The SGR calculations also need to account for this inevitable spending. Additionally, the impact of CMS coverage decisions is excluded from the SGR entirely, even though those decisions significantly influence patient demand. Such changes in law and regulation are likely very beneficial for patient care, but inappropriately result in negative payment updates through the SGR calculation. These suggested adjustments represent clear and decisive steps to resolve some of the inadequacies of the current Medicare reimbursement formula.

As you are aware, beginning January 2006, SGR-driven cuts in Medicare payments will carve a $95 billion, 30-some percent crater out of Medicare provider payments between now and the year 2014. All parties agree that such cuts are unsustainable. One solution is to fix the SGR formula that generates the automatic cuts. We understand the difficulty in taking this action as this fix bumps up against the federal budget deficit, now projected to run some $450 billion per year for some time. We respectfully request that you make these administrative improvements now in order to facilitate congressional efforts to reform the system before 2006.

Additionally, we are also aware that CMS and Congress are rapidly moving forward with plans to institute a Pay for Performance payment system. We understand that under Pay for Performance proposals Medicare Part B providers would be paid according to the quality and efficiency of the services they provide. We appreciate Congress' and CMS' efforts to seek the expertise of professional provider associations in developing quality measures for each specialty. To date, our work with Congressional members and committees in reviewing Pay for Performance (Value-based Purchasing) legislation has meant that CRNAs continue to play a leadership role in shaping legislation and in developing measures specific to anesthesia services. The 33,000 members of the AANA look forward to continued opportunities to extend to CMS our profession's longstanding commitment to improving anesthesia patient safety.

Comment No. 3 – TEACHING ANESTHESIOLOGISTS - Payment Policies for Anesthesia Teaching Services

We welcome the opportunity to comment on the appropriateness of allowing anesthesiologists to receive 100 percent of the fee for involvement in teaching up to two concurrent resident cases. The American Society of Anesthesiologists' (ASA) proposal to change the rules in this way would provide major new incentives to teach anesthesiology residents, and significant disincentives to nurse anesthesia education. Changing the anesthesia teaching rules to further dramatically favor one type of anesthesia provider over another would be harmful to the healthcare system and to patients' access to healthcare services. The AANA respectfully requests that the teaching rules maintain an **equitable balance** between various providers so that the rules do not unfairly advantage one type of provider over another.

Additionally, we believe teaching rules should generally permit Medicare to reimburse for services provided to Medicare patients by student nurse anesthetists so long as the services meet medical necessity and other ordinary criteria, without reduced reimbursements on account of the involvement of a student nurse anesthetist who is already an experienced critical care registered nurse, or an anesthesiology resident. CMS in its payment policies should recognize that the service provided is a whole anesthesia service regardless of the providers involved. At CMS' direction, we would welcome the opportunity for nurse anesthetists and anesthesiologists to work together to develop a consensus proposal to address problems with the anesthesia teaching rules for the general public good.

Inequity in Anesthesia Teaching Rules Already Exists

Currently, teaching CRNAs can bill for base units and actual time, based on the amount of time the teaching CRNA is present with a student nurse anesthetist during each of two concurrent cases. Likewise, a teaching anesthesiologist can bill for base units and actual time, based on the amount of time the anesthesiologist is present with an anesthesiology resident during each of two concurrent cases. (See attached "Anesthesia Teaching Rules Diagrams.")

However, inequity already exits when an anesthesiologist is teaching student nurse anesthetists. Currently, a teaching anesthesiologist can bill for only 50 percent of the fee schedule for each of two concurrent cases involving student nurse anesthetists. Generally, the discontinuous time model is thought to provide larger payments than the medical direction model. Consequently, there is a financial incentive for anesthesiologists to teach anesthesiology residents over student nurse anesthetists and/or to choose the more challenging and many times more financially lucrative procedures for the residents. To graduate from an accredited nurse anesthesia educational program and qualify to take the national certification examination student nurse anesthetists must have specific experience with a wide range of cases with varying complexity. Changing the teaching rules in the way ASA has proposed would thus hinder student nurse anesthetists' ability to get that necessary experience. This preference for teaching residents over student nurse anesthetists continues when a medically directed CRNA is teaching a student nurse anesthetist, the anesthesiologist can bill for 50% of that service under medical direction and the CRNA can bill for 50% of the service. (See attached "Anesthesia Teaching Rules Diagrams.")

Changing the teaching rules so that a teaching anesthesiologist could bill 100% for each of two concurrent cases involving residents further exacerbates the existing gap between teaching student nurse anesthetists and anesthesiology residents. The components of a quality anesthesia service are the same regardless of the type of provider. Likewise, the value of teaching the provision of quality anesthesia services should be the same regardless of type of provider and the type of student.

Faculty Shortage: A Challenge Faced by All Specialties

In the proposed rule, the ASA is cited as attributing "the loss of teaching anesthesiologists and an inability to recruit new faculty" to inadequate Medicare payments. However, the problem of faculty recruitment and retention is faced by all specialties. In the AANA's experience, resolving the challenge of faculty recruitment

and retention requires a much broader, comprehensive approach than changing the teaching payment rules. In fact, rather than increasing the number of anesthesia faculty and anesthesia providers, the proposed change would reduce the number of anesthesia providers by creating further financial disincentives to teach student nurse anesthetists as well as disincentives to involve teaching CRNAs in the anesthesia educational process.

The AANA and nurse anesthesia program directors throughout the country, despite federal funding inequities for allied professional education programs and faculty shortages faced by all specialties, continue to successfully answer the demand for anesthesia providers. The numbers speak for themselves. In 2000, 83 nurse anesthesia programs had been established, and in 2006 it is projected that that number will jump to 105 nurse anesthesia programs throughout the U.S. Likewise, the number of clinical sites in which student nurse anesthetists receive necessary training and experience in the provision of anesthesia and other services has grown from 650 clinical sites in 2000, to 1500 clinical sites projected for 2006. *[Council on Accreditation of Nurse Anesthesia Educational Programs (COA). Annual Report.)]* In 2000, nurse anesthesia programs reported that 1075 student nurse anesthetists graduated from their programs, and in 2006 that number will increase to 2035 graduates. *(Council on Certification of Nurse Anesthetists)* Simultaneously, the COA increased and strengthened the didactic and clinical practice education requirements expected to be met by all accredited nurse anesthesia programs. *(2004 Standards for Accreditation of Nurse Anesthesia Educational Programs)* Further, the findings of a federal manpower study conducted in 1993-94, suggests that nurse anesthesia programs must graduate between 1500 to 1700 students per year to meet the demand for anesthesia providers by 2010. *(*Abt Associates, Inc. *Study: Estimation of Work Force Requirements in Anesthesiology.* September 16, 1994.*)* With over 2000 graduates projected in 2006, nurse anesthesia programs are well on their way to meeting current and future anesthesia demands.

Much of the success of nurse anesthesia programs is due to the AANA's and nurse anesthesia programs directors' commitment to addressing in a comprehensive way faculty recruitment and retention challenges. One way many nurse anesthesia programs

do this is to look to non-CRNA faculty such as from the biology, chemistry and physiology departments at the educational institution in which the program is located, to teach these subjects to the student nurse anesthetists. Additionally, the AANA has initiated faculty development programs that help defray some of the education costs of student nurse anesthetists and CRNAs who wish to become nurse anesthesia faculty members. Without a doubt, being a faculty member is a very challenging job. Nurse anesthesia faculty members site the extraordinary time commitment, university administrative "red tape" and financial difficulties with keeping a program afloat as the reasons why they decline to become faculty or why they return to private practice. Consequently, throughout the year, the AANA sponsors numerous programs that provide valuable insights and guidance on developing and cultivating quality nurse anesthesia programs including grant writing seminars which have helped to bring in additional outside funds into nurse anesthesia programs. However, CRNA education program faculty members report that the number one reason why they remain as faculty is the reward of giving back to their profession by guiding students to become quality anesthesia providers. (Horton, Betty J, CRNA, DNSc; Gerbasi, Francis, CRNA, PhD; Lovell, Sandra, CRNA, MA. *Preliminary data for unpublished study on faculty retention for nurse anesthesia programs.* 2004.) Because of the high demand for anesthesia services and professionals in the United States, more money in and of itself is insufficient to resolve faculty retention problems in healthcare professions.

Relative Benefit of Nurse Anesthesia Education

Given the marketplace demand for nurse anesthetists and the cost benefit of using CRNAs it would be unwise to further promulgate teaching rules that would inadvertently discourage CRNAs from educating future anesthesia providers. (Gunn, Ira P. *CRNA: The Clinical Forum for Nurse Anesthetists.* W.B. Saunders, Publisher: Vol. 4, p 163-171. November 1998.) Based on data gathered from the Texas Higher Education Coordinating Board and the U.S. Department of Health and Human Services' Health Care Finance Administration, the cost of educating a nurse anesthetist is considerably less than the cost of training an anesthesiologist. According to the data it costs an average of $59,000 to educate a nurse anesthetist to provide anesthesia services,

compared to over $635,000 to train an anesthesiologist. (Gunn, Ira P. *Health education costs, provider mix and healthcare reform: A case in point—nurse anesthetists and anesthesiologists*. Journal of the American Association of Nurse Anesthetists. Vol. 64, No. 1. p. 48 – 52, 48. February 1996.) Relative anesthesia patient safety outcomes are comparable among nurse anesthetists and anesthesiologists, with Pine having recently concluded, "the type of anesthesia provider does not affect inpatient surgical mortality." (Pine, Michael MD et al. *Surgical mortality and type of anesthesia provider*. Journal of American Association of Nurse Anesthetists. Vol. 71, No. 2, p. 109 – 116. April 2003.) Similar conclusions have been reached by the National Academy of Sciences in 1977, Forrest in 1980, Bechtholdt in 1981, the Minnesota Department of Health in 1994 and others.

Additionally, we note that the system of teaching rules and graduate medical education already provides the training of anesthesiology residents advantages not enjoyed by the education of student nurse anesthetists. Currently, Medicare pays substantially more to hospitals that operate a Graduate Medical Education (GME) program for training anesthesiology residents than to nurse education programs that educate nurse anesthetists. According to CMS, Medicare made over $9 billion in direct GME payments and IME (indirect medical education) payments combined in 2002 to teaching hospitals. (*Direct Graduate Medical Education (GME) Payment.* CMS Health Care Industry Market Update. Acute Care Hospitals Vol. II, p. 6. November 12, 2002.) Alternatively, each year Medicare payments for nursing and allied health education programs total roughly $250 million. (Lisk, Craig. *Medicare Payments for Nursing and Allied Health Programs.* Medicare Payment Advisory Commission (Medpac): Public Meeting. p. 273-318, 276. April 12, 2001.) Two-thirds of these payments are for nursing education programs, which are paid to just under 300 hospitals. One-third of the payments are for allied health professional training programs that go to approximately 550 hospitals. In essence, Medicare pays nearly $9 billion more for physician training than for nursing education.

Under the GME program a hospital receives Medicare funding calculated for each resident fulfilling his or her residency requirements in that hospital. (42 CFR §415.178,

42 CFR §414.46) Whether the GME program is operated by the hospital or another facility such as a medical school, the hospital will receive the same amount of funding per enrolled resident. Prior to the year 2000 and passage of the Balanced Budget Refinement Act (BBRA), Medicare consistently paid hospitals an estimated $20,000 to well over $100,000 per resident in direct GME funding. (*Adjusting for local differences in resident training costs: study due March 2002.* Medicare Payment Advisory Commission (Medpac). Meeting Brief. December 13-14, 2001.) The BBRA did not specifically call for a gross reduction in GME payments to hospitals, rather it mandated that the variation in hospital payments be reduced.

In contrast, nurse anesthesia programs are primarily funded through tuition and fees paid by student nurse anesthetists. Most students pay for at least a portion of their tuition by taking out loans. Additionally, students and nurse anesthesia programs must often pay fees to clinical sites in which the students gain necessary anesthesia training and experience.

Additionally, under the nursing and allied health education programs Medicare does not provide funding for each student nurse anesthetist who is fulfilling his or her clinical requirements at that hospital. (42 CFR 413.85, 66 Fed. Reg. 3358, January 12, 2001.) For hospitals to receive Medicare funding for a nursing education program, the hospital must operate the program. If the qualifying hospital operates the nursing program, the hospital will receive funding to cover only the "reasonable costs" of operating a nurse anesthesia program. Reasonable costs include basic costs such as the cost of employing a CRNA instructor. For qualifying hospital-based CRNA educational programs Medicare does not provide funding according to the number of student anesthetists working at a hospital, as the GME program does for residents. On account of these constraints, hospitals receive far more in Medicare funding for training anesthesiologists than for educating nurse anesthetists. This added funding under the GME program creates an incentive for hospitals to include a GME anesthesiologist program to the hospital, but creates a disincentive to include a nurse anesthetist program at the same hospital.

CMS' Previous Responses to ASA's Request

As you may recall, in the August 15, 2003, proposed rule for the CY2004 Physician Fee Schedule (68 Fed. Reg. 49030), the American Society of Anesthesiologists requested the following changes to the teaching anesthesiologist payment rules; (1) CMS change the teaching payment regulations so that teaching anesthesiologists would be paid in a similar manner to teaching surgeons (Surgeons can be paid the full fee for each of the two overlapping surgeries involving residents.); (2) the teaching anesthesiologist be able to choose case-by-case whether to seek payment similar to the teaching CRNA or based on medical direction rules; and (3) The teaching payment regulations for teaching anesthesiologists not require the teaching anesthesiologist to participate in the pre- and post-op anesthesia care to obtain full base units.

In answer to ASA's request and AANA comments, CMS in the November 7, 2003, Final Rule (68 Fed. Reg. 63195) denied all three of the ASA's requests. Instead, CMS held that teaching anesthesiologists, like teaching CRNAs, can now bill base units and actual time, based on the amount of time the physician is present with the resident during each of two concurrent cases. CMS clarified that the new policy for teaching anesthesiologists applies ***only*** when there are (1) two concurrent cases, and (2) the cases involve residents so that anesthesiologists cannot simultaneously apply the one-to-two teaching ratio and the one-to-four medical direction ratio. (Allowing anesthesiologists to simultaneously apply the one-to-two teaching ratio and the one-to-four teaching ratio would have resulted in anesthesiologists cherry-picking anesthesia cases. The anesthesiologist could assign his residents to the anesthesia cases that would net more reimbursement funds for the anesthesiologist and assign the medically directed CRNAs to the cases that would net the anesthesiologist and the CRNAs less in reimbursement.) Additionally, CMS in the final rule further clarified that to bill base units, the anesthesiologist ***must*** be present with the resident during the pre- and post- anesthesia care included in the base units.

Last year, in the November 15, 2004, final rule for the CY2005 Physician Fee Schedule (69 Fed. Reg. 66236), CMS denied the American Society of Anesthesiologists (ASAs)

request to change the teaching rules stating that there are inherent differences in the key or critical services between anesthesia and surgical services, and that payment is therefore different for each specialty.

In the alternative, we appreciate the initiative CMS took in 2002, to clarify the rule that allows a non-medically directed CRNA to receive partial payment when the CRNA is involved in two concurrent cases involving student nurse anesthetists. (66 Fed. Reg. 3358, January 12, 2001) Previously, non-medically directed CRNAs were reimbursed for only one case though the CRNA concurrently supervised two cases involving student nurse anesthetists. This rule clarification is an example of a regulation that removes a disincentive for CRNAs to contribute their years of experience in nurse anesthesia with more Student nurse anesthetists as well as to provide more patients with access to quality anesthesia care.

Fiscal Impacts of Offsetting Anesthesiologist's Proposal

As issued by the ASA in 2004, CMS reportedly estimated the cost of the anesthesiologists' teaching rules proposal at $34 million per year *(ASA comment to CMS, 9/3/2004)*. CMS has requested information about options to offset the cost of this proposal. Considering that Part B is a closed system, it is possible to consider the relative impacts of various offsets from within Part B.

The ASA recommended in their comment to CMS (9/3/2004) to offset the expenditure through an across-the-board reduction in the conversion factors for all Part B services. CMS estimates its 2005 allowed charges for all Part B services are $65.8 billion *(69 FR 66235, Nov. 15, 2004)*. The cost of the anesthesiologists' proposal amounts to $34 million / $65.8 billion, or 0.05 percent of all Part B charges. A 0.05 percent reduction from the 2005 Part B conversion factor of $37.8975 would reduce the conversion factor by $0.0189, to $37.8785, and would reduce the 2005 anesthesia conversion factor of $17.76 by 0.9 cents per unit. The impacts of this reduction on all Part B providers, including specialties of internal medicine, family practice, radiology, surgery, emergency medicine and others, would vary based on the volume and intensity of services each

healthcare professional offers to Medicare beneficiaries. The AMA Relative Value Unit Committee (AMA-RUC) process is the one by which physician organizations determine their willingness to reduce their reimbursement in order to benefit one specialty. We are unaware whether the ASA's proposal has been subject to the AMA-RUC process, a process that generally excludes representatives of the nurse anesthesia profession from full participation in its ordinary business. Nor are we aware other medical specialties have expressed willingness to reduce their Medicare reimbursements to benefit certain teaching anesthesiologists on top of CMS' proposed 4.3 percent negative update for 2006.

It is also worth examining the impact of alternative revenue sources, such as from the Medicare anesthesia payment. CMS reports its allowed charges for anesthesiology in 2005 are $1.422 billion for anesthesiology, and $485 million for nurse anesthetists, for a total of $1.907 billion. The mean Medicare Part B anesthesia conversion factor for 2005 is approximately $17.76 per unit (69 FR 66235, Nov. 15, 2004). The $34 million annual cost of the ASA proposal is $34 million / $1.907 billion, or 1.78 percent of all anesthesia charges. Offsetting the cost of the ASA proposal from Medicare allowed anesthesia charges across the board would reduce the 2005 anesthesia CF by 31.66 cents a unit, to $17.44. The costs of this reduction to each anesthesia provider may be estimated applying certain common assumptions. The AANA annual survey of CRNAs reports each CRNA provides a mean 800 cases per year, at a mean of 12 units per case. If 100 percent of that CRNA's cases were personally performed and provided to Medicare beneficiaries, the cost of the ASA proposal offset from anesthesia payment equals 31.66c * 800 * 12 = $3,040 per year. The formula may be prorated for important factors, including Medicare case mix and the propensity to bill cases as medically directed. A common supposition that Medicare might account for one-third of a CRNA's case mix would render the formula as (31.66c * 800 * 12) / 3 = $1,003 per year. In general the same principles apply to reimbursement of CRNAs and anesthesiologists, with the exception that the impacts multiply as anesthesiologists bill medical direction for up to four simultaneous cases.

We do not have reason to question the underlying problem described by the anesthesiologists, that their residency programs are having trouble retaining faculty and maintaining fiscal soundness. However, nurse anesthetists strenuously object to paying up to a thousand dollars or more per year in reduced Medicare reimbursements solely in order to provide increased Medicare reimbursement to certain anesthesiologists teaching medical residents in certain cases. The CMS might further consider whether *anesthesiologists* in general would recoil against such costs being imposed on their own practice in order to provide increased Medicare reimbursement to certain teaching anesthesiologists. To our knowledge, such a question has not been put to the general population of anesthesiologists. It is not unreasonable to conclude the agency cannot reasonably secure acceptance for the teaching policy change recommended by the anesthesiologists if the offsetting spending cut lies within Part B in general, or the anesthesia payment in particular.

We conclude there are problems in the anesthesia teaching rules worth fixing, primarily that they reduce Medicare payment in many instances when safe anesthesia care is being provided to Medicare beneficiaries when student nurse anesthetists or medical residents are involved. The calculations above underscore our general point, that the agency should direct the anesthesiologists and nurse anesthetists to develop a consensus proposal to address problems with the anesthesia teaching rules to the general public good.

Revised Payment Rules for Teaching Anesthesiologists Remain Untested

In the proposed rule, the ASA is cited as stating that it is "not aware of any teaching anesthesia programs that have arranged their practices to meet the conditions necessary to bill under the revised policy." We understand this to mean that anesthesiology teaching programs have not yet tried to use the "discontinuous time model" for payment. Under the discontinuous time model a teaching anesthesiologist can bill for base units and actual time, based on the amount of time the anesthesiologist is present with an anesthesiology resident during each of two concurrent cases. Previously, anesthesiologists could be paid under a medical direction model of only 50 percent of the fee schedule for each of the two concurrent cases. Generally, the discontinuous time model is thought to provide

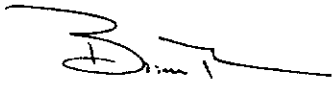
larger payments than the medical direction model. In our view, it seems that it would be beneficial for anesthesiology programs to try to use the discontinuous time model and determine the financial benefit that would result before instituting a more substantial change to the teaching rules that would have a negative impact on nurse anesthesia education and the production of more nurse anesthetists.

Conclusion

We believe when reviewing proposed changes to the current anesthesia teaching rules that CMS should thoroughly examine how changes to the rules on teaching anesthesiologists might impact teaching CRNAs, other providers of healthcare services, and services to Medicare patients. Teaching rules ought to maintain an equitable balance between various providers so that the rules do not unfairly advantage one type of provider over another. Currently, the teaching rules are not equitable in that they provide benefits and incentives to anesthesiologists and resident anesthesiologists that are not made available to teaching CRNAs or to student nurse anesthetists.

We thank you for the opportunity to comment on the proposed rules. Should you have any questions regarding these matters, please feel free to contact the AANA Director of Federal Government Affairs, Frank Purcell, at 202.484.8400.

Sincerely,

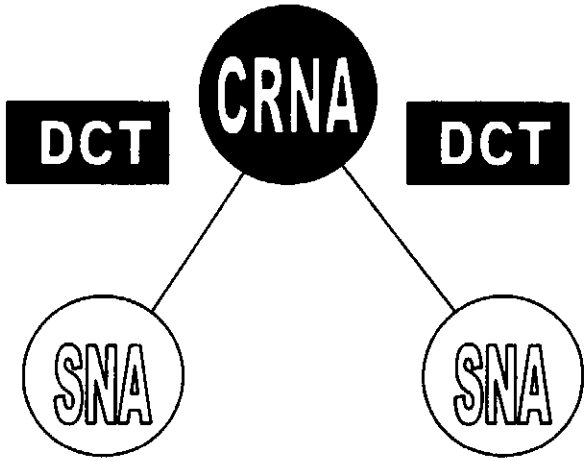


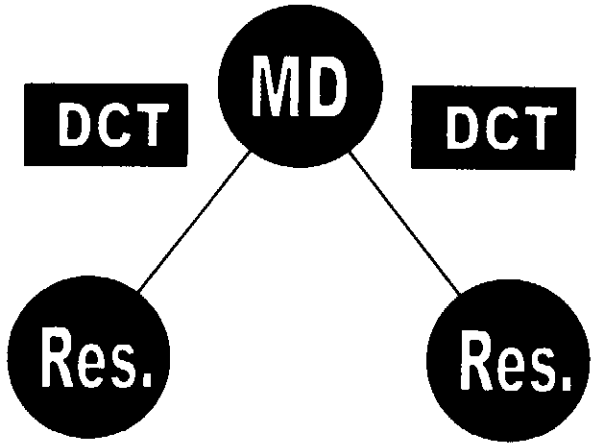
Brian D. Thorson, CRNA, MA
AANA President

cc: Jeffery M. Beutler, CRNA, MS, AANA Executive Director
Frank Purcell, AANA Director of Federal Government Affairs

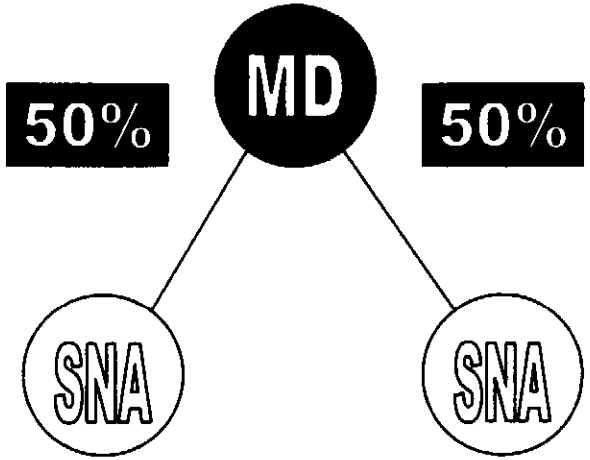
Anesthesia Teaching Rules Diagrams

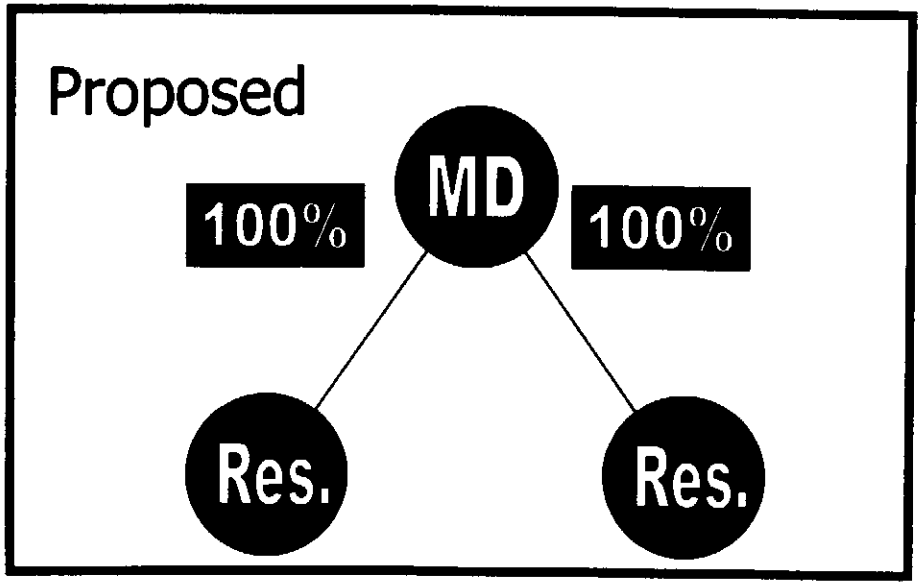
CURRENT





[Discontinuous time (DCT) = time w/ SNA (student nurse anesthetist)/Res.(resident) or w/ the patient, and is > 50% payment.]





911

Congress of the United States
House of Representatives

September 28, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

To whom it may concern:

We understand Medicare is collecting information on the teaching physician policy for anesthesiologists as part of its 2006 Part B update proposed rule (70 FR 45789, 8/8/2005). In the interest of securing beneficiaries' access to safe anesthesia care, we have significant concerns with changes that would exacerbate inequities in how the Medicare system treats teaching Certified Registered Nurse Anesthetists (CRNAs) and anesthesiologists, and ask that changes be developed by a consensus process involving both types of anesthesia professionals.

Each year since 2003, CMS has been presented a proposal to change the anesthesia teaching rules so that teaching anesthesiologists would be paid in a similar manner to surgeons, establishing major new incentives to teach anesthesiology residents, and significant disincentives to teach nurse anesthetists. Educating anesthesia professionals is important, and we appreciate CMS' continued consideration of this issue. However, changing the anesthesia teaching rules to further dramatically favor one type of anesthesia provider over another would be harmful to the healthcare system and to patients' access to healthcare services. Such teaching rules ought not unfairly advantage one type of provider over another, an outcome that would impede Medicare beneficiaries' access to safe anesthesia care, especially in rural and medically underserved areas.

So that patients anywhere in the country will continue to have access to the safe anesthesia care that they need, we are requesting that CMS work with both nurse anesthetists and anesthesiologists in developing a consensus proposal to address issues in the anesthesia teaching rules.

Sincerely,

Melissa A. Hart

Bart Stupak

Thelma Drake

Ron Lewis

Sherrod Brown

Jerry V. Costello

Dave Hobson

Rosa L. DeLauro

Lois Capps

Chris Chabot

Stephanie Tubbs Jones

Ted Strickland

Mike D

J. Anderson

Mary Bono

Carolyn McCarthy

Melissa A. Hart
Member of Congress
4th District (Pennsylvania)

Thelma Drake
Member of Congress
2nd District (Virginia)

Phil English
Member of Congress
3rd District (Pennsylvania)

Sherrod Brown
Member of Congress
13th District (Ohio)

Dave Hobson
Member of Congress
7th District (Ohio)

Lois Capps
Member of Congress
23rd District (California)

Stephanie Herseth
Member of Congress
At-Large (South Dakota)

Mike Doyle
Member of Congress
14th District (Pennsylvania)

Mary Bono
Member of Congress
45th District (California)

Bart Stupak
Member of Congress
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Maurice Hinchey
Member of Congress
2nd District (Kentucky)

Ron Lewis
Member of Congress
2nd District (Kentucky)

Jerry V. Costello
Member of Congress
12th District (Illinois)

Rosa DeLauro
Member of Congress
3rd District (Connecticut)

Chris Chocola
Member of Congress
2nd District (Indiana)

Ted Strickland
Member of Congress
6th District (Ohio)

Jay Inslee
Member of Congress
1st District (Washington)

Carolyn McCarthy
Member of Congress
4th District (New York)

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SUITE 220
TUCSON, AZ 85704
(520) 575-8633

912

September 26, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
314G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

File code: CMS-1502-P
Issue identifier: Teaching Anesthesiologists

Dear Dr. McClellan:

Enclosed you will find information from the American Society of Anesthesiologists and the Arizona Society of Anesthesiologists in relation to the current payment policy for the Medicare anesthesiology teaching rule. Academic anesthesiologists from my state have spoken with me about their reimbursement system, which I believe merits further review.

It appears to me that the current practice of reducing the reimbursement for anesthesiologists who supervise two medical residents in overlapping to 50 percent for each case is problematic in the short term for the residency programs, and over time, contributes to the shortage of anesthesiologists in private practice. The safety and quality of services rendered to Medicare beneficiaries are always the primary concern, and I hope CMS will maintain the highest standards in these areas while also paying physicians appropriately.

I have also heard from the nurse anesthetists and want to ensure that a disincentive to train certified registered nurse anesthetists (CRNAs) is not created through any changes to the anesthesiologist reimbursement proposals. I ask you to consider the comments I have enclosed, and work towards a proposal with the American Society of Anesthesiologists and the American Association of Nurse Anesthetists to address the problems in the 2006 Physician Fee Schedule Payment Rule.

I expect no action to be taken on this matter which would be inconsistent with existing rules and regulations. As always, I thank you for your leadership and look forward to hearing from you.

Sincerely,

Jon Kyl

JON KYL
United States Senator

SEP 2005

913

Mrs. James L. Mason
59 Aspen Meadows Circle
Santa Rosa, CA 95409

To: The Center for Medicare & Medicaid Services

my Husband and I are 81 years and we appreciate receiving the benefits given by Medicare for us.

We have lived in Santa Rosa almost 21 years and we have watched as many good physicians have moved to a more realistic re-imbursement by Medicare community. They still are moving and many who remain are refusing new Medicare recipients in Sonoma County California.

Santa Rosa is no longer as rural and certainly not as rural as Napa County which is given a higher fee. Thank

Mrs. James L. Mason

SEP 2005 914

Santa Cruz County Medical Society

September 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: "GPCIs"

I am writing on behalf of the Santa Cruz County Medical Society in response to the proposed rules (70 FR 45783) regarding Medicare physician payment localities and GPCIs. Our medical society is in support of the proposed rules to remove Santa Cruz and Sonoma Counties from Locality 99.

In 1997, HCFA applied a 5 percent threshold to existing localities to consolidate them into comparable cost areas creating our current national physician fee schedule structure (61 FR 59494). The intent of current Medicare law is to reimburse providers according to the cost of providing services, make adjustments for geographic differences in those costs, and distribute payments accordingly. In 1997, based on Santa Cruz County Geographic Adjustment Factors [GAFs], Santa Cruz County should have been placed in its own payment locality. Instead of applying the 5% iterative rule using county costs as the unit of comparison, HCFA averaged the cost of providing care between Santa Cruz County and San Benito County. Due to this oversight, Santa Cruz County was placed in Locality 99.

In 1996, HCFA chose between multiple options presented by Health Economics Research, Inc. Option 1i, 5-percent threshold, was chosen. Under this option, payment localities from 1996 were used as the building blocks for creating revised payment localities. Presumably, this was the rationale for treating Santa Cruz County and San Benito County as a combined unit, rather than examining their county-specific GAFs. However, in the same final rules (61 FR 59494), when examining subcounty localities, HCFA stated, "We proposed to use counties as the basic locality structure...Using counties as the basic locality unit provides a national uniform physician fee structure." It is problematic that CMS decided to utilize larger units than counties when considering Santa Cruz and San Benito counties but CMS utilized county-specific costs in most other circumstances. This seems as if it were either an arbitrary decision or an oversight on the part of HCFA.

Since 1997, Santa Cruz County has been the most negatively impacted county in the country from this misapplication of the 5% iterative rule. The damage to access to care in our county is significant. As the demographics in our State have changed, particularly with the growth of Silicon Valley, our cost of providing care has increased dramatically.

1595 Soquel Drive, Suite 340 Santa Cruz, CA 95065 (831)479-7226 Fax(831)479-7223

SEP 2005

September 27, 2005

Centers for Medicare + Medicaid Services
Department of Health and Human Services, CMS-1052-P
PO Box 8017
Baltimore MD 21244-8017

Dear Centers,

I live in Mendocino County and have to drive two hours to Sonoma County to see specialists for

Cardiology
Dermatology
Endocrinology
Gastroenterology
Gynecology and
Opthamology

Unless Sonoma County County, California physicians are given added reimbursement, I will have to drive even further to Marin County, which will necessitate an overnight stay with hotel and restaurant costs.

Please increase the reimbursement in Sonoma County, California.

Sincerely,
Dr. Vivian Green
Dr. Vivian Green

PO Box 575
Gualala, CA 95445

SEP 30 2005 916

Sutter Santa Cruz

A Sutter Health Affiliate

2025 Soquel Avenue
Santa Cruz, CA 95062

September 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: "GPCIs"

Dear Sirs:

I am writing on behalf of the Sutter Health affiliates in Santa Cruz County, California in support of the August proposed rule. I represent a licensed acute care hospital, the Sutter Maternity and Surgery Center, a home health agency (the Visiting Nurses Association of Santa Cruz), and the Santa Cruz health care division of the Palo Alto Medical Foundation, which consists of 130 providers (physicians, podiatrists, audiologists, nurse practitioners, physical and occupational therapists, optometrists, and speech pathologists).

My perspective is unique because of the varied components of my organization. I have addressed CMS staff in person on numerous occasions and have been most appreciative of the openness of CMS in sharing source documents and in being receptive to our suggestions when we have had differing views of this issue.

In general, I feel that the proposed rule is an extraordinarily positive statement by CMS on many levels. It demonstrates true and courageous leadership addressing a long-standing and divisive issue.

The following is how I sense that different stakeholders view this issue:

<u>CMS</u>

The 1996 rule that reconfigured the pre-existing 210 localities into the current 89 localities was flawed. The pre-existing localities, which had been originally configured in the 1960s, formed the basis for the 'new' localities. Three states (MA, PA, and MO) had slight changes made to those localities. CMS should have applied the iterative 5% rule to individual counties in each state rather than to the pre-existing localities. Further, CMS should have not paved the way for ongoing disputes between providers, CMS, Congress, beneficiaries, and state medical societies by requiring future locality revisions to be directly linked to the wishes of physician professional organizations. CMS has not revised any localities since 1996 and is well aware at this time that the locality problem is in need of substantial reform.

The August rule acknowledges for the first time that CMS bears the ultimate responsibility for managing physician fee schedule areas. It is ironic that Congress has delegated to CMS the

mandate to do so and, after nine years of inaction by CMS, that many representatives from California are in opposition to the proposed rule.

CMS appropriately selected the most problematic region in the nation (the SF Bay Area) and appropriately proposed a rule change, which would have a negligible impact on the remaining counties within California's locality 99. The current leadership of CMS deserves credit for addressing a problem whose origins date to first years of Medicare.

CMS must work with Congress, MedPAC, and provider organizations to create a long-term solution to this problem. It is important that CMS acknowledge that the two-county CA solution is the first step in a broader and more comprehensive solution to the fee schedule area problem.

Multi-locality Versus Single-locality States

It is prudent at this time to concentrate on payment discrepancies in multi-locality states prior to resolving such disparities in single-locality states. Large "Rest-of State" localities in multi-locality states redistribute dollars from high cost counties to lower cost counties. This also occurs in single locality states. However, in large heterogeneous states such as Texas and California this redistribution of payments from urban to rural areas is inconsistent. Santa Cruz and Sonoma currently support payments to rural CA counties. The urban localities in the SF Bay Area do not. Revisions to the current localities when instituted as you have proposed in an incremental manner must begin in those multi-locality states with the largest payment discrepancies.

The locality problem (commonly referred to as the "GPCI problem") is nevertheless a national problem. Broader solutions to these issues on a national level will certainly arise from Congress. We applaud the leadership of CMS for initiating the solution in the most problematic multi-locality state, California.

CMA

The CMA has unfairly been delegated the authority to craft a CA solution. The 2004 CMA proposal was widely praised but apparently was inconsistent with how CMS interprets its authority to institute changes to payment localities. The CMA will respond to CMS' request for response to the proposed rule by recommending for a legislative solution to the problem. CMA had no other choice but to decline to directly comment on the two-county proposal. CMA's silence on the two-county proposal should not be interpreted as non-support but rather a statement that this state medical society is no longer willing to be inappropriately designated as the decision-maker in a matter of federal policy. The CMA knows full well that it is an important voice as it represents half of California's physicians. It also is aware that it does not represent a dozen or so of the other types of providers eligible to bill CMS for services to Medicare beneficiaries.

CMS must develop a process for future revisions that no longer necessitates that state medical societies must initiate and approve any proposed changes to fee schedule areas. CMS must clearly identify the process for these revisions and they should be automatically applied at each three-year recalculation of the GPCIs.

California County Medical Societies

CMS will receive very positive responses from Sonoma and Santa Cruz Counties' Medical Societies. It will also receive mixed responses from other county professional societies. If the

proposed rule had clearly identified that the two county proposal was meant to establish a process that would precede the necessary development of a process that would guarantee to other CA counties then you would received congratulatory comments rather than comments engendered by the divisiveness of the current process. The comments that you received from the Santa Barbara County Medical Society are the most thoughtful and incisive that you will receive. It is important to note that Santa Barbara County represents a "losing" county as defined by the CMS 1996 rule.

The California Delegation

The 2004 CMA proposal was widely applauded by the CA delegation. The two-county proposed rule has understandably elicited a more polarized response. Congress has imposed on CMS the requirement to manage fee schedule areas under the constraints of budget neutrality. We applaud the comments of Senator Boxer, as the only statewide federally elected official, who supports the two county proposal. Members of House who oppose your proposed rule should redefine the rules established by Congress that have tied the hands of CMS and the CMA over the past ten years rather than decry the first locality revision proposed by CMS in a decade.

Other Providers

CMS chose not to implement the CMA 2004 proposal as a demonstration project because of its effect on non-physician providers. CMS has acknowledged the fact that the CMA should really only have input on fee schedule changes as they relate to changes in payments to its member physicians. CMA does not represent the majority of types of licensed providers that currently provide services to Medicare beneficiaries. These include: speech pathologists, occupational therapists, physician therapists, licensed clinical social workers, clinical psychologists, optometrists, physical therapists, audiologists, optometrists, nurse practitioners, and physician assistants. CMS should consider the responses to this rule from state medical societies acknowledging that organized physicians groups must not be inappropriately empowered by CMS to overrule proposed rule changes that affect these other types of providers.

Beneficiaries

CMS will hear from many beneficiaries who receive care in Sonoma and Santa Cruz Counties. Access is eroding in these two counties as more and more providers re-locate to adjoining counties. The boundary discrepancies between Sonoma and Marin Counties, and between Santa Cruz and Santa Clara Counties, have real and deleterious effects on the beneficiaries of our two counties. It is incomprehensible to our beneficiaries why this decision is controversial. It is well understood that the proposed rule would decrease payments to the providers in the remaining 47 counties in Locality 99 by considerably less than 0.1%. This actually translates to less than two cents for a 99213 established office visit.

MedPAC

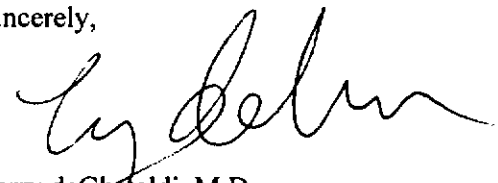
MedPAC is analyzing this problem from a national perspective. MedPAC and Congress are considering revisions either based on the 5% (or other) threshold applied to all counties or to a transition to MSA-based physician payment localities congruent to the hospital-based localities currently utilized by CMS. CMS should acknowledge that this issue is widely recognized to be substantive and unlikely to be resolved by the two-county proposal. It would be to CMS' credit if it were to implement the two-county proposal AND to express a willingness to work with all stakeholders to develop a comprehensive solution to this issue during 2006.

Santa Cruz County

Since 1999, this county has been the most disadvantaged county in California's Locality 99. It has persistently had the highest boundary payment between it and adjoining counties in the nation. And, it has led the debate on identifying the problem and in the creation of an equitable and comprehensive solution. The 2004 proposed rule, which assigned the highest GAFs to Santa Clara and San Mateo Counties in the nation, exacerbated our problem. Our northernmost incorporated city, Scotts Valley, has two dozen primary care providers. It is situated less than seven miles from Silicon Valley (Santa Clara County) where providers receive 24% more for the same services. Acknowledging this fact as the basis for the proposed rule, and why a solution must begin in Santa Cruz County and why it must begin in 2006, brings credibility to CMS.

Thank you for working with our providers and our beneficiaries in bringing this important issue to a resolution,

Sincerely,



Larry deGhetaldi, M.D.
Sutter Santa Cruz CEO
President SC Division Palo Alto Medical Foundation

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SEP 2005 917

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sbecker@mcguirewoods.com
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September 28, 2005

VIA U.S. PRIORITY MAIL
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: Diane Milstead and Gaysha Brooks, CMS-1502-P
P.O. Box 8017
Baltimore, Maryland 21244-8017

Re: NUCLEAR MEDICINE AND POSITION EMISSION TOMOGRAPHY SERVICES

Dear Ms. Milstead and Ms. Brooks:

Upon review of the comments relating to nuclear medicine services set forth in the Federal Register, Volume 70, Number 151, p. 45854, published August 8, 2005, we feel compelled to address what we believe are problematic aspects of the commentary. The Centers for Medicare & Medicaid Services ("CMS") proposes to categorize nuclear medicine services and positron emission tomography ("PET") as designated health services. We would discourage the outright designation of such services as designated health services for several reasons and suggest reasonable alternatives to the immediate designation of such services.

First, the propensity of CMS to tie physician investment and increased referrals to financial incentives does not take into account the various factors that drive physician use of improved technology. Notably, CMS fails to consider the correlation of increased usage to advances in technology and leading thought on disease diagnosis and treatment. In its commentary, CMS acknowledges that technological improvements have been made with respect to nuclear medicine and PET scanner services and also notes its expanding Medicare coverage of such services. However, CMS accepts as dispositive that increased referrals to physician-owned entities which provide such services are due to financial incentives rather than the improved services and diagnosis achieved by utilizing better equipment. The failure of CMS to consider the potential correlation of increased usage and improved technology may ultimately have a negative impact on the future provision of quality health care as physicians may hesitate to invest in new technology or services for fear that CMS will ultimately decide to prohibit such investment.

CMS' commentary does not provide examples of the extent to which advances in nuclear medicine and PET scan services have improved the quality of care and drive physician decision-making. However, examples exist which support the claim that increased

referrals for such services are not based on financial incentives. For example, oncologists are using PET scanner technology to identify and localize cancers. In the case of nuclear medicine services, certain types of scans which today are used to measure how the stomach empties its contents for patients with gastorparesis were not typically used in a gastroenterologist's practice a mere five years ago. Such scans allow for better diagnoses and avoid invasive procedures. Accordingly, increased referrals for PET scans or nuclear medicine services by oncologists and gastroenterologists, respectively, are often not indicative of overutilization but rather indicate the effective utilization of new or improved technology to treat or diagnose traditional problems. Again, the propensity of CMS to correlate physician investment to increased referrals, while an easy correlation to draw, is not accurate and does not take into account the full picture of improved technology and patient care.

Second, patient care has improved due to physician investment in entities providing nuclear medicine and PET services. Specifically, the ability to invest in new technology and bring such technology to use has led to improved diagnostic and treatment ability. As scans today provide greater clarity in images, specialists have been able to utilize nuclear medicine and PET scan services for purposes never previously considered. This results in lower costs and improved patient care.

Third, not only does physician investment in entities providing nuclear medicine and PET scan services lead to better quality care at a lower cost, physician investment in such entities has also allowed for increased access to such services. Specifically, nuclear medicine and PET scan services that were not otherwise available to certain patient populations have been made available because of provider investment in nuclear medicine and PET scan services. Nuclear medicine and PET scan services require more expensive equipment than traditional radiology services and therefore physician investment in such equipment fills a necessary gap where large health care providers have been unable to afford such equipment or choose not to acquire such equipment. Accordingly, to the extent large health care providers decide not to invest in or cannot afford to invest in such equipment, physician investment in such equipment has filled the gap.

In the alternative, if CMS decides that is in the best interest of the current and future patient population to categorize nuclear health services and PET scan services as designated health services, we encourage CMS to set forth an extensive grandfather provision in the new rule which will allow physician investors in entities currently performing nuclear medicine and PET services to continue referring to such entities.

In conclusion, we ask that you strongly reconsider categorizing nuclear medicine and PET services as designated health services. We encourage CMS to consider that studies regarding increased usage to which it cites its commentary is also a function of improved technology and better diagnostic and treatment modalities which ultimately improve the quality of patient care. Moreover, in situations where treatment or diagnostic modalities are expensive or require the specific skill of a trained expert such as in the case of nuclear

medicine and PET services, physician investment can help bring new technology to areas which otherwise would not have access. Finally, to the extent that medical technology is constantly evolving and changing, we urge that CMS alter its pattern of retroactively prohibiting physician investment in new technology and services. This pattern of retroactively prohibiting the latest technology or service growth area will dampen the spirit of innovation in the provision of quality patient care and may inhibit the ability to provide the highest quality care. If this pattern continues, physicians will hesitate to make the investments needed to continue to provide high quality care for fear that CMS will ultimately determine that such investments present fraud and abuse risks.

Should you have any questions regarding the above, please do not hesitate to contact me at (312)750-6016.

Very truly yours,

Scott Becker

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SEP 2005 918

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Chief Executive Officer
Christine W. McEntee

September 29, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1502-P
P.O. Box 8017
Baltimore, MD 21244-8018

Dear Dr. McClellan:

The American College of Cardiology (ACC) is a 30,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled **Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 [CMS-1502-P]** published in the **Federal Register** on August 1, 2005. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

Practice Expenses

CMS has proposed a significant change in its methodology for calculating practice expense RVUs. If provisions outlined in the proposed rule are implemented, the direct practice expense portion of the RVUs will be calculated on the basis of the CPEP/PEAC direct practice expense inputs alone. CMS notes that one of its goals in implementing this change is to develop a practice expense methodology that is clear and more intuitive. However, CMS has not released enough data or provided enough detail about the new method described in the proposed rule for physicians and other stakeholders to gain a thorough understanding of how the RVUs will be determined. We urge CMS to provide a more data and a more detailed explanation, along with examples of how RVUs for specific codes were determined.

Supplemental practice expense data

The Balanced Budget Refinement Act of 1999 (BBRA) directed HHS to establish a process for integrating supplemental data into the practice expense component "to the maximum extent practicable and consistent with sound data practices." CMS subsequently established through a rulemaking process standard criteria for the submission and acceptance of supplemental practice expense survey data. These criteria are rigorous and are designed to ensure that specialty supplemental surveys are comparable to the SMS survey, nationally representative of the specialty, and of adequate precision. In addition, by requiring that surveys be conducted by independent contractors with data submitted directly to CMS's contractor, the criteria ensure that specialties cannot manipulate the survey process or data analysis. CMS makes the results of the contractor's analysis available to the public on its website. Given the rigorous and detailed analysis CMS's contractor has conducted on the supplemental surveys, these data are very likely superior to the SMS data that have been used to calculate practice expense RVUs.

The ACC believes that CMS's acceptance of the supplemental practice expense survey data meeting the published criteria has been an important component of efforts to refine the resource based practice RVUs. CMS has asked for comments on issues related to appropriate determination of indirect costs for all specialties. An SMS-type survey of all specialties that meets the criteria for reliability and representation that CMS has imposed on the supplemental surveys might be the gold standard for gathering these data. However, unresolved questions about who would fund and conduct such a survey mean that it could not occur soon. For the near term, we believe CMS must use the best data available now. Therefore, we recommend that CMS incorporate the supplemental data already submitted and accepted and that CMS continue to accept, evaluate, and incorporate additional supplemental surveys.

The College is pleased that CMS has incorporated the supplemental practice expense survey data submitted for cardiology and the other specialties that submitted data consistent with the acceptance criteria. Like other specialties that submitted data, the cardiovascular physician community (encompassing the ACC, the American Society of Echocardiography, the American Society of Nuclear Cardiology, the

Heart Rhythm Society, and the Society for Cardiovascular Angiography and Interventions) invested significant resources to conduct its supplemental survey. Cardiology undertook the project with no guarantee the data would meet the criteria for acceptance and, if accepted, would result in changes favorable to cardiology. The process for submitting, evaluating, and incorporating supplemental practice expense data exemplifies the strong, effective public-private cooperation that has been so important to the ongoing improvement of Medicare's RBRVS. We believe it is essential that CMS continue to engage in good faith efforts with both the physician community as a whole and with individual specialty societies to obtain the data necessary to support the physician fee schedule.

However, the ACC did note some confusion about the practice expense per hour figures CMS actually used to calculate the proposed practice expense RVUs. Specifically, it is not clear whether all specialties' supplemental data were deflated to 1995 levels in a consistent manner. The following table compares the practice expense per hour figures listed in Table 14 of the proposed rule, Table 14 of the September 1 correction notice, and the Lewin reports on supplemental data for 2005 and 2006.

	Practice Expense Per Hour		
Specialty	**Table 14 NPRM**	**Table 14 Correction Notice**	**Lewin Reports**
Radiology	96.3	136.7	159.41
Cardiology	156.3	184.3	215.15
Radiation Oncology	128.3	138.0	145.88
Urology	121.7	163.2	163.18
Dermatology	152.1	212.5	212.49
Allergy/ Immunology	179.6	233.7	233.67
Gastroenterology	85.00	133.2	133.03

The comparison shows substantial differences among the practice expense per hour figures from the Lewin report for radiology, cardiology, and radiation oncology, Table 14 of the Proposed Rule and Table 14 in the Correction Notice. Practice expense per hour figures for urology,

dermatology, allergy/immunology, and gastroenterology, however, are the same in the Table 14 Correction Notice and the Lewin report. We also note that the practice expense per hour figures for urology, dermatology, allergy/immunology, and gastroenterology that were published in the Proposed Rule were lower than the figures published in the correction notice. One possible explanation is that CMS failed to adjust the data from some of the specialties to 1995 levels, while the other supplemental data were adjusted. It is also possible that the discrepancies among Table 14 (Correction Notice), Table 14 (Proposed Rule), and the Lewin report data reflect only printing errors. The ACC strongly urges CMS to investigate these discrepancies, correct any errors, and publish a correction as soon as possible.

Remote Cardiac Event Monitoring Services

The ACC is concerned that the practice expense RVU reductions proposed for remote cardiac event monitoring services (CPT codes 93012, 93226, 93232, 93271, 93733 and 93736) may have a serious negative impact on patient access to these important services. Remote cardiac event monitoring services differ from most other services on the physician fee schedule in ways that limit the ability of the practice expense methodology to adequately capture costs. A facility or physician practice providing these services must have the infrastructure to provide monitoring capability 24 hours a day, seven days a week. The practice expense methodology is designed to capture the costs of services centered on a specific physician-patient encounter. The costs associated with around the clock availability of equipment and highly trained personnel do not fit well into this model. The ACC recommends that CMS examine this issue and work closely with the involved provider community to ensure that direct and indirect costs are adequately reflected in the practice expense RVUs for cardiac event monitoring services.

Cardiac PET Studies

Addendum B of the proposed rule includes no practice expense RVUs for CPT 78491 (Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress) and CPT 78492 (Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest or stress) in either the facility or non-facility setting. The

ACC believes the omission of practice expense RVUs for 78491 and 78492 is an error. We urge CMS to publish the proposed RVUs for these two codes in a correction notice as soon as possible.

Supply and Equipment Items Needing Specialty Input
CMS requested specialty input on a number of supply and equipment items. Several of those items identified in Tables 18 and 19 of the proposed rule indicate that cardiology is the primary specialty associated with the supply or equipment. The ACC is aware of CMS's need for assistance. We are currently gathering the necessary information, but the data are not available yet. We will provide the information to the appropriate CMS staff as quickly as we can.

Multiple diagnostic imaging procedure reduction

CMS proposes to reduce payment for some multiple diagnostic imaging procedures provided during the same session. Specifically, CMS asserts that when multiple imaging procedures using the same modality are performed on contiguous body parts some clinical labor, supply, and equipment costs overlap. CMS therefore plans to reduce the technical component payment for the second and any subsequent procedure within each of 11 families of imaging procedures by 50 percent. The proposed rule states that CMS based this decision on an analysis of the direct practice expense inputs used to establish the resource based practice expense relative value units. CMS also notes that a similar multiple procedure payment reduction is in effect for surgical procedures.

By focusing the proposed payment reduction for multiple diagnostic imaging services only on the technical component, CMS does correctly recognize that the physician work associated with imaging services – that is, interpreting the image(s) and writing a report – does not decrease when more than one procedure is performed. For surgical services, physician work decreases significantly when more than one procedure is performed because much of the physician work included in the payment for a surgical procedure stems from pre- and post-procedure evaluation and management services that occur during the global surgical period. Most of the physician practice expenses associated with surgical procedures, particularly those not performed in the physician office, are also associated with those pre- and post-surgical evaluation and management services. It may not be unreasonable, then, to assume that since pre- and post-procedure E&M services are not increased substantially when an additional surgical

procedure is performed during the same operative session, a significant payment reduction is therefore appropriate.

The ACC believes, though, that CMS has erred in assuming that the same payment reduction for practice expenses for multiple surgical procedures should be applied to practice expenses (i.e., the technical component) of multiple diagnostic imaging procedures. There is no global package associated with diagnostic imaging services. The pre- and post-procedure activities and resources provided to patients undergoing diagnostic imaging procedures are typically not as extensive as those required for surgical patients. Therefore, the costs associated with pre- and post-service activities are likely to comprise a much smaller portion of the payment for diagnostic imaging procedures than for surgical procedures. Consequently, it is unclear to us that extension of the multiple surgical procedure payment reduction to the technical component of multiple diagnostic imaging services is appropriate.

To determine whether CMS's assertion that the direct practice expense input data used under the physician fee schedule do indeed support the proposed 50 percent reduction in technical component payments, the ACC conducted its own analysis of the clinical labor, supply, and equipment inputs associated with the CPT codes within Family 2 (CT and CTA of Chest/Thorax/Abdomen/Pelvis) and Family 4 MRI and MRA of Chest/Abdomen/Pelvis). Results of that analysis follow.

Clinical labor

CMS identified the following activities as those are not repeated when multiple imaging services are performed during the same session:

- Greeting the patient
- Positioning and escorting the patient
- Providing education and obtaining consent
- Retrieving prior exams
- Setting up the IV
- Preparing and cleaning the room.

According to the process the Practice Expense Advisory Committee (PEAC) established for determining clinical labor time, the activities CMS enumerates as not repeated occur during the pre- and post-service periods. Our analysis of the

direct practice expense inputs found that, within Family 2, clinical labor costs associated with pre- and post-service activities average 0.99percent of total direct practice expenses. Pre- and post-service clinical labor account for a mean of 0.65percent of direct practice expenses for the codes in Family 4. Clearly, these data document minimal clinical labor cost savings when multiple procedures within Families 2 and 4 are performed during the same session.

Supplies

The proposed rule also outlines CMS's assumption that additional supplies, with the exception of film, are not used when more than one imaging procedure within a family is performed. If this were the case we would expect to see little variation in supply costs within a family since supplies of the same type and in the same amount would be used for each procedure. Examination of the practice expense data for Family 2 shows that supply costs range from a low of $10.36 for CPT 74150 to a high of $55.88 for CPT 75635. Within Family 4, supply costs range from $12.02 for 72195 to $28.62 for 72197. The variation suggests that, although certain basic supply items (for example, patient gowns, gloves, and examination table paper) are used for all the procedures within a family, some procedures do require additional, more expensive supplies. However, even CMS's assumption that no additional supplies other than film would be required to perform an additional procedure were valid, actual savings on supplies would be small. Supplies account for an average of 7percent of direct practice expenses in Family 2 and 4percent in Family 4.

Equipment

The cost of purchasing and maintaining expensive medical equipment accounts for the vast majority of practice expenses associated with diagnostic imaging procedures – an average of 83percent of total direct costs in Family 2 and an average of 89 percent in Family 4. CMS states in the proposed rule that "equipment time... [is] allocated on the basis of clinical staff time and... should be reduced accordingly." Since, as noted above, the clinical staff activities CMS identified as those not duplicated when multiple procedures are performed account for a very small proportion of clinical staff time for the procedures in Families 2 and 4, it seems unlikely that equipment time and, thus, equipment cost would be reduced significantly.

The ACC acknowledges that some savings in physician practice expenses may be achieved when multiple diagnostic imaging procedures are performed on contiguous body parts. However, our analysis of the same data CMS used to

support its decision leads us to conclude that an accurate estimate of the savings in the physician office setting would fall far below 50 percent.

The Practice Expense Advisory Committee (PEAC) invested considerable effort in establishing standard times for common clinical staff activities (e.g., greeting the patient, cleaning the room), as well as basic supply packages for similar types of services. Analysis of these standard times and supply packages might provide a more valid basis for a multiple diagnostic imaging payment reduction than does application of a policy developed for surgical services. We urge CMS to conduct a more careful analysis of this issue before implementing a policy that may significantly affect physicians' ability to provide diagnostic imaging services in the office setting.

Nuclear Medicine Services and Supplies

CMS proposes to include nuclear medicine services and supplies in the definition of radiology services subject to the Stark restrictions on physician referral. If implemented, the designation would mean that physicians could no longer refer patients for nuclear medicine supplies and services to facilities with which they or family members have a financial relationship.

The ACC neither supports nor opposes the revision of the definition of radiology services to include nuclear medicine services and supplies. We were pleased to note that CMS has stated that exemptions for in-office ancillary services and rural areas remain in force and will, of course, apply to nuclear medicine services. Maintaining the in-office ancillary exemption is essential to maintaining Medicare patients' access to high-quality, efficient imaging services.

CMS also acknowledges that its previous guidance on this issue may have led physicians to invest in nuclear medicine facilities. Physicians who, in good faith, entered into currently legal business arrangements with facilities providing nuclear medicine services should receive some consideration in implementation of this policy change. The regulatory timeline for the physician fee schedule does not provide adequate advance notice for physicians to divest themselves of what may be very complex business relationships and to arrange alternative sources of care for their patients. The ACC encourages CMS to provide either an exemption or delayed effective date for arrangements already in place when the proposed rule was published.

The College is troubled by the assumption underlying CMS's justification for including nuclear medicine services under the self-referral prohibition: that rising volume of imaging services reflects inappropriate overutilization motivated by physicians' financial self-interest. We disagree. There are multiple, complex factors affecting the growth in the volume of imaging services under Medicare Part B. These include, among others:

- Advances in imaging technology
- Substitution of non-invasive diagnostic imaging tools for invasive diagnostic procedures
- Changing Medicare beneficiary demographics
- Movement of imaging procedures from the hospital to the outpatient setting.

The ACC is a founding member of the Coalition for Patient Centered Imaging (CPCI), a group of professional medical specialty organizations that has joined together to ensure patient access to high quality, timely, and effective in-office imaging services. Please refer to CPCI's comments on the proposed rule for a more detailed discussion of the factors affecting utilization of imaging services under Medicare Part B in greater depth.

SGR

The ACC is disappointed that CMS has failed to respond to requests from the physician community and members of Congress to implement its administrative authority to remove the cost of physician-administered drugs from the calculation of actual expenditures from the update adjustment factor (UAF) component of the SGR system. Including the cost of physician-administered drugs in the UAF formula is inappropriate. Price increase is a major contributor to increases in spending on physician-administered drugs. Physicians have no control over these price increases. In addition, CMS includes drug costs in actual expenditures, but cannot account adequately for those costs in setting targets for allowed expenditures. This contributes to the failure of the SGR system to set realistic targets for physician spending.

Most other components of the SGR system are established in statute, and thus, are beyond CMS's control. We believe, though, that CMS does have the authority to remove drug costs from the formula both prospectively and retroactively. This action would facilitate enactment of a more comprehensive remedy by producing

a more moderate and realistic estimate of the cost of a fundamental solution to the SGR system.

CMS solicited input on ways to ensure that physicians are paid adequately and that Medicare pays only for necessary and beneficial care. The ACC is pleased that CMS has initiated a dialogue with the physician community about measurement and reporting of physician performance and quality care. The College is well-positioned to assist CMS in this effort. The ACC-National Cardiovascular Data Registry (NCDR) operates confidential quality measurement programs for cardiac and vascular facilities. We have also begun the process of developing criteria for the appropriate use of selected cardiovascular services. The ACC welcomes the opportunity to share our experience in these ventures with CMS as the agency works to strengthen quality measurement and reporting in the Medicare program.

Recognizing the high level of interest among both private and public sector payers in pay-for- performance or value-based purchasing programs, the ACC recently developed and approved a set of principles against which the College will evaluate any pay-for-performance/value-based purchasing proposals. A brief summary of these principles follows.

Any pay-for-performance program should be:

- Built on evidence-based, well established and proven performance measures.
- Provide adequate incentives for investments in structure, best practices, and tools that can lead to improvement and high quality care.
- Reward process, outcome and improvement, and sustainability.
- Assign attribution of credit for performance to physicians in ways that are credible and encourage collaboration.
- Favor the use of clinical data over claims based data.
- Set targets for performance through a national consensus process.
- Address appropriateness.
- Not be punitive.
- Audit performance measure data.
- Establish transparent provider rating methods.
- Not create perverse incentives nor adverse consequences.
- Invest in outcomes and health services research.

We would be happy to provide CMS with more information about the College's pay-for-performance principles.

Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 301-498-2398 or rkelly@acc.org with any questions.

Sincerely,

Pamela Douglas, MD, FACC
President

MAYO CLINIC

SEP 2005 919

200 First Street SW
Rochester, Minnesota 55905
507-284-2511

September 28, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, Maryland 21244-8017

We appreciate the opportunity to comment on the Proposed Rule of August 8, 2005 regarding changes to the Physician Fee Schedule for calendar year 2006. We offer the following comments for your consideration.

TEACHING ANESTHESIOLOGISTS

F. Payment for Teaching Anesthesiologist
Allowing teaching anesthesiologists to identify the critical portion of the anesthesia service and provide concurrent anesthesia teaching services will appropriately align teaching physician reimbursement methods with other teaching surgeons and medical physicians. Teaching anesthesiologists should be reimbursed at 100% of the physician fee schedule for supervision of concurrent anesthesia cases when the critical portions do not overlap. As with other teaching services, the teaching anesthesiologist would identify and be involved in the critical portion of the anesthesia service.

When more than two concurrent cases are provided, the teaching anesthesiologist will continue to bill under medical direction or supervision as appropriate. We believe this consistent mechanism of reimbursement will allow teaching anesthesiologists fair and equitable reimbursement.

MULTIPLE PROCEDURE REDUCTION

J. Multiple Procedure Reduction for Diagnostic Imaging
CMS states that under the resource-based practice expense (PE) methodology, specific PE inputs of clinical labor, supplies and equipment are used to calculate PE relative value units (RVU) such as:

- Greeting the patient
- Positioning and escorting the patient
- Providing education and obtaining consent
- Retrieving prior exams
- Setting up the IV
- Preparing and cleaning the room
- Technician time to perform the exam

CMS states they do not believe these same inputs are needed to perform multiple procedures on the same day. CMS is proposing a 50 percent reduction in the technical payment for these

services although CMS presents no hard data that would support a 50 percent reduction for radiology other than that there is some duplication of effort and "potential" savings. Prior to implementing such a drastic reduction in payment for these services, we recommend that CMS conduct a valid study to measure the time savings and practice expense reduction involved in performing multiple procedures within each of these families. We see no solid justification for a 50 percent reduction in reimbursement. Instead, CMS is basing this decision on recommendations from MedPAC. MedPAC states that there are savings in clerical time, preparation and supplies when patients have multiple studies of the same modality performed on contiguous body parts. MedPAC goes on to state that since CMS has a policy of reducing payment for multiple surgical procedures; they should have this same policy for radiology imaging services. To compare radiology imaging services to surgical services is not a reasonable comparison. The savings on multiple surgical services can be tied directly to the timesaving related to the surgical opening and closing of the patient. To what extent this is true for the radiology services listed is unknown.

We would argue that the work effort involved for the technologist does not change significantly when doing multiple areas. For example, if a CT of the pelvis follows a CT of the abdomen, the work effort for the technologist is not reduced. It takes just as much time to scan two separate areas (pelvis and abdomen) on one patient having both areas as it does for two patients scanned for each area. The question becomes of the total work time how much does each of the components contribute the overall PE for the technical component of these radiology services and does it vary across families of codes.

For example, in ultrasound we find that in some situations clinical labor activities do require duplication of work depending upon the scenario. We would like to comment on each of the above clinical labor activities and why we feel Medicare's assumptions are incorrect.

1. Greeting the patient: There are situations where two different sonographers may greet the patient. With the current national shortage of sonographers this may be more common than believed. Scenario: A male sonographer takes the next patient to be scanned. The patient is a female. The exams ordered are a pelvis complete or limited and a transvaginal ultrasound. The male sonographer completes the trans abdominal pelvis ultrasound and asks a female sonographer to complete the transvaginal exam. In this case two different sonographers would greet the patient.

2. Positioning and escorting the patient: nearly every combination of exams listed in Family 1 results in repositioning the patient and/or the table. Scenario: The primary care physician orders an ultrasound of the pelvis and a transvaginal ultrasound. The pelvis ultrasound is performed in the supine position. Performing the transvaginal ultrasound requires getting the patient up, reconfiguring the table and using stirrups.

3. Providing education and obtaining consent: We agree that obtaining consent is not duplicated for subsequent imaging when performing multiple procedures. However, prior to and during each separate exam, the sonographer provides a full explanation (education) of the procedure to the patient.

4. Retrieving prior exams: We agree that retrieving of prior exams for multiple procedures requires very little or no additional clinical labor activity. However, we would like to point out that each prior exam must be thoroughly reviewed by the sonographer resulting in additional clinical labor activity. This review includes images from other modalities, which further compounds the amount of activity necessary when multiple procedures are performed.
5. Preparing and cleaning the room: Again, we disagree with Medicare's statement that this activity is not duplicated with multiple procedures. Any procedure performed in combination with a transvaginal ultrasound requires the following:
    a. additional table preparation for the transvaginal exam (e.g. stirrups);
    b. the sonographer leaves the room to retrieve a transvaginal probe. Transvaginal probes must be disinfected and JCAHO policy dictates that probes disinfected with Cidex must be stored outside the exam room.

Also, scanning time for multiple ultrasound exams performed on contiguous body parts is equal to the same exams performed in a single session. Furthermore, we believe that scanning time makes up the vast majority of the clinical labor activities of ultrasound procedures. This could vary depending on the family of codes. For example, CT scans and ultrasound scans and MRI or MRA scans might vary considerably affecting cost in each of these component parts. It is for this reason that we strongly oppose an across the board reduction of 50 percent for these services.

Lastly, CMS has also listed codes within families that are already edited for unbundling. For example, performing a CT without dye and then performing a CT with dye should be billed under the code for CT with and without dye as recommended by American Medical Association Current Procedural Terminology coding. It is a misconception that these would be billed separately because Medicare already requires that the two codes be bundled into the most expensive code under the Correct Coding Initiative edits.

Thank you for the opportunity to comment on the proposed rule. Please feel free to contact either Brenda Mickow at (507) 284-1871 or me at (507) 284-4627, if you have any questions.

Very truly yours,

Ronald W. Grousky
Medicare Coordinator
Mayo Clinic

RWG/rpv

cc: Brenda Mickow

L/dept/sal/sal/rwg/ltr/PFS comment 2005

SEP 2005 920

INDIANA UNIVERSITY

SCHOOL OF MEDICINE

September 19, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-P
P. O. Box 8017
Baltimore, MD 21244-8017

Reference: TEACHING ANESTHESIOLOGISTS

To Whom It May Concern:

I am a member of the faculty of the Department of Anesthesia, Indiana University School of Medicine, a position I have held for a number of years. During this time I have cared for some of the most critically ill patients in the state and have helped educate the next generation of anesthesiologists. Indiana University Department of Anesthesia is the only anesthesia residency program in the state, and approximately seventy-five percent of the anesthesiologists practicing in Indiana were educated by this program.

In the past few years, there has been a steady decline in the health of academic anesthesia, now reaching the point where it is vital that something be done. The financial health of these programs is poor due to the low levels of reimbursement. Teaching institutions shoulder the largest share of Medicaid patients and are also penalized since 1996 by concurrency rules for their care of Medicare patients. The income of teaching anesthesiologists across the Nation averages 50-60% of that of the private practice anesthesiologist, despite comparable work hours and the added responsibilities of teaching young physicians. As a result, many anesthesiologists have been driven out of the academic setting and into private practice. This has resulted in the closure of several residency programs in recent years. Now there is a national shortage of anesthesiologists, coupled with a growing demand for their services fueled by our aging population.

This very serious situation would be greatly helped by the elimination of the concurrency rules for teaching anesthesiologists which reduces payment when an anesthesiologist supervises more than one resident. The anesthesiologist is the only acute care physician penalized in such a way. For example, if a surgeon performs an operation with a resident in one operating room (and is present for all the key parts of the procedure), then begins surgery on a second patient (while the resident finishes the first procedure), the surgeon is paid the full surgical fee for both patients. In contrast, teaching anesthesiologists are reimbursed at a reduced rate even though they perform the pre-anesthetic examination and evaluation, prescribe the anesthetic plan, personally participate in the most demanding procedures of the anesthetic included induction and emergence, monitor the course of anesthesia administration at frequent intervals, remain physically present and available for immediate diagnosis and treatment of emergencies, and provide indicated post-anesthesia care for each patient.

This rule is both inequitable and unwise, and will ultimately lead to a continuing shortage of anesthesiologists, to the detriment of American patients.

I urge you, in the strongest possible way, to correct this discriminatory policy against teaching anesthesiologists, relative to other teaching physicians.

Sincerely,
Kenneth A Haselby MD
Kenneth Haselby, M.D.
AssociateProfessor of Clinical Anesthesia

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SEP 2005 921

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Carlos U. Arancibia, MD
Professor and Chairman

September 28, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Baltimore, MD 21244-8017

Dear Dr. McClellan:

I have been an anesthesiologist for more than 27 years and I have served as the Chairman, Department of Anesthesiology, Virginia Commonwealth University, since 2000. I have spent my professional life dedicated to academic medicine and I have seen many changes and lived through many periods of uncertainty. However, I am forced to write to you now because I believe that our specialty will be irrevocably damaged if the Centers for Medicare and Medicaid Services (CMS) do not change the Medicare anesthesiology teaching payment policy.

Our department includes 32 anesthesiologists, 33 residents and 29 nurse anesthetists. We provide anesthesia care to more than 20,000 patients per year; 28% of them are Medicare recipients and 15% Medicaid recipients. We are the safety net of our community and we are very proud of our mission. However, we are reimbursed at the rate of $16.97 per ASA unit, which places us below the 20th percentile nationally. In order to maintain the services required from us, our hospital is subsidizing in excess of 45% of our expenses, and we are having an increasing problem recruiting and retaining personnel because we are not competitive in our market. Our hospital is diligently working to maintain our commitment to the city and the Commonwealth, but I do not believe that we will be able to sustain our efforts unless there is a change in the CMS teaching rules.

An internist may supervise residents in four overlapping outpatient visits and collect 100% of the fee for each when certain requirements are met. A surgeon may supervise residents in two overlapping operations and CMS will pay 100% of the fee for each case. However, since 1995 the teaching anesthesiologist who supervises two residents in those same two overlapping cases will collect only 50% of the Medicare fee. This penalty is unfair, unreasonable and discriminates against our specialty. Correcting this inequity will go a long way toward assuring the application of Medicare's teaching payment rules consistently across medical specialties and towards assuring that anesthesiology teaching is reimbursed on par with other teaching physicians. I urge you to end the payment penalty for teaching anesthesiology.

Sincerely,

Carlos U. Arancibia, M.D.
Professor and Chairman
Department of Anesthesiology

an equal opportunity/affirmative action university

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Congress of the United States
House of Representatives
Washington, DC 20515–3216

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DEMOCRATIC STEERING
COMMITTEE

September 22, 2005

Dr. Mark B. McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

I was the sponsor of the original medical nutrition therapy benefit bills in the mid 90s and cosponsor of the 1999 bill that eventually became law, as Section 105 of PL 106-544, entitled "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes and Renal Disease".

As you review the rule pertaining to medical nutrition therapy benefits, please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law.

I have reviewed the comments of Midtown Nutrition Care and would ask that they be given every consideration as the rule in question is reviewed.

Sincerely,

José E. Serrano

José E. Serrano
Member of Congress

MIDTOWN NUTRITION CARE
119 WEST 57TH STREET—SUITE 1414
NEW YORK, NY 10019
(212) 333-4243

September 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Specific Re: Impact of Proposed Elimination of Nonphysician Work Pool on Medical Nutrition Therapy Services (CPT 97802-4)

Specific CMS Language: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change....We, therefore, welcome all comments on these proposed changes..." Federal Register, August 8, 2005, p. 45777

Dear Sir or Madam:

Midtown Nutrition Care respectfully submits the following comments that will show how CMS may not only avoid any negative impact on medical nutrition therapy services, but also increase access to these important preventive medicine services.

History of Medical Nutrition Therapy Reimbursement

1. August 4, 1995, 104th Congress, 1st Session, Representative Serrano introduced the first medical nutrition therapy bill, HR 2247, "Medical Nutrition Therapy Act of 1995". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]

2. July 17, 1996, 104th Congress, 2nd Session, Senator Bingaman introduced S 1964, "Medical Nutrition Therapy Act of 1996". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]

3. January 7, 1997, 105th Congress, 1st Session, Representative Serrano introduced HR 288, "Medical Nutrition Therapy Act of 1997". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]

4. June 24, 1997, 105th Congress, 1st Session, Senators Craig and Bingaman introduced S Amdt 454, which became Section 5105 of PL 105-33, "Study on Medical Nutrition Therapy Services." It provides "(a) Study: The Secretary of Health and Human Services shall request the National Academy of Sciences, in conjunction with the United States Preventive Services Task Force, to analyze the expansion or modification of preventive benefits provided to medicare beneficiaries under title XVIII of the Social Security Act to include medical nutrition therapy services by a registered dietitian. (b) Report: (1) Initial report: Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit a report on the findings of the analysis conducted under subsection (a) to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate. (2) Contents: Such report shall include specific findings with respect to the expansion or modification of coverage of medical nutrition therapy services by a registered dietitian for medicare beneficiaries regarding—(A) cost to the medicare system; (B) savings to the medicare system; (C) clinical outcomes; and (D) short and long term benefits to the medicare system. (3) Funding: From funds appropriated to the Department of Heath and Human Services for fiscal years 1998 and 1999, the Secretary shall provide such funding as may be necessary for the conduct of the analysis by the National Academy of Sciences under this section."

5. March 18, 1999, 106th Congress, 1st Session, Representative Johnson, on behalf of herself, Representative Serrano, and numerous others, introduced HR 1187, "Medical Nutrition Therapy Act of 1999". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined under the fee schedule established under section 1848(b) [the physician fee schedule] for the same services if furnished by a physician." [emphasis supplied]

6. December 15, 1999, the Institute of Medicine of the National Academy of Sciences issued its report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly, Evaluating Coverage of Nutrition Services for the Medicare Population," National Academy Press, Washington, DC, 2000, ISBN 0-309-06846-0. Among its findings was: "The registered dietitian is currently the single identifiable group of health professionals qualified to provide nutrition therapy. It is recognized that other health care professionals in particular fields may be qualified to provide nutrition therapy and should be considered on an individual basis as a reimbursable provider." (Page 272 of published report)

7. December 2000, 106th Congress, 2nd Session, Congress enacted PL 106-554, which contains Section 105, "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes and Renal Disease." Relevant reimbursement language is "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) [the

physician fee schedule] for the same services if furnished by a physician." [emphasis supplied] Other relevant language is: "The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional."

8. August 2, 2001, CMS published in the Federal Register its proposed rule for the medical nutrition therapy benefit which was to become available on January 1, 2002. Part of the proposed rule was "Payment for Medical Nutrition Therapy (§414.64)." It states, in relevant part: "The statute specifically provides that medical nutrition therapy services may only be provided by registered dietitians or nutrition professionals. We do not believe that physicians will be able to satisfy the qualification requirements and therefore will not be able to provide this service themselves. Therefore, we are not establishing physician work RVUs for this service. We interpret section 105(c)(2) of BIPA to mean that if a physician were to furnish this service, that the service was performed 'incident to' the physicians treatment plan and provided by a registered dietitian or nutrition professional." [emphasis supplied]

9. November 1, 2001, CMS published in the Federal Register its final rule. Among the responses to the comments received was: "While medical nutrition therapy may be performed by a physician who is also a registered dietitian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy service. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount.... We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would never meet the statutory requirements to be considered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered dietitians or nutrition professionals. In these circumstances, our payment the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dietitian or nutrition professional." [emphasis supplied] (Page 55279 of 2001 Federal Register)

10. Earlier in the final rule CMS states: "The American Dietetic Association (ADA) and many individuals submitted comments concerning the proposed reimbursement rate for medical nutrition therapy services. They stated that the proposed reimbursement rate for these services is too low and would result in limited beneficiary access to these services since private practice dietitians will chose not to participate....They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress....The commentators also stated that any refinement of medical nutrition therapy values should

be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commentators acknowledge that physicians may perform other tasks besides nutrition assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a comment that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by non-physician providers....We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy." [emphasis supplied] (Page 55278 of 2001 Federal Register)

Using a Reimbursement Methodology That Includes a Physician Work Value Will Not Only Avoid Any Negative Impact On Medical Nutrition Therapy Services From the Elimination of the Nonphysician Work Pool, But Will Also Increase Access To These Preventive Medicine Services

11. We agree that Congress probably did not envision a particular amount or particular E/M service, but did Congress intend to pay nutritionists 85% of what a physician is paid for administering chemotherapy or performing the technical component of a diagnostic x-ray? Or did Congress intend to pay dietitians 85% of what it costs a physician to employ a dietitian to provide the services? If Congress had intended to focus on a dietitian's work value, then why didn't the law establish a separate fee schedule for dietitians (as Medicare has for psychologists and as the 1995, 1996 and 1997 bills had envisioned)?

12. After the 1995, 1996 and 1997 bills by Representative Serrano and Senator Bingaman that would have established a separate dietitian fee schedule, and after the 1997 Craig and Bingaman amendment established a study to be made of "medical nutrition therapy services by a registered dietitian", what did Representatives Johnson, Serrano and others intend when they introduced in March 1999 a bill that would have paid dietitians the amount determined under the physician fee schedule for the same services if furnished by a physician instead of pursuant to a separate dietitian fee schedule? And after the December 1999 report by the National Academy of Sciences found the registered dietitian to be the single identifiable group qualified to provide medical nutrition therapy (although others may be qualified), what did Congress intend when they passed in December 2000 a law that continued to determine payment not pursuant to a separate dietitian fee schedule but by paying 85% (instead of 100% as in the Johnson bill) of the amount determined under the physician fee schedule for the same services if performed by a physician, and also defined the providers to be registered dietitians or other nutrition professionals?

13. Could it possibly be that Congress intended by not having a separate dietitian fee schedule that Congress meant to exclude physician work value? Or, is it at least as likely that Congress intended to pay 85% of what a physician would be paid, including physician work value, so as to insure that reimbursement would be fixed at a level that would enable a sufficient number of dietitians to participate so that Medicare

beneficiaries would have access to this preventive benefit (and preventive benefits are what Congress want all entitled beneficiaries to get so as to hold down costs over the long term). The original sponsor of the medical nutrition therapy benefit and cosponsor of the bill that eventually became the law has asked CMS to "...please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law." (See copy of September 22, 2005 letter to CMS from Representative Serrano, attached as Exhibit "A")

14. That the envisioned access has not been provided can be seen from the fact that prior to passage the CBO estimated the annual cost of medical nutrition therapy services to be $60 million, whereas only about $1 million per year has been spent annually since the benefit became available in 2002. This represents visits by only about 250,000 beneficiaries out of an estimated 8 million plus beneficiaries with diabetes and renal disease (the two conditions for which Medicare currently provides medical nutrition therapy benefits). Only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. Journal of the American Dietetic Association, June 2005, p. 990 (copy, along with p.995, footnote references, attached as Exhibit "B").

15. There is a lengthy discussion in the November 1, 2001 final rule (Pages 55278-80 of 2001 Federal Register) stating that work value should not be included because medical nutrition therapy services do not involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel involved in most evaluation and management services by physicians. However, the evaluation and management code to which the medical nutrition therapy codes was compared for the basis of valuation is Preventive Medicine Service Counseling and/or Risk Factor Reduction Intervention (CPT Code 99401) which, unlike most evaluation and management codes, does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel! (A copy of the CPT's entire Preventive Medicine Services section, 2 pages, is attached as Exhibit "C".)

16. We think the reason CMS did not notice that CPT Code 99401 does not generally involve these components is because 2 interrelated points had been raised in comments to the proposed rule. First that CMS should compare the 15-minute medical nutrition therapy code CPT 97802 to the 15-minute office visit code CPT 99213, rather than to the 15-minute preventive medicine counseling code CPT 99401; and second that a physician's work value should be included in valuing medical nutrition therapy services. Therefore, it was natural for CMS to look at the medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components of CPT Code 99213, and not notice that these components are generally lacking in CPT Code 99401. (Attached as Exhibit "D" is a copy of the entire final rule "Payment for Medical Nutrition Therapy" discussion, pp. 55278-55281.)

17. Because CPT Code 99401 does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and

clinical personnel, the valuation of CPT Code 99401 is already significantly lower than other 15-minute evaluation and management service codes that involve these components, see 2005 Relative Value Units for the following codes (Pages 66666, 66668 and 66671 of 2004 Federal Register):

15-minute Code	Work RVU	Non-facility Practice Expense RVU	Malpractice RVU	Non-facility Total
99213 (Office Visit)	**0.67**	**0.69**	**0.03**	**1.39**
99241 (Office Consultation)	**0.64**	**0.64**	**0.05**	**1.33**
99401 (Prev Medicine Counseling)	**0.48**	**0.62**	**0.01**	**1.11**
97802 (Med Nutrition Therapy)	**0.00**	**0.47**	**0.01**	**0.48**

18. The discussion by CMS that stated that work value should not be included because medical nutrition therapy services do not involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel was set forth for the first time in the final 2001 rule, and not in the proposed 2001 rule. Therefore, CMS was unable to receive comments that might have pointed out that CPT Code 99401 also does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel (so while the lack of these components may be a good reason for cross walking the medical nutrition therapy codes to CPT Code 99401, rather than to CPT Code 99213, it is not a good reason to disregard physician work value).

19. However at this time CMS can take notice that CPT Code 99401 does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel, and therefore could (and should) continue the comparison to CPT Code 99401, but utilize the CPT Code 99401 work value, plus the CPT Code 99401 practice and malpractice expense RVUs for valuing the medical nutrition therapy codes (and then paying a physician 80% of 100%, and a dietitian 80% of 85%, of the total of these 3 values). This would be analogous to the payment of physician assistants and nurse practitioners 80% of 85% of CPT Code 99213 or other evaluation and management services that, as appropriate for their practice, contain medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components. And this would allow a physician who is also a dietitian to be paid appropriately (80% of 100%) for medical nutrition

therapy services since a physician cannot otherwise use CPT Code 99401 because while it has been valued, CPT Code 99401 is a noncovered service for which Medicare payment may not be made. (Page 66671 of 2004 Federal Register; Page 45999 of 2005 Federal Register)

20. As in the 2001 final rule, the valuation of the 15-minute individual medical nutrition therapy Code 97803 should continue to be the same as the valuation of the 15-minute individual medical nutrition therapy Code 97802; and the valuation of the 30-minute group medical nutrition therapy Code 97804 should continue to approximate the hourly valuation of the individual medical nutrition therapy codes based on an assumption of an average of 5 patients in a group (that is, each RVU value for the 30-minute group increment should be determined by multiplying the corresponding RVU value for the individual 15-minute increment by 2, then dividing by 5).

21. Unlike the issue of medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components, which was raised for the first time in the 2001 final rule, the issue of whether the two individual 15-minute codes would be valued the same or differently was fully discussed in the 2001 proposed rule, in comments thereto, and in the final rule, which stated as follows: "We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commentator that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (Page 55281 of 2001 Federal Register)

22. That reasoning was sound in 2001 and remains sound, and should continue to be followed, rather than create a 0.01 less RVU for CPT code 97803 as proposed at Page 45997 of the August 8, 2005 Federal Register.

Our Practice

23. Our group practice, Midtown Nutrition Care, has seven full-time Registered Dietitians who see approximately 700 patients per month, about 1/3 of which have diabetes or kidney disease.

24. We are providers for all the major commercial insurance companies in our area. These currently pay an average of $42.53 per 15-minute increment for CPT Codes 97802 and 97803 (which codes are valued equally by the commercial insurers we bill these codes). Copies of explanations of benefits (with patient identifiers deleted), which show

these amounts to be $50, $44.80, $40.32 and $35 per 15-minute increment, are attached as Exhibit "E".

25. Because Medicare currently pays only about $18 per 15-minute increment for our geographical area, which is one of the highest in the nation (and would be reduced an additional 10% under the proposed 2006 physician fee schedule) we cannot afford to see Medicare patients and none of us has become a Medicare provider. We therefore turn away a couple of Medicare patients per day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the private practice nutritionists in our area accept Medicare.

26. If payment for the 15-minute increment were to a little more than double as proposed above it would roughly equal the average we are receiving from commercial insurance companies in our area and we would all become providers and accept Medicare. Based on my experience as co-reimbursement chair for the New York State Dietetic Association I also believe that the vast majority of private practice nutritionists in my area and nationwide would do likewise. Therefore, if the above proposal is followed it will not only avoid any negative impact from the elimination of the nonphysician work pool, it will also provide appropriate access to care for all Medicare beneficiaries entitled to these services.

Sincerely yours,

Robert Howard, RD, JD
Managing Partner

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September 22, 2005

Dr. Mark B. McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

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As you review the rule pertaining to medical nutrition therapy benefits, please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law.

I have reviewed the comments of Midtown Nutrition Care and would ask that they be given every consideration as the rule in question is reviewed.

Sincerely,

José E. Serrano
Member of Congress

EXHIBIT "A"
1 PAGE

mation packets, meetings and conference calls, and support developing language that describe MNT services provided by RDs as a component of the CCI program.

MEDICARE ADVANTAGE

Medicare+Choice will be replaced with Medicare Advantage effective January, 2006. CMS announced on December 6, 2004 that there will be 26 Medicare Advantage regions established across the nation for health insurance plans wishing to participate in the new program. Participating health insurance plans will be required to service the entire region. Each Medicare Advantage regional plan will have a network of providers who agree to contractually specified reimbursement levels for covered benefits.

The intent of this new provision is to have traditional fee-for-service Medicare compete head to head on prices with private insurance companies. In order to gain sufficient support to pass the bill, this new provision is a 6-year demonstration program in up to six standard metropolitan statistical areas (SMSAs). Private insurers will be able to begin bidding to serve Medicare beneficiaries in regions beginning in 2006. Payment rates would be based on a blended average of the bids. The traditional Medicare system will compete with private plans in selected SMSAs beginning in 2010. There are significant incentives in the new law to encourage private insurance companies to participate in this program.

How the Medicare Advantage program affects utilization of the Medicare MNT coverage, and the two new programs that include MNT benefits, remains to be seen. There is the potential for significant growth in MNT services. According to the proposed rules released by CMS, beginning in 2006, the Medicare Advantage program will have to "enrich the range of benefit choices available to enrollees, including not only improved prescription drug benefits, but also other benefits not covered by traditional Medicare, and the opportunity to share in savings where plans can deliver benefits at lower costs" (78).

MEDICARE MNT'S IMPACT ON PRIVATE INSURANCE PLANS' COVERAGE

ADA researchers conducted an environmental scan in 2002 to determine if the MNT benefit (which went into effect January 1, 2002) had increased the coverage of nutrition services provided by RDs within private insurance or health care plans. While the scan is not representative of all managed care organizations or the health care marketplace, a positive change in coverage was noted since 1999, when a benchmark was set (79). The growth in coverage of dietetic services are attributable to a number of factors: costs, consumer demand, and recognition of MNT, the availability of data on the effectiveness of nutrition interventions, and new tools such as codes that allow direct reimbursement to dietetic professionals. Dietetics professionals may find an increasingly receptive environment for their knowledge and skills, and involvement in disease management services, as more private sector plans reported contracting with RDs for nutrition services. Additionally, several plans in the 2002 scan indicated they follow Medicare's lead in adopting CPT codes.

MEDICARE MNT UTILIZATION RATES

During the first year of Medicare MNT coverage under Medicare, 4,125 individuals enrolled as MNT providers and billed approximately $800,000 for individual and group MNT services (80). (When Congress was considering the MNT bill in 2000, it was estimated that a scaled-down MNT bill establishing coverage to beneficiaries with diabetes, cardiovascular disease, and/or renal disease, would cost a little less than $1 billion per year [81].) Recent CMS data indicates nearly 7,000 registered dietitians or licensed nutrition professionals have enrolled as providers of MNT (82). Only 211,000 Medicare beneficiaries received MNT services since the benefit's inception, yielding approximately $3.3 million of new revenue for RDs.

Those are disappointing statistics inasmuch that they indicate an underutilization of the MNT benefit. Based on estimates from the National Diabetes Information Clearinghouse and United States Renal Data System, approximately 8.6 million individuals (or 18.3%) at least 60 years old are diagnosed with diabetes or acute renal failure, making most of them eligible for MNT Medicare services (83). In terms of income potential to RDs, the CBO-projected $60 million annual outlays for Medicare MNT for diabetes and kidney disease are far higher than the actual $1 million annual average. Data provided by CMS indicate a small but growing demand for Medicare MNT for diabetes and kidney disease when beneficiaries obtain a referral by their physicians.

How the Medicare Advantage program affects utilization of the Medicare MNT coverage, and the two new programs that include MNT benefits, remains to be seen.

There are a number of reasons to expect greater demand for Medicare MNT services. First of all, the Medicare Modernization Act includes two MNT components, one of which is the Initial Preventive Physical Examination, which went into effect January 1, 2005. The American Diabetes Association estimates that more than one-third of Americans with diabetes do not know they have the disease (84). If the "Welcome to Medicare" physical is successful in identifying people who have diabetes but did not know it, the utilization rate for MNT should show a significant increase.

The chronic care provisions of the Medicare Modernization Act also provide an opportunity for significant growth in MNT utilization, because MNT also is a component of that provision. Currently, 78% of the Medicare population has one or more chronic conditions that require ongoing medical management (85). Almost two thirds (63%) have two or more chronic conditions, and 20% of Medicare beneficiaries have five or more chronic conditions (86). Therefore, participating in Medicare's new chronic care disease management

EXHIBIT "B"
PAGE 1 OF 2

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99373 complex or lengthy (eg, lengthy counseling session with anxious or distraught patient, detailed or prolonged discussion with family members regarding seriously ill patient, lengthy communication necessary to coordinate complex services of several different health professionals working on different aspects of the total patient care plan)

Care Plan Oversight Services

Care Plan Oversight Services are reported separately from codes for office/outpatient, hospital, home, nursing facility or domiciliary services. The complexity and approximate physician time of the care plan oversight services provided within a 30-day period determine code selection. Only one physician may report services for a given period of time, to reflect that physician's sole or predominant supervisory role with a particular patient. These codes should not be reported for supervision of patients in nursing facilities or under the care of home health agencies unless they require recurrent supervision of therapy.

The work involved in providing very low intensity or infrequent supervision services is included in the pre- and post-encounter work for home, office/outpatient and nursing facility or domiciliary visit codes.

99374 **Physician supervision** of a patient under care of home health agency (patient not present) in home, domiciliary or equivalent environment (eg, Alzheimer's facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99375 30 minutes or more

99377 **Physician supervision** of a hospice patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99378 30 minutes or more

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99379 **Physician supervision** of a nursing facility patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99380 30 minutes or more

Preventive Medicine Services

The following codes are used to report the preventive medicine evaluation and management of infants, children, adolescents and adults.

The extent and focus of the services will largely depend on the age of the patient.

If an abnormality/ies is encountered or a preexisting problem is addressed in the process of performing this preventive medicine evaluation and management service, and if the problem/abnormality is significant enough to require additional work to perform the key components of a problem-oriented E/M service, then the appropriate Office/Outpatient code 99201-99215 should also be reported. Modifier '-25' should be added to the Office/Outpatient code to indicate that a significant, separately identifiable Evaluation and Management service was provided by the same physician on the same day as the preventive medicine service. The appropriate preventive medicine service is additionally reported.

An insignificant or trivial problem/abnormality that is encountered in the process of performing the preventive medicine evaluation and management service and which does not require additional work and the performance of the key components of a problem-oriented E/M service should not be reported.

The "comprehensive" nature of the Preventive Medicine Services codes 99381-99397 reflects an age and gender appropriate history/exam and is NOT synonymous with the "comprehensive" examination required in Evaluation and Management codes 99201-99350.

Codes 99381-99397 include counseling/anticipatory guidance/risk factor reduction interventions which are provided at the time of the initial or periodic comprehensive preventive medicine examination. (Refer to codes 99401-99412 for reporting those counseling/anticipatory guidance/risk factor reduction interventions that are provided at an encounter separate from the preventive medicine examination.)

Immunizations and ancillary studies involving laboratory, radiology, other procedures, or screening tests identified with a specific CPT code are reported separately. For immunizations, see 90471-90474 and 90476-90749.

New Patient

99381 **Initial comprehensive preventive medicine** evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate immunization(s), laboratory/diagnostic procedures, new patient; infant (age under 1 year)

99382 early childhood (age 1 through 4 years)

99383 late childhood (age 5 through 11 years)

99384 adolescent (age 12 through 17 years)

99385 18-39 years

99386 40-64 years

99387 65 years and over

Established Patient

99391 **Periodic comprehensive preventive medicine** reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate immunization(s), laboratory/diagnostic procedures, established patient; infant (age under 1 year)

99392 early childhood (age 1 through 4 years)

99393 late childhood (age 5 through 11 years)

99394 adolescent (age 12 through 17 years)

99395 18-39 years

99396 40-64 years

99397 65 years and over

Counseling and/or Risk Factor Reduction Intervention

New or Established Patient

These codes are used to report services provided to individuals at a separate encounter for the purpose of promoting health and preventing illness or injury.

Preventive medicine counseling and risk factor reduction interventions provided as a separate encounter will vary with age and should address such issues as family problems, diet and exercise, substance abuse, sexual practices, injury prevention, dental health, and diagnostic and laboratory test results available at the time of the encounter.

These codes are not to be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes. For counseling groups of patients with symptoms or established illness, use 99078.

Preventive Medicine, Individual Counseling

99401 **Preventive medicine counseling** and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes

99402 approximately 30 minutes

99403 approximately 45 minutes

99404 approximately 60 minutes

Preventive Medicine, Group Counseling

99411 **Preventive medicine counseling** and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes

99412 approximately 60 minutes

Other Preventive Medicine Services

99420 **Administration and interpretation** of health risk assessment instrument (eg, health hazard appreisal)

99429 **Unlisted preventive** medicine service

Newborn Care

The following codes are used to report the services provided to newborns in several different settings.

For newborn hospital discharge services provided on a date subsequent to the admission date of the newborn, use 99238.

For discharge services provided to newborns admitted and discharged on the same date, use 99435.

99431 **History and examination** of the normal newborn infant, initiation of diagnostic and treatment programs and preparation of hospital records. (This code should also be used for birthing room deliveries.)

99432 **Normal newborn care** in other than hospital or birthing room setting, including physical examination of baby and conference(s) with parent(s)

99433 **Subsequent hospital care,** for the evaluation and management of a normal newborn, per day

99435 **History and examination** of the normal newborn infant, including the preparation of medical records. (This code should only be used for newborns assessed and discharged from the hospital or birthing room on the same date.)

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Payment for Medical Nutrition Therapy (§ 414.64)

Section 105(c) of the BIPA requires that we pay for medical nutrition therapy services at 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the physician fee schedule for the same services if the services had been furnished by a physician. Based upon consultation with the American Dietetic Association (ADA) to assess the types of resource inputs used to furnish a 15-minute medical nutrition therapy session by a registered dietitian or professional nutritionist, we proposed the following:

For CPT code 97802—Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes, we did not propose physician work RVUs for this service, based on the statutory provision that specifically provides that medical nutrition therapy services may only be furnished by registered dietitians or nutrition professionals. For practice expense, we proposed 0.47 RVUs and, for malpractice, we proposed 0.01 RVUs for a total of 0.48 RVUs.

For CPT code 97803—Reassessment and intervention, individual, face-to-face with the patient, each 15 minutes, we proposed 0.0 work RVUs, 0.34 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.35 RVUs.

For CPT code 97804—Group, 2 or more individuals, each 30 minutes, we proposed 0.0 work RVUs, 0.14 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.15 RVUs. To determine payment, the RVUs shown above would need to be multiplied by the physician fee schedule conversion factor and 0.85 (to reflect the statutory requirement that payment be 85 percent of the amount determined under the physician fee schedule).

We also stated that, consistent with the definition in the CPT's Physical Medicine Rehabilitation codes, a group is considered to be 2 or more individuals and that Medicare co-payments and deductibles would apply for medical nutritional therapy services.

Comment: The American Dietetic Association (ADA) and many individuals submitted comments concerning the proposed reimbursement rate for medical nutrition therapy services. They stated that the proposed reimbursement rate for these services is too low and would result in limited beneficiary access to these services since private practice dietitians will choose not to participate. Some commenters referenced reimbursement rates currently paid by private insurers of $85 to $125 for 1 to 1½ hours for an initial visit and $85 per hour for follow-up. They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress. Commenters indicated that the statute clearly states that medical nutrition therapy payment should be 80 percent of the lesser of the actual charge or 85 percent of the amount determined under the physician fee schedule for the same service, provided by a physician. According to commenters, physicians who are also registered dietitians, use E/M codes 99213 through 99215 and 99244 when providing medical nutrition therapy services. The commenters stated that E/M codes 99203 through 99205 are appropriate reference points for determining medical nutrition therapy payment. The commenters also stated that any refinement of medical nutrition therapy values should be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commenters acknowledge that physicians may perform other tasks besides nutritional assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a comment that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by non-physician providers. The HCPAC indicated that it evaluated each of the medical nutrition therapy codes and compared them to services that are available to other providers but not nutritionists (for example, physical therapy services). The comment further stated that the 15 percent reduction should not apply because the HCPAC took this into account when developing the recommendations. The HCPAC further added that there should be work values for medical nutrition therapy just as there are for physical and occupational therapy.

Response. We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy. Section 105(c) of the BIPA states that "the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) of the Act for the same services if furnished by a physician." The BIPA Conference Report indicates that payment will equal "the lesser of the actual charge for the service or 85 percent of the amount that would be paid under the physician fee schedule if such services were provided by a physician." The statute and Conference Report direct us to establish the physician fee schedule amount for nutrition therapy services. The Medicare allowed charge would equal 100 percent of the physician fee schedule amount if the services are performed by a physician and 85 percent of the physician fee schedule amount if the services are performed by a registered dietitian or nutrition professional. The commenters suggest that physicians currently bill for an E/M service when they provide nutrition services. We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered dietitian to an E/M service provided by a physician. Registered dietitians do not take medical histories, they are not trained to and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/M code to report the provision of counseling or coordination of care, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be appropriate for him or her to report an E/M service. Further, we note that the E/M services include not only an amount attributable to physician work, but also payment for physician practice expenses. For instance, a level 3 new patient office visit (CPT code 99203) includes payment for 30 minutes of nurse time. A level 3 established patient office visit (CPT code 99213) includes 36 minutes of nurse time. Both of these codes include additional compensation for medical equipment and supplies that are typically used in an office visit but are not used as part of a medical nutrition therapy service. If we were to adopt the commenters' view and crosswalk values for medical nutrition therapy to an E/M service, we would be including payment not only for the counseling service of the practitioner, but also, inappropriately for the costs of clinical personnel that are not involved in the nutrition therapy service.

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Commenters indicated that the statute established the 85 percent adjustment to account for activities that are typically performed by a physician during an E/M service are not performed by a nutritionist. The statute and legislative history do not indicate that the 85 percent adjustment is intended to serve this purpose. In fact, the commenters themselves note that "consistent with other non-physician providers, reimbursement is set at a percentage of the physician's fee schedule." Under the physician fee schedule, we will pay a physician 80 percent of 100 percent of the physician fee schedule amount, and, if a non-physician practitioner provides an identical service, Medicare pays 80 percent of 85 percent of the physician fee schedule amount. For instance, under CPT code 99213, a level 3 established patient office visit is one of the most common services provided by physicians, physician assistants and nurse practitioners. Even though the service is considered to be identical, we can by law pay a physician assistant and nurse practitioner only 85 percent of what we pay a physician to do the same service. Thus, in the case of other practitioners, the percentage does not reflect that a non-physician practitioner provides fewer services than a physician. Because there is no indication in the statute that the 85 percent adjustment should apply differently in the context of medical nutrition therapy than for other services performed by non-physician practitioners, we believe it is appropriate to pay 80 percent of 100 percent of the physician fee schedule amount when medical nutrition therapy is provided by a physician and 80 percent of 85 percent of the physician fee schedule amount when the service is provided by a registered dietitian or nutrition professional.

In response to the comment about payment rates of private insurers for medical nutrition therapy, we cannot use such information in a relative value system to establish payment. Section 1848(c) of the Act requires us to establish RVUs that recognize the relative resources involved in furnishing different physician fee schedule services. Thus, our role is to establish the appropriate relative payment amounts. The total payment amount is determined under a formula prescribed in section 1848(d) of the Act. We have no authority to change the formula.

In response to the HCPAC recommendation, we reiterate that it is inappropriate to compare medical nutrition therapy services to E/M services performed by physicians. While medical nutrition therapy may be performed by a physician who is also a registered dietitian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount. In this unusual circumstance, we are paying for a medical nutrition therapy service provided by a physician under section 1861(s)(2)(V) and not a physician's service under section 1861(s)(1) of the Act.

Comment: One comment indicated that the 85 percent adjustment should not apply because the RVUs we used are not based on physician work or physician practice expenses to deliver the service. This commenter indicated that we proposed an inadequate payment by not following the statutory scheme and proceeded to apply a 15 percent discount that is neither fair nor reasonable.

Response. The statute requires us to establish a physician fee schedule amount for the service and pay 80 percent of 100 percent of the amount if the service is provided by a physician and 80 percent of 85 percent if the service is provided by a registered dietitian or nutrition professional. We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would not meet the statutory requirements to be considered registered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered dietitians or nutrition professionals. In these circumstances, our payment to the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dietitian or nutrition professional. We believe the statute would not allow a physician who does not meet the statutory requirements for a registered dietitian or nutrition professional to be paid for a medical nutrition therapy service. If a physician provides medical nutrition counseling as part of a patient encounter that meets the requirements for an E/M service, the physician can bill Medicare for a physician's service.

Comment: We received one comment requesting that we clarify that Medicare will pay qualified providers in private practice settings or physician offices where they may be independent contractors. The commenter also asked how we intend to pay for medical nutrition therapy in the hospital outpatient department. The commenter also asked for clarification on reassignment of payment if a registered dietitian is an employee of physicians or hospital outpatient facilities.

Response: Medicare will pay qualified dietitians and nutrition professionals who enroll in the Medicare program regardless of whether they provide medical nutrition therapy services in an independent practice setting, hospital outpatient department or any other setting, with the exception of services provided to patients in an inpatient stay in a hospital or skilled nursing facility. In these circumstances, our payment to the hospital or skilled nursing facility includes payment for medical nutrition therapy. If a qualified practitioner provides medical nutrition therapy in any other setting, including a private practice setting, section 1833(a)(1)(T) of the Act requires that Medicare payment equal 80 percent of the lesser of actual charges or 80 percent of 85 percent of the amount determined under the physician fee schedule. Payment in the hospital outpatient department will be made under the physician fee schedule, not under the hospital outpatient prospective payment system.

Current rules regarding reassignment of benefits would apply to medical nutrition therapy. We want to emphasize that medical nutrition therapy cannot be provided incident to a physician's service unless the physician also meets the qualifications to bill Medicare as a registered dietitian or nutrition professional.

Comment: Commenters objected to the methodology used to establish the proposed RVUs for this service. They believe it is inappropriate to use the top-down or no-work pool methodology to determine medical nutrition therapy payment. They believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The

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commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness. They disagree with our assertion in the proposed rule that physicians do not perform nutrition services and assert that it is inappropriate to use the top-down or zero-work methodology to establish the RVU for medical nutrition therapy.

Response: We use the top-down methodology or no-work pool methodology to price the practice expense RVUs for all services priced under the Medicare physician fee schedule. Given that the statute indicates that medical nutrition therapy should be paid using the physician fee schedule, we believe it is reasonable and appropriate to use the same methodologies that we use to develop RVUs for other physician fee schedule services. With respect to use of the preventive medicine service, we used a service that we felt had similar practice expenses to medical nutrition therapy. It is not clear why practice expenses for a counseling service would differ based on the health status of the patient.

Comment: A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT code 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe that the value of CPT codes 97802 and 97803 should be identical. The commenters indicated that E/M services provided by physicians do not receive the same discount. The commenter also stated that the payment for CPT code 97804 was less than for other group services and gave the example of a nurse or pharmacist providing nutrition instruction under the diabetes self-management training benefit.

Response: We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services. (We note that the RVU units between the proposed and final rule show some marginal change because of changes made in the practice expense methodology that affect all physician fee schedule services). We do not agree with the comment that "evaluation and management services provided by physicians do not receive the same discount." E/M service are not time based services and, as stated above, for many reasons are inappropriate comparisons to medical nutrition therapy service codes.

Comment: Many commenters stated that co-payments must be structured so that they are not barriers to the medical nutrition therapy benefit.

Response: Section 105(c) of the BIPA modifies section 1833(a)(1) of the Act to add subparagraph (T) that requires that Medicare payment equal 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under physician fee schedule. The statute requires the same coinsurance for medical nutrition therapy services that applies to other Part B services.

Comment: Commenters suggested that initial medical nutrition therapy sessions for treatment of diabetes or renal disease should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803. New diagnoses due to a change in medical condition or unanticipated complications should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803.

Response: At the present time, we are requiring that medical nutrition therapy be reported by using CPT codes 97802, 97803, and 97804. We will revisit our coding requirements when we publish the NCD for medical nutrition therapy. The NCD will set forth the structure of the medical nutrition therapy benefit in detail. We will make a decision concerning creation or modification of codes and creation of modifiers for reporting medical nutrition therapy once the NCD has been published. Until the NCD is published, creation or modification of codes and creation of modifiers would be premature. Therefore, we are requiring that the initial individual medical nutrition therapy visit be reported as CPT code 97802 and all follow up visits (for interventions and reassessments) for individual medical nutrition therapy be reported as CPT code 97803. All group medical nutrition therapy visits should be reported as CPT code 97804 whether they are initial or follow up visits.

Comment: Commenters urged us to define medical nutrition therapy descriptors consistently. They stated that the descriptors in Table 5 of the proposed rule should agree with the descriptors in § 414.132.

Response: We agree. We will make the descriptors for medical nutrition therapy consistent with the nomenclature in CPT and our regulations.

Comment: We received a comment that recommended that we consider including additional items in the practice expense inputs for medical nutrition therapy. The commenter indicated that inputs should include staff costs for training on billing procedures, Health Insurance Portability and Accountability Act training, audit expenses, and other costs resulting from Medicare policies and procedures. The commenter indicated that expenses of registered dietitians in private practice differ little from other practitioners.

Response: There are two major data sources used in the practice expense methodology—estimates of direct inputs and aggregate practice expense per hour information from the AMA's Socioeconomic Monitoring Survey. At this time, we are using the practice expense per hour for all physicians to establish the practice expense RVUs for medical nutrition therapy. We are not currently using the estimates of direct expenses for medical nutrition therapy because the services are valued in the no-work pool. However, we are researching alternatives to the no-work pool that would allow all no-work services to be priced under the top-down methodology. If we develop such an alternative, the estimates of direct expenses will be important in determining the RVUs for medical nutrition therapy. Indirect expenses are based on physician work and direct inputs. We believe that many of the costs identified by this commenter are indirect costs that would likely be included in practice expenses reported through the SMS survey. Since the commenter has suggested that practice expenses for private practice registered dietitians differ little from other

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practitioners, we believe the average practice expense per hour for all physicians is sufficient to use in the practice expense methodology.

Result of Evaluation of Comments

The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the rate for CPT code 97802. We are also changing the payment rate for CPT code 97804 using the assumption that the code will normally be billed for 4 to 6 patients with the average of 5. Using these revised values, the payment rate for group medical nutrition therapy will approximate the hourly rate paid for other medical nutrition therapy services.

F. Telehealth Services

Beginning October 1, 2001, the BIPA amended section 1834 of the Act to specify that we pay a physician (as defined in section 1861(r) of the Act) or a practitioner (described in section 1842(b)(18)(C) of the Act) for telehealth services that are furnished via a telecommunications system to an eligible telehealth individual.

The BIPA defined Medicare telehealth services as professional consultations, office or other outpatient visits, and office psychiatry services identified as of July 1, 2000, by CPT codes 99241 through 99275; 99201 through 99215, 90804 through 90809 and 90862 (and as we may subsequently modify) and any additional service we specify. The BIPA defines an eligible telehealth individual as an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

Section 1834(m) of the Act, as added by the BIPA, limited an originating site to a physician's or practitioner's office, hospital, critical access hospital, rural health clinic, or Federally qualified health center. Additionally, the BIPA specified that the originating site must be located in one of the following geographic areas:

- In an area that is designated as a rural health professional shortage area (HPSA) under section 332(a)(1)(A) of the Public Health Service Act.
- In a county that is not included in a Metropolitan Statistical Area (MSA).

However, an entity participating in a Federal telemedicine demonstration project that has been approved by, or receives funding from us as of December 31, 2000 would not be required to be in a rural HPSA or non-MSA.

The BIPA also required that we pay a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth beneficiary an amount equal to the amount that the physician or practitioner would have been paid under Medicare had the service been furnished without the use of a telecommunications system.

This section also provided for a facility fee payment for the period beginning October 1, 2001 through December 31, 2002, to the originating site of $20. For each subsequent year, the facility fee for the preceding year is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The BIPA also amended section 1833(a)(1) of the Act to specify that the amount paid must be 80 percent of the lesser of the actual charge or the amounts specified in new section 1834(m)(2) of the Act.

In order for us to have this benefit expansion implemented timely, we have used a program memorandum. The program memorandum was effective October 1, 2001. This final rule will be effective January 1, 2002.

The rule published on August 2, 2001 proposed to establish policies for implementing the provisions of section 1834(m) of the Act, as added by the BIPA, that change Medicare payment for telehealth services.

We proposed to revise § 410.78 to specify that Medicare beneficiaries are eligible for telehealth services only if they receive services from an originating site located in either a rural HPSA as defined by section 332(a)(1)(A) of the Public Health Services Act or in a county outside of a MSA as defined by section 1886(d)(2)(D) of the Act.

1. Definitions

Section 1834(m)(4)(F) of the Act, which was added by the BIPA and became effective for services beginning October 1, 2001, defined telehealth services as professional consultations, office and other outpatient visits, individual psychotherapy, pharmacologic management, and any additional service we specify. Additionally, this provision identified covered services by HCPCS codes identified as of July 1, 2000. We proposed to revise § 410.78 to implement this coverage expansion to include the following services (and corresponding CPT codes):

- Consultations (codes 99241 through 99275).
- Office and other outpatient visits (codes 99201 through 99215).
- Individual psychotherapy (codes 90804 through 90809).
- Pharmacologic management (code 90862).

We solicited comments regarding the guidelines that we should use to make additions or deletions of services. We also solicited comments about specific services that may be appropriate to be covered under the Medicare telehealth benefit.

In this final rule, we are specifying at § 410.78 that, except for the use of store and forward technology in the demonstration programs conducted in Alaska or Hawaii, an interactive telecommunications system must be used and the medical examination of the patient must be at the control of the physician or practitioner at the distant site. We are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and physician or practitioner at the distant site. We are also specifying that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

A patient need not be present for a Federal telemedicine demonstration program conducted in Alaska or Hawaii. We are specifying that for Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system. Additionally, we are specifying that the physician or practitioner at the distant site must be affiliated with the demonstration program.

We are defining asynchronous, store and forward technologies, as the transmission of the patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patient's medical condition and adequate for rendering or confirming a diagnosis or treatment plan. Finally, we are defining the originating site as the location of an eligible telehealth individual at the time the service being furnished via a telecommunications system occurs.

2. Conditions of Payment

The BIPA changed the telepresenter requirements. In accordance with section 1834(m)(2)(C) of the Act, a

EXHIBIT "D"
PAGE 4 OF 4

Provider Explanation of Benefits

PROVIDER NAME	PROVIDER NUMBER	STATEMENT DATE	TAX ID
MIDTOWN NUTRITION CARE	9203E	03/10/05	132845837

SITE NUMBER	CHECK NUMBER
100	0000026514400

Empire BlueCross BlueShield

Detail of Claims

PATIENT NAME	PATIENT ACCOUNT NUMBER	MEMBER ID	CONTRACT TYPE	CLAIM NUMBER
[redacted]	132171	[redacted]		50610214700 PSU CODE 15

		Submitted Charges	Charges Not Allowed	Allowed Amount
Service Information	Procedure Code: 97802 Service Type/Place: 6 OFC Date(s): 02/25/05 - 02/25/05 No. of Units: 6	$300.00	$0.00	$300.00

Payment Calculation	Allowed Amount	$300.00
	Copayment	5.00
	Plan Payment for this Service:	$295.00
	Total Patient Responsibility:	*$5.00*
	Total Payment for this Claim:	*$295.00*

6 x $50.00

[redacted]

THE FACE OF THIS DOCUMENT HAS A BLUE BACKGROUND. IF NOT BLUE, DO NOT CASH.

⑈0026514400⑈ ⑆061209756⑆ 2079900411485⑈

EXHIBIT "E"
PAGE 1 OF 4

REMITTANCE ADVICE

Vendor Name: ROBERT L HOWARD
Vendor ID #: P2845837-P2679923
Member Name: [redacted]
Member ID: [redacted]
Patient Acct #: 12542-1

TIN: 132845837
Check Number: 28419702 01-12-2005
Provider Name: GROSSANO, DEBRA
Provider ID: P2679923
Claim #: 4357N16329

Serv Date	CPT Code	Description	QTY	Billed Amt	Max Amt	Withhold Amt	Deductible Amt	Copay/Co-ins Amt	Adj Code	COB Amt	Payment Amt
12-20-04	97802	MED NUTRIT TX INIT 1:1-PT EA 15	6	300.00	258.80			10.00			258.80
TOTAL CLAIM				300.00	258.80	0.00		10.00		0.00	258.80

	Billed Amt	Max Amt	Withhold Amt	Deductible Amt	Copay/Co-ins Amt	COB Amt	Payment Amt
Claim Payment Summary	300.00	258.80			10.00		258.80

Check Summary

Total Paid 258.80
Check Date..... January 12, 2005
Paid To..... ROBERT L HOWARD
Check Number..... 28419702

6 X $44.80
FREEDOM PLAN

ATTENTION: THIS MAILING MAY CONTAIN DOCUMENTATION ON VARIOUS MATTERS

Oxford Health Plans (NY), Inc.

Please see last page for Appeals Rights

DETACH HERE DETACH HERE

Oxford Health Plans (NY), Inc.
7700 Main St. Trumbull, CT 06611

Chase Manhattan Bank Delaware
Wilmington, DE, 19801

62-26
311

28419702

4691-09

January 12, 2005

PAY:

Two Hundred Fifty Eight Dollars and 80 Cents********** 258.80

**********AUTO**3-DIGIT 100
N 038 9750
ROBERT L HOWARD
[illegible] STE 1414
NEW YORK NY 10019-2401

Authorized Signature
(not valid after 180 days)

⑈28419702⑈ ⑆031100267⑆ 6301446914 509⑈

EXHIBIT "E" - PAGE 2 OF 4

[redacted]

REMITTANCE ADVICE

Vendor Name: ROBERT L HOWARD
Vendor ID #: P2845837-P442628
Member Name: [redacted]
Member ID: [redacted]
Patient Acct #: 12164-1

TIN: 132845837
Check Number: 28582141
Provider Name: GOLDFARB, BETH
Provider ID: P2586860
Claim #: 5022N17157

02-12-2005

[redacted]

Serv Date	CPT Code	Description	QTY	Billed Amt	Max Amt	Withheld Amt	Deductible Amt	Copay/Co-ins Amt	Adj Code	COB Amt	Payment Amt
01-20-05	97803	MED NUTRIT TX; F/U 1:1-PT EA 15	2	100.00	80.64			15.00			65.64
TOTAL CLAIM: 5022N17157				100.00	80.64	0.00		15.00		0.00	65.64

	Billed Amt	Max Amt	Withheld Amt	Deductible Amt	Copay/Co-ins Amt	COB Amt	Payment Amt
Claim Payment Summary	100.00	80.64			15.00		65.64

Check Summary

Total Paid 65.64
Check Date..... February 12, 2005
Paid To..... ROBERT L HOWARD
Check Number..... 28582141

2 X 40.32
LIBERTY PLAN

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Oxford Health Plans (NY), Inc.

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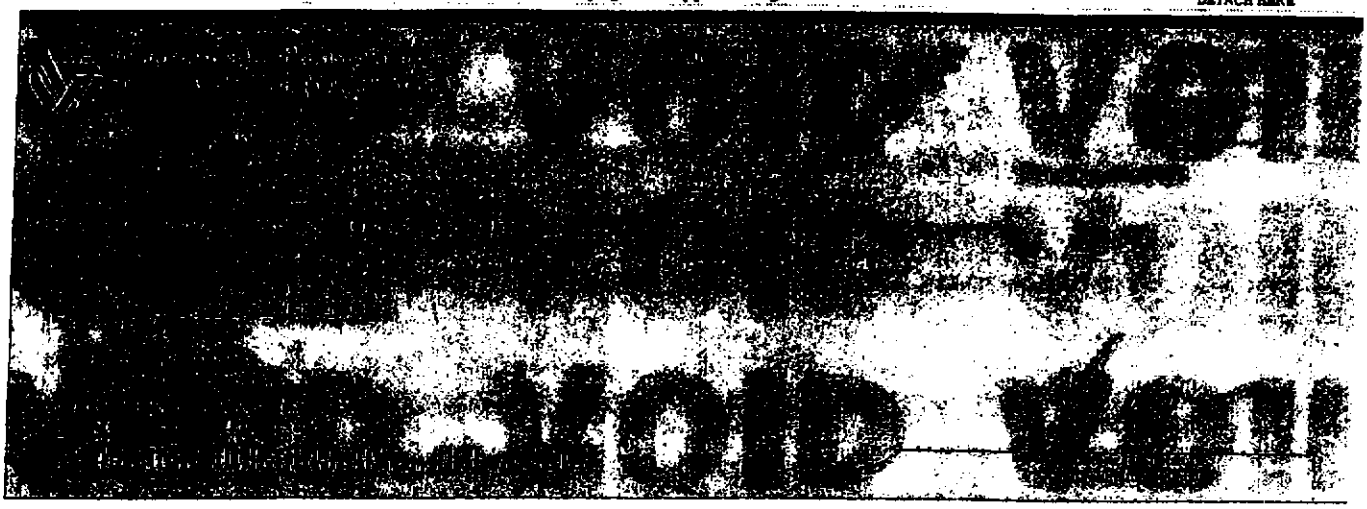

⑈28582141⑈ ⑆031100267⑆ 6301446914 509⑈

EXHIBIT "E" - PAGE 3 OF 4

GHI
GROUP HEALTH INCORPORATED
P.O. BOX 2814
NEW YORK, N.Y. 10116-2814

PAY TO THE ORDER OF

DATE | CHECK NUMBER

MIDTOWN NUTRITION CARE
119 WEST 57TH ST.
STE 1414
NEW YORK , NY 10019-2401

GROUP HEALTH INCORPORATED P.O. BOX 2814, NEW YORK, N.Y. 10116-2814 DETACH BEFORE CASHING EXPLANATION OF BENEFITS CHECK NUMBER

Check Date: 08/13/04 9582195

Provider: GOLDFARB BETH R RD

The information below summarizes GHI's claim settlement(s) for the service(s) and patient(s) listed.

Subscriber(s)/ Service(s)	Certificate(s)/ Service Date(s)	Claim Number(s)	Acct No(s)/ Patient(s)	Charge(s) Submitted	CoPayment(s) Applied	Benefit Payment(s)	Note(s)
			11620-1				
PHYSICIAN EDUCAT SVC	07/31/04	EMC6171966	NEAL	$50.00	$15.00	$20.00	
PHYSICIAN EDUCAT SVC	07/31/04	EMC6171966	NEAL	50.00	15.00	20.00	
PHYSICIAN EDUCAT SVC	07/31/04	EMC6171966	NEAL	50.00	15.00	20.00	
PHYSICIAN EDUCAT SVC	07/31/04	EMC6171966	NEAL	50.00	15.00	20.00	
TOTALS				$200.00	$60.00	$80.00	

4 X $35.00

CALLED "PHYSICIAN EDUCAT SVC" BY GHI, BUT THIS NAME IS USED FOR CPT 97802, AS BILLED

Payment Summary

Basic Allowance	$140.00
Co-payment	60.00
Payment To You	$80.00

Note(s):

To report suspected fraud, call GHI's Fraud Hotline at 1-888-4-KO-FRAUD (1-888-456-3728) or e-mail kofraud@ghi.com

EXHIBIT "E"
PAGE 4 OF 4

3296475

8099870-99

MIDTOWN NUTRITION CARE
Jennifer DePaolo, RD / Beth Goldfarb, RD
Kristin Greenspan, RD / Debra Grossano, RD / Robert Howard, RD
Laurie Simon, RD / Carolyn Vlachos, RD
NYS Licensed Dietitian-Nutritionists
119 West 57th Street, Suite 1414
New York, N.Y. 10019
Tel: (212) 333-4243
FAX: (212) 333-3468
email: midtown.nutrition@verizon.net
website: www.midtownnutrition.com

FAX COVER SHEET

TO: Munir Madyun

RE: CMS Letter

DATE & TIME: 9/23/05 3 PM

FAX NO: (202) 225-6001

PHONE NO: (202) 225-4361

TOTAL PAGES INCLUDING COVER PAGE: 22

COMMENTS:

Copy of my signed submission, with exhibits. Thanks again.

Bob

MIDTOWN NUTRITION CARE
119 WEST 57TH STREET—SUITE 1414
NEW YORK, NY 10019
(212) 333-4243

September 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Specific Re: Impact of Proposed Elimination of Nonphysician Work Pool on Medical Nutrition Therapy Services (CPT 97802-4)

Specific CMS Language: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change....We, therefore, welcome all comments on these proposed changes..." Federal Register, August 8, 2005, p. 45777

Dear Sir or Madam:

Midtown Nutrition Care respectfully submits the following comments that will show how CMS may not only avoid any negative impact on medical nutrition therapy services, but also increase access to these important preventive medicine services.

History of Medical Nutrition Therapy Reimbursement

1. August 4, 1995, 104th Congress, 1st Session, Representative Serrano introduced the first medical nutrition therapy bill, HR 2247, "Medical Nutrition Therapy Act of 1995". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]

2. July 17, 1996, 104th Congress, 2nd Session, Senator Bingaman introduced S 1964, "Medical Nutrition Therapy Act of 1996". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]

3. January 7, 1997, 105th Congress, 1st Session, Representative Serrano introduced HR 288, "Medical Nutrition Therapy Act of 1997". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph." [emphasis supplied]

4. June 24, 1997, 105th Congress, 1st Session, Senators Craig and Bingaman introduced S Amdt 454, which became Section 5105 of PL 105-33, "Study on Medical Nutrition Therapy Services." It provides "(a) Study: The Secretary of Health and Human Services shall request the National Academy of Sciences, in conjunction with the United States Preventive Services Task Force, to analyze the expansion or modification of preventive benefits provided to medicare beneficiaries under title XVIII of the Social Security Act to include medical nutrition therapy services by a registered dietitian. (b) Report: (1) Initial report: Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit a report on the findings of the analysis conducted under subsection (a) to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate. (2) Contents: Such report shall include specific findings with respect to the expansion or modification of coverage of medical nutrition therapy services by a registered dietitian for medicare beneficiaries regarding—(A) cost to the medicare system; (B) savings to the medicare system; (C) clinical outcomes; and (D) short and long term benefits to the medicare system. (3) Funding: From funds appropriated to the Department of Heath and Human Services for fiscal years 1998 and 1999, the Secretary shall provide such funding as may be necessary for the conduct of the analysis by the National Academy of Sciences under this section."

5. March 18, 1999, 106th Congress, 1st Session, Representative Johnson, on behalf of herself, Representative Serrano, and numerous others, introduced HR 1187, "Medical Nutrition Therapy Act of 1999". Relevant reimbursement language was "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined under the fee schedule established under section 1848(b) [the physician fee schedule] for the same services if furnished by a physician." [emphasis supplied]

6. December 15, 1999, the Institute of Medicine of the National Academy of Sciences issued its report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly, Evaluating Coverage of Nutrition Services for the Medicare Population," National Academy Press, Washington, DC, 2000, ISBN 0-309-06846-0. Among its findings was: "The registered dietitian is currently the single identifiable group of health professionals qualified to provide nutrition therapy. It is recognized that other health care professionals in particular fields may be qualified to provide nutrition therapy and should be considered on an individual basis as a reimbursable provider." (Page 272 of published report)

7. December 2000, 106th Congress, 2nd Session, Congress enacted PL 106-554, which contains Section 105, "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes and Renal Disease." Relevant reimbursement language is "...the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) [the

physician fee schedule] for the same services if furnished by a physician." [emphasis supplied] Other relevant language is: "The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional."

8. August 2, 2001, CMS published in the Federal Register its proposed rule for the medical nutrition therapy benefit which was to become available on January 1, 2002. Part of the proposed rule was "Payment for Medical Nutrition Therapy (§414.64)." It states, in relevant part: "The statute specifically provides that medical nutrition therapy services may only be provided by registered dietitians or nutrition professionals. We do not believe that physicians will be able to satisfy the qualification requirements and therefore will not be able to provide this service themselves. Therefore, we are not establishing physician work RVUs for this service. We interpret section 105(c)(2) of BIPA to mean that if a physician were to furnish this service, that the service was performed 'incident to' the physicians treatment plan and provided by a registered dietitian or nutrition professional." [emphasis supplied]

9. November 1, 2001, CMS published in the Federal Register its final rule. Among the responses to the comments received was: "While medical nutrition therapy may be performed by a physician who is also a registered dietitian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy service. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount.... We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would never meet the statutory requirements to be considered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered dietitians or nutrition professionals. In these circumstances, our payment the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dietitian or nutrition professional." [emphasis supplied] (Page 55279 of 2001 Federal Register)

10. Earlier in the final rule CMS states: "The American Dietetic Association (ADA) and many individuals submitted comments concerning the proposed reimbursement rate for medical nutrition therapy services. They stated that the proposed reimbursement rate for these services is too low and would result in limited beneficiary access to these services since private practice dietitians will chose not to participate....They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress....The commentators also stated that any refinement of medical nutrition therapy values should

be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commentators acknowledge that physicians may perform other tasks besides nutrition assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a comment that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by non-physician providers....We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy." [emphasis supplied] (Page 55278 of 2001 Federal Register)

Using a Reimbursement Methodology That Includes a Physician Work Value Will Not Only Avoid Any Negative Impact On Medical Nutrition Therapy Services From the Elimination of the Nonphysician Work Pool, But Will Also Increase Access To These Preventive Medicine Services

11. We agree that Congress probably did not envision a particular amount or particular E/M service, but did Congress intend to pay nutritionists 85% of what a physician is paid for administering chemotherapy or performing the technical component of a diagnostic x-ray? Or did Congress intend to pay dietitians 85% of what it costs a physician to employ a dietitian to provide the services? If Congress had intended to focus on a dietitian's work value, then why didn't the law establish a separate fee schedule for dietitians (as Medicare has for psychologists and as the 1995, 1996 and 1997 bills had envisioned)?

12. After the 1995, 1996 and 1997 bills by Representative Serrano and Senator Bingaman that would have established a separate dietitian fee schedule, and after the 1997 Craig and Bingaman amendment established a study to be made of "medical nutrition therapy services by a registered dietitian", what did Representatives Johnson, Serrano and others intend when they introduced in March 1999 a bill that would have paid dietitians the amount determined under the physician fee schedule for the same services if furnished by a physician instead of pursuant to a separate dietitian fee schedule? And after the December 1999 report by the National Academy of Sciences found the registered dietitian to be the single identifiable group qualified to provide medical nutrition therapy (although others may be qualified), what did Congress intend when they passed in December 2000 a law that continued to determine payment not pursuant to a separate dietitian fee schedule but by paying 85% (instead of 100% as in the Johnson bill) of the amount determined under the physician fee schedule for the same services if performed by a physician, and also defined the providers to be registered dietitians or other nutrition professionals?

13. Could it possibly be that Congress intended by not having a separate dietitian fee schedule that Congress meant to exclude physician work value? Or, is it at least as likely that Congress intended to pay 85% of what a physician would be paid, including physician work value, so as to insure that reimbursement would be fixed at a level that would enable a sufficient number of dietitians to participate so that Medicare

beneficiaries would have access to this preventive benefit (and preventive benefits are what Congress want all entitled beneficiaries to get so as to hold down costs over the long term). The original sponsor of the medical nutrition therapy benefit and cosponsor of the bill that eventually became the law has asked CMS to "...please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law." (See copy of September 22, 2005 letter to CMS from Representative Serrano, attached as Exhibit "A")

14. That the envisioned access has not been provided can be seen from the fact that prior to passage the CBO estimated the annual cost of medical nutrition therapy services to be $60 million, whereas only about $1 million per year has been spent annually since the benefit became available in 2002. This represents visits by only about 250,000 beneficiaries out of an estimated 8 million plus beneficiaries with diabetes and renal disease (the two conditions for which Medicare currently provides medical nutrition therapy benefits). Only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. Journal of the American Dietetic Association, June 2005, p. 990 (copy, along with p.995, footnote references, attached as Exhibit "B").

15. There is a lengthy discussion in the November 1, 2001 final rule (Pages 55278-80 of 2001 Federal Register) stating that work value should not be included because medical nutrition therapy services do not involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel involved in most evaluation and management services by physicians. However, the evaluation and management code to which the medical nutrition therapy codes was compared for the basis of valuation is Preventive Medicine Service Counseling and/or Risk Factor Reduction Intervention (CPT Code 99401) which, unlike most evaluation and management codes, does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel! (A copy of the CPT's entire Preventive Medicine Services section, 2 pages, is attached as Exhibit "C".)

16. We think the reason CMS did not notice that CPT Code 99401 does not generally involve these components is because 2 interrelated points had been raised in comments to the proposed rule. First that CMS should compare the 15-minute medical nutrition therapy code CPT 97802 to the 15-minute office visit code CPT 99213, rather than to the 15-minute preventive medicine counseling code CPT 99401; and second that a physician's work value should be included in valuing medical nutrition therapy services. Therefore, it was natural for CMS to look at the medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components of CPT Code 99213, and not notice that these components are generally lacking in CPT Code 99401. (Attached as Exhibit "D" is a copy of the entire final rule "Payment for Medical Nutrition Therapy" discussion, pp. 55278-55281.)

17. Because CPT Code 99401 does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and

clinical personnel, the valuation of CPT Code 99401 is already significantly lower than other 15-minute evaluation and management service codes that involve these components, see 2005 Relative Value Units for the following codes (Pages 66666, 66668 and 66671 of 2004 Federal Register):

15-minute Code	Work RVU	Non-facility Practice Expense RVU	Malpractice RVU	Non-facility Total
99213 (Office Visit)	**0.67**	**0.69**	**0.03**	**1.39**
99241 (Office Consultation)	**0.64**	**0.64**	**0.05**	**1.33**
99401 (Prev Medicine Counseling)	**0.48**	**0.62**	**0.01**	**1.11**
97802 (Med Nutrition Therapy)	**0.00**	**0.47**	**0.01**	**0.48**

18. The discussion by CMS that stated that work value should not be included because medical nutrition therapy services do not involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel was set forth for the first time in the final 2001 rule, and not in the proposed 2001 rule. Therefore, CMS was unable to receive comments that might have pointed out that CPT Code 99401 also does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel (so while the lack of these components may be a good reason for cross walking the medical nutrition therapy codes to CPT Code 99401, rather than to CPT Code 99213, it is not a good reason to disregard physician work value).

19. However at this time CMS can take notice that CPT Code 99401 does not generally involve medical histories, physical examinations or medical decisions, or the use of medical equipment and supplies and clinical personnel, and therefore could (and should) continue the comparison to CPT Code 99401, but utilize the CPT Code 99401 work value, plus the CPT Code 99401 practice and malpractice expense RVUs for valuing the medical nutrition therapy codes (and then paying a physician 80% of 100%, and a dietitian 80% of 85%, of the total of these 3 values). This would be analogous to the payment of physician assistants and nurse practitioners 80% of 85% of CPT Code 99213 or other evaluation and management services that, as appropriate for their practice, contain medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components. And this would allow a physician who is also a dietitian to be paid appropriately (80% of 100%) for medical nutrition

therapy services since a physician cannot otherwise use CPT Code 99401 because while it has been valued, CPT Code 99401 is a noncovered service for which Medicare payment may not be made. (Page 66671 of 2004 Federal Register; Page 45999 of 2005 Federal Register)

20. As in the 2001 final rule, the valuation of the 15-minute individual medical nutrition therapy Code 97803 should continue to be the same as the valuation of the 15-minute individual medical nutrition therapy Code 97802; and the valuation of the 30-minute group medical nutrition therapy Code 97804 should continue to approximate the hourly valuation of the individual medical nutrition therapy codes based on an assumption of an average of 5 patients in a group (that is, each RVU value for the 30-minute group increment should be determined by multiplying the corresponding RVU value for the individual 15-minute increment by 2, then dividing by 5).

21. Unlike the issue of medical history, physical examination, medical decision, medical equipment, medical supplies and clinical personnel components, which was raised for the first time in the 2001 final rule, the issue of whether the two individual 15-minute codes would be valued the same or differently was fully discussed in the 2001 proposed rule, in comments thereto, and in the final rule, which stated as follows: "We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commentator that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (Page 55281 of 2001 Federal Register)

22. That reasoning was sound in 2001 and remains sound, and should continue to be followed, rather than create a 0.01 less RVU for CPT code 97803 as proposed at Page 45997 of the August 8, 2005 Federal Register.

Our Practice

23. Our group practice, Midtown Nutrition Care, has seven full-time Registered Dietitians who see approximately 700 patients per month, about 1/3 of which have diabetes or kidney disease.

24. We are providers for all the major commercial insurance companies in our area. These currently pay an average of $42.53 per 15-minute increment for CPT Codes 97802 and 97803 (which codes are valued equally by the commercial insurers we bill these codes). Copies of explanations of benefits (with patient identifiers deleted), which show

these amounts to be $50, $44.80, $40.32 and $35 per 15-minute increment, are attached as Exhibit "E".

25. Because Medicare currently pays only about $18 per 15-minute increment for our geographical area, which is one of the highest in the nation (and would be reduced an additional 10% under the proposed 2006 physician fee schedule) we cannot afford to see Medicare patients and none of us has become a Medicare provider. We therefore turn away a couple of Medicare patients per day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the private practice nutritionists in our area accept Medicare.

26. If payment for the 15-minute increment were to a little more than double as proposed above it would roughly equal the average we are receiving from commercial insurance companies in our area and we would all become providers and accept Medicare. Based on my experience as co-reimbursement chair for the New York State Dietetic Association I also believe that the vast majority of private practice nutritionists in my area and nationwide would do likewise. Therefore, if the above proposal is followed it will not only avoid any negative impact from the elimination of the nonphysician work pool, it will also provide appropriate access to care for all Medicare beneficiaries entitled to these services.

Sincerely yours,

Robert Howard, RD, JD
Managing Partner

JOSÉ E. SERRANO
16TH DISTRICT, NEW YORK

WASHINGTON OFFICE:
2227 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3216
(202) 225-4361
FAX: (202) 225-6001

DISTRICT OFFICE:
788 SOUTHERN BOULEVARD
BRONX, NY 10455
(718) 620-0084
FAX: (718) 620-0658

www.house.gov/serrano

Congress of the United States
House of Representatives
Washington, DC 20515–3216

COMMITTEE:
APPROPRIATIONS
SUBCOMMITTEES:
RANKING DEMOCRAT
COMMERCE, JUSTICE, STATE, AND JUDICIARY
HOMELAND SECURITY

MEMBER, CONGRESSIONAL
HISPANIC CAUCUS

MEMBER, CONGRESSIONAL
BLACK CAUCUS

VICE CHAIR
DEMOCRATIC STEERING
COMMITTEE

September 22, 2005

Dr. Mark B. McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

I was the sponsor of the original medical nutrition therapy benefit bills in the mid 90s and cosponsor of the 1999 bill that eventually became law, as Section 105 of PL 106-544, entitled "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes and Renal Disease".

As you review the rule pertaining to medical nutrition therapy benefits, please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing a zero work value for nutrition therapy severely limits access to these services and thus subverts the intent of the law.

I have reviewed the comments of Midtown Nutrition Care and would ask that they be given every consideration as the rule in question is reviewed.

Sincerely,

José E. Serrano
Member of Congress

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mation packets, meetings and conference calls, and support developing language that describe MNT services provided by RDs as a component of the CCI program.

MEDICARE ADVANTAGE

Medicare+Choice will be replaced with Medicare Advantage effective January, 2006. CMS announced on December 6, 2004 that there will be 26 Medicare Advantage regions established across the nation for health insurance plans wishing to participate in the new program. Participating health insurance plans will be required to service the entire region. Each Medicare Advantage regional plan will have a network of providers who agree to contractually specified reimbursement levels for covered benefits.

The intent of this new provision is to have traditional fee-for-service Medicare compete head to head on prices with private insurance companies. In order to gain sufficient support to pass the bill, this new provision is a 6-year demonstration program in up to six standard metropolitan statistical areas (SMSAs). Private insurers will be able to begin bidding to serve Medicare beneficiaries in regions beginning in 2006. Payment rates would be based on a blended average of the bids. The traditional Medicare system will compete with private plans in selected SMSAs beginning in 2010. There are significant incentives in the new law to encourage private insurance companies to participate in this program.

How the Medicare Advantage program affects utilization of the Medicare MNT coverage, and the two new programs that include MNT benefits, remains to be seen. There is the potential for significant growth in MNT services. According to the proposed rules released by CMS, beginning in 2006, the Medicare Advantage program will have to "enrich the range of benefit choices available to enrollees, including not only improved prescription drug benefits, but also other benefits not covered by traditional Medicare, and the opportunity to share in savings where plans can deliver benefits at lower costs" (78).

MEDICARE MNT'S IMPACT ON PRIVATE INSURANCE PLANS' COVERAGE

ADA researchers conducted an environmental scan in 2002 to determine if the MNT benefit (which went into effect January 1, 2002) had increased the coverage of nutrition services provided by RDs within private insurance or health care plans. While the scan is not representative of all managed care organizations or the health care marketplace, a positive change in coverage was noted since 1999, when a benchmark was set (79). The growth in coverage of dietetic services are attributable to a number of factors: costs, consumer demand, and recognition of MNT, the availability of data on the effectiveness of nutrition interventions, and new tools such as codes that allow direct reimbursement to dietetic professionals. Dietetics professionals may find an increasingly receptive environment for their knowledge and skills, and involvement in disease management services, as more private sector plans reported contracting with RDs for nutrition services. Additionally, several plans in the 2002 scan indicated they follow Medicare's lead in adopting CPT codes.

MEDICARE MNT UTILIZATION RATES

During the first year of Medicare MNT coverage under Medicare, 4,125 individuals enrolled as MNT providers and billed approximately $800,000 for individual and group MNT services (80). (When Congress was considering the MNT bill in 2000, it was estimated that a scaled-down MNT bill establishing coverage to beneficiaries with diabetes, cardiovascular disease, and/or renal disease, would cost a little less than $1 billion per year [81].) Recent CMS data indicates nearly 7,000 registered dietitians or licensed nutrition professionals have enrolled as providers of MNT (82). Only 211,000 Medicare beneficiaries received MNT services since the benefit's inception, yielding approximately $3.3 million of new revenue for RDs.

Those are disappointing statistics inasmuch that they indicate an underutilization of the MNT benefit. Based on estimates from the National Diabetes Information Clearinghouse and United States Renal Data System, approximately 8.6 million individuals (or 18.3%) at least 60 years old are diagnosed with diabetes or acute renal failure, making most of them eligible for MNT Medicare services (83). In terms of income potential to RDs, the CBO-projected $60 million annual outlays for Medicare MNT for diabetes and kidney disease are far higher than the actual $1 million annual average. Data provided by CMS indicate a small but growing demand for Medicare MNT for diabetes and kidney disease when beneficiaries obtain a referral by their physicians.

How the Medicare Advantage program affects utilization of the Medicare MNT coverage, and the two new programs that include MNT benefits, remains to be seen.

There are a number of reasons to expect greater demand for Medicare MNT services. First of all, the Medicare Modernization Act includes two MNT components, one of which is the Initial Preventive Physical Examination, which went into effect January 1, 2005. The American Diabetes Association estimates that more than one-third of Americans with diabetes do not know they have the disease (84). If the "Welcome to Medicare" physical is successful in identifying people who have diabetes but did not know it, the utilization rate for MNT should show a significant increase.

The chronic care provisions of the Medicare Modernization Act also provide an opportunity for significant growth in MNT utilization, because MNT also is a component of that provision. Currently, 78% of the Medicare population has one or more chronic conditions that require ongoing medical management (85). Almost two thirds (63%) have two or more chronic conditions, and 20% of Medicare beneficiaries have five or more chronic conditions (86). Therefore, participating in Medicare's new chronic care disease management

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99373 complex or lengthy (eg, lengthy counseling session with anxious or distraught patient, detailed or prolonged discussion with family members regarding seriously ill patient, lengthy communication necessary to coordinate complex services of several different health professionals working on different aspects of the total patient care plan)

Care Plan Oversight Services

Care Plan Oversight Services are reported separately from codes for office/outpatient, hospital, home, nursing facility or domiciliary services. The complexity and approximate physician time of the care plan oversight services provided within a 30-day period determine code selection. Only one physician may report services for a given period of time, to reflect that physician's sole or predominant supervisory role with a particular patient. These codes should not be reported for supervision of patients in nursing facilities or under the care of home health agencies unless they require recurrent supervision of therapy.

The work involved in providing very low intensity or infrequent supervision services is included in the pre- and post-encounter work for home, office/outpatient and nursing facility or domiciliary visit codes.

99374 **Physician supervision** of a patient under care of home health agency (patient not present) in home, domiciliary or equivalent environment (eg, Alzheimer's facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99375 30 minutes or more

99377 **Physician supervision** of a hospice patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99378 30 minutes or more

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99379 **Physician supervision** of a nursing facility patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes

99380 30 minutes or more

Preventive Medicine Services

The following codes are used to report the preventive medicine evaluation and management of infants, children, adolescents and adults.

The extent and focus of the services will largely depend on the age of the patient.

If an abnormality/ies is encountered or a preexisting problem is addressed in the process of performing this preventive medicine evaluation and management service, and if the problem/abnormality is significant enough to require additional work to perform the key components of a problem-oriented E/M service, then the appropriate Office/Outpatient code 99201-99215 should also be reported. Modifier '-25' should be added to the Office/Outpatient code to indicate that a significant, separately identifiable Evaluation and Management service was provided by the same physician on the same day as the preventive medicine service. The appropriate preventive medicine service is additionally reported.

An insignificant or trivial problem/abnormality that is encountered in the process of performing the preventive medicine evaluation and management service and which does not require additional work and the performance of the key components of a problem-oriented E/M service should not be reported.

The "comprehensive" nature of the Preventive Medicine Services codes 99381-99397 reflects an age and gender appropriate history/exam and is NOT synonymous with the "comprehensive" examination required in Evaluation and Management codes 99201-99350.

Codes 99381-99397 include counseling/anticipatory guidance/risk factor reduction interventions which are provided at the time of the initial or periodic comprehensive preventive medicine examination. (Refer to codes 99401-99412 for reporting those counseling/anticipatory guidance/risk factor reduction interventions that are provided at an encounter separate from the preventive medicine examination.)

Immunizations and ancillary studies involving laboratory, radiology, other procedures, or screening tests identified with a specific CPT code are reported separately. For immunizations, see 90471-90474 and 90476-90749.

New Patient

99381 **Initial comprehensive preventive medicine** evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate immunization(s), laboratory/diagnostic procedures, new patient; infant (age under 1 year)

99382 early childhood (age 1 through 4 years)

99383 late childhood (age 5 through 11 years)

99384 adolescent (age 12 through 17 years)

99385 18-39 years

99386 40-64 years

99387 65 years and over

Established Patient

99391 **Periodic comprehensive preventive medicine** reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate immunization(s), laboratory/diagnostic procedures, established patient; infant (age under 1 year)

99392 early childhood (age 1 through 4 years)

99393 late childhood (age 5 through 11 years)

99394 adolescent (age 12 through 17 years)

99395 18-39 years

99396 40-64 years

99397 65 years and over

Counseling and/or Risk Factor Reduction Intervention

New or Established Patient

These codes are used to report services provided to individuals at a separate encounter for the purpose of promoting health and preventing illness or injury.

Preventive medicine counseling and risk factor reduction interventions provided as a separate encounter will vary with age and should address such issues as family problems, diet and exercise, substance abuse, sexual practices, injury prevention, dental health, and diagnostic and laboratory test results available at the time of the encounter.

These codes are not to be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes. For counseling groups of patients with symptoms or established illness, use 99078.

Preventive Medicine, Individual Counseling

99401 **Preventive medicine counseling** and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes

99402 approximately 30 minutes

99403 approximately 45 minutes

99404 approximately 60 minutes

Preventive Medicine, Group Counseling

99411 **Preventive medicine counseling** and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes

99412 approximately 60 minutes

Other Preventive Medicine Services

99420 **Administration and interpretation** of health risk assessment instrument (eg, health hazard appraisal)

99429 **Unlisted preventive** medicine service

Newborn Care

The following codes are used to report the services provided to newborns in several different settings.

For newborn hospital discharge services provided on a date subsequent to the admission date of the newborn, use 99238.

For discharge services provided to newborns admitted and discharged on the same date, use 99435.

99431 **History and examination** of the normal newborn infant, initiation of diagnostic and treatment programs and preparation of hospital records. (This code should also be used for birthing room deliveries.)

99432 **Normal newborn care** in other than hospital or birthing room setting, including physical examination of baby and conference(s) with parent(s)

99433 **Subsequent hospital care,** for the evaluation and management of a normal newborn, per day

99435 **History and examination** of the normal newborn infant, including the preparation of medical records. (This code should only be used for newborns assessed and discharged from the hospital or birthing room on the same date.)

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Payment for Medical Nutrition Therapy (§ 414.64)

Section 105(c) of the BIPA requires that we pay for medical nutrition therapy services at 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the physician fee schedule for the same services if the services had been furnished by a physician. Based upon consultation with the American Dietetic Association (ADA) to assess the types of resource inputs used to furnish a 15-minute medical nutrition therapy session by a registered dietitian or professional nutritionist, we proposed the following:

For CPT code 97802—Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes, we did not propose physician work RVUs for this service, based on the statutory provision that specifically provides that medical nutrition therapy services may only be furnished by registered dietitians or nutrition professionals. For practice expense, we proposed 0.47 RVUs and, for malpractice, we proposed 0.01 RVUs for a total of 0.48 RVUs.

For CPT code 97803—Reassessments and intervention, individual, face-to-face with the patient, each 15 minutes, we proposed 0.0 work RVUs, 0.34 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.35 RVUs.

For CPT code 97804—Group, 2 or more individuals, each 30 minutes, we proposed 0.0 work RVUs, 0.14 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.15 RVUs. To determine payment, the RVUs shown above would need to be multiplied by the physician fee schedule conversion factor and 0.85 (to reflect the statutory requirement that payment be 85 percent of the amount determined under the physician fee schedule).

We also stated that, consistent with the definition in the CPT's Physical Medicine Rehabilitation codes, a group is considered to be 2 or more individuals and that Medicare co-payments and deductibles would apply for medical nutritional therapy services.

Comment: The American Dietetic Association (ADA) and many individuals submitted comments concerning the proposed reimbursement rate for medical nutrition therapy services. They stated that the proposed reimbursement rate for these services is too low and would result in limited beneficiary access to these services since private practice dietitians will choose not to participate. Some commenters referenced reimbursement rates currently paid by private insurers of $85 to $125 for 1 to 1½ hours for an initial visit and $85 per hour for follow-up. They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress. Commenters indicated that the statute clearly states that medical nutrition therapy payment should be 80 percent of the lesser of the actual charge or 85 percent of the amount determined under the physician fee schedule for the same service, provided by a physician. According to commenters, physicians who are also registered dietitians, use E/M codes 99213 through 99215 and 99244 when providing medical nutrition therapy services. The commenters stated that E/M codes 99203 through 99205 are appropriate reference points for determining medical nutrition therapy payment. The commenters also stated that any refinement of medical nutrition therapy values should be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commenters acknowledge that physicians may perform other tasks besides nutritional assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a comment that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by non-physician providers. The HCPAC indicated that it evaluated each of the medical nutrition therapy codes and compared them to services that are available to other providers but not nutritionists (for example, physical therapy services). The comment further stated that the 15 percent reduction should not apply because the HCPAC took this into account when developing the recommendations. The HCPAC further added that there should be work values for medical nutrition therapy just as there are for physical and occupational therapy.

Response. We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy. Section 105(c) of the BIPA states that "the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) of the Act for the same services if furnished by a physician." The BIPA Conference Report indicates that payment will equal "the lesser of the actual charge for the service or 85 percent of the amount that would be paid under the physician fee schedule if such services were provided by a physician." The statute and Conference Report direct us to establish the physician fee schedule amount for nutrition therapy services. The Medicare allowed charge would equal 100 percent of the physician fee schedule amount if the services are performed by a physician and 85 percent of the physician fee schedule amount if the services are performed by a registered dietitian or nutrition professional. The commenters suggest that physicians currently bill for an E/M service when they provide nutrition services. We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered dietitian to an E/M service provided by a physician. Registered dietitians do not take medical histories, they are not trained to and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/M code to report the provision of counseling or coordination of care, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be be appropriate for him or her to report an E/M service. Further, we note that the E/M services include not only an amount attributable to physician work, but also payment for physician practice expenses. For instance, a level 3 new patient office visit (CPT code 99203) includes payment for 50 minutes of nurse time. A level 3 established patient office visit (CPT code 99213) includes 36 minutes of nurse time. Both of these codes include additional compensation for medical equipment and supplies that are typically used in an office visit but are not used as part of a medical nutrition therapy service. If we were to adopt the commenters' view and crosswalk values for medical nutrition therapy to an E/M service, we would be including payment not only for the counseling service of the practitioner, but also, inappropriately for the costs of clinical personnel that are not involved in the nutrition therapy service.

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Commenters indicated that the statute established the 85 percent adjustment to account for activities that are typically performed by a physician during an E/M service are not performed by a nutritionist. The statute and legislative history do not indicate that the 85 percent adjustment is intended to serve this purpose. In fact, the commenters themselves note that "consistent with other non-physician providers, reimbursement is set at a percentage of the physician's fee schedule." Under the physician fee schedule, we will pay a physician 80 percent of 100 percent of the physician fee schedule amount, and, if a non-physician practitioner provides an identical service, Medicare pays 80 percent of 85 percent of the physician fee schedule amount. For instance, under CPT code 99213, a level 3 established patient office visit is one of the most common services provided by physicians, physician assistants and nurse practitioners. Even though the service is considered to be identical, we can by law pay a physician assistant and nurse practitioner only 85 percent of what we pay a physician to do the same service. Thus, in the case of other practitioners, the percentage does not reflect that a non-physician practitioner provides fewer services than a physician. Because there is no indication in the statute that the 85 percent adjustment should apply differently in the context of medical nutrition therapy than for other services performed by non-physician practitioners, we believe it is appropriate to pay 80 percent of 100 percent of the physician fee schedule amount when medical nutrition therapy is provided by a physician and 80 percent of 85 percent of the physician fee schedule amount when the service is provided by a registered dietitian or nutrition professional.

In response to the comment about payment rates of private insurers for medical nutrition therapy, we cannot use such information in a relative value system to establish payment. Section 1848(c) of the Act requires us to establish RVUs that recognize the relative resources involved in furnishing different physician fee schedule services. Thus, our role is to establish the appropriate relative payment amounts. The total payment amount is determined under a formula prescribed in section 1848(d) of the Act. We have no authority to change the formula.

In response to the HCPAC recommendation, we reiterate that it is inappropriate to compare medical nutrition therapy services to E/M services performed by physicians. While medical nutrition therapy may be performed by a physician who is also a registered dietitian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount. In this unusual circumstance, we are paying for a medical nutrition therapy service provided by a physician under section 1861(s)(2)(V) and not a physician's service under section 1861(s)(1) of the Act.

Comment: One comment indicated that the 85 percent adjustment should not apply because the RVUs we used are not based on physician work or physician practice expenses to deliver the service. This commenter indicated that we proposed an inadequate payment by not following the statutory scheme and proceeded to apply a 15 percent discount that is neither fair nor reasonable.

Response. The statute requires us to establish a physician fee schedule amount for the service and pay 80 percent of 100 percent of the amount if the service is provided by a physician and 80 percent of 85 percent if the service is provided by a registered dietitian or nutrition professional. We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would not meet the statutory requirements to be considered registered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered dietitians or nutrition professionals. In these circumstances, our payment to the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dietitian or nutrition professional. We believe the statute would not allow a physician who does not meet the statutory requirements for a registered dietitian or nutrition professional to be paid for a medical nutrition therapy service. If a physician provides medical nutrition counseling as part of a patient encounter that meets the requirements for an E/M service, the physician can bill Medicare for a physician's service.

Comment: We received one comment requesting that we clarify that Medicare will pay qualified providers in private practice settings or physician offices where they may be independent contractors. The commenter also asked how we intend to pay for medical nutrition therapy in the hospital outpatient department. The commenter also asked for clarification on reassignment of payment if a registered dietitian is an employee of physicians or hospital outpatient facilities.

Response: Medicare will pay qualified dietitians and nutrition professionals who enroll in the Medicare program regardless of whether they provide medical nutrition therapy services in an independent practice setting, hospital outpatient department or any other setting, with the exception of services provided to patients in an inpatient stay in a hospital or skilled nursing facility. In these circumstances, our payment to the hospital or skilled nursing facility includes payment for medical nutrition therapy. If a qualified practitioner provides medical nutrition therapy in any other setting, including a private practice setting, section 1833(a)(1)(T) of the Act requires that Medicare payment equal 80 percent of the lesser of actual charges or 80 percent of 85 percent of the amount determined under the physician fee schedule. Payment in the hospital outpatient department will be made under the physician fee schedule, not under the hospital outpatient prospective payment system.

Current rules regarding reassignment of benefits would apply to medical nutrition therapy. We want to emphasize that medical nutrition therapy cannot be provided incident to a physician's service unless the physician also meets the qualifications to bill Medicare as a registered dietitian or nutrition professional.

Comment: Commenters objected to the methodology used to establish the proposed RVUs for this service. They believe it is inappropriate to use the top-down or no-work pool methodology to determine medical nutrition therapy payment. They believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The

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commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness. They disagree with our assertion in the proposed rule that physicians do not perform nutrition services and assert that it is inappropriate to use the top-down or zero-work methodology to establish the RVU for medical nutrition therapy.

Response: We use the top-down methodology or no-work pool methodology to price the practice expense RVUs for all services priced under the Medicare physician fee schedule. Given that the statute indicates that medical nutrition therapy should be paid using the physician fee schedule, we believe it is reasonable and appropriate to use the same methodologies that we use to develop RVUs for other physician fee schedule services. With respect to use of the preventive medicine service, we used a service that we felt had similar practice expenses to medical nutrition therapy. It is not clear why practice expenses for a counseling service would differ based on the health status of the patient.

Comment: A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT code 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe that the value of CPT codes 97802 and 97803 should be identical. The commenters indicated that E/M services provided by physicians do not receive the same discount. The commenter also stated that the payment for CPT code 97804 was less than for other group services and gave the example of a nurse or pharmacist providing nutrition instruction under the diabetes self-management training benefit.

Response: We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services. (We note that the RVU units between the proposed and final rule show some marginal change because of changes made in the practice expense methodology that affect all physician fee schedule services). We do not agree with the comment that "evaluation and management services provided by physicians do not receive the same discount." E/M service are not time based services and, as stated above, for many reasons are inappropriate comparisons to medical nutrition therapy service codes.

Comment: Many commenters stated that co-payments must be structured so that they are not barriers to the medical nutrition therapy benefit.

Response: Section 105(c) of the BIPA modifies section 1833(a)(1) of the Act to add subparagraph (T) that requires that Medicare payment equal 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under physician fee schedule. The statute requires the same coinsurance for medical nutrition therapy services that applies to other Part B services.

Comment: Commenters suggested that initial medical nutrition therapy sessions for treatment of diabetes or renal disease should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803. New diagnoses due to a change in medical condition or unanticipated complications should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803.

Response: At the present time, we are requiring that medical nutrition therapy be reported by using CPT codes 97802, 97803, and 97804. We will revisit our coding requirements when we publish the NCD for medical nutrition therapy. The NCD will set forth the structure of the medical nutrition therapy benefit in detail. We will make a decision concerning creation or modification of codes and creation of modifiers for reporting medical nutrition therapy once the NCD has been published. Until the NCD is published, creation or modification of codes and creation of modifiers would be premature. Therefore, we are requiring that the initial individual medical nutrition therapy visit be reported as CPT code 97802 and all follow up visits (for interventions and reassessments) for individual medical nutrition therapy be reported as CPT code 97803. All group medical nutrition therapy visits should be reported as CPT code 97804 whether they are initial or follow up visits.

Comment: Commenters urged us to define medical nutrition therapy descriptors consistently. They stated that the descriptors in Table 5 of the proposed rule should agree with the descriptors in § 414.132.

Response: We agree. We will make the descriptors for medical nutrition therapy consistent with the nomenclature in CPT and our regulations.

Comment: We received a comment that recommended that we consider including additional items in the practice expense inputs for medical nutrition therapy. The commenter indicated that inputs should include staff costs for training on billing procedures, Health Insurance Portability and Accountability Act training, audit expenses, and other costs resulting from Medicare policies and procedures. The commenter indicated that expenses of registered dietitians in private practice differ little from other practitioners.

Response: There are two major data sources used in the practice expense methodology—estimates of direct inputs and aggregate practice expense per hour information from the AMA's Socioeconomic Monitoring Survey. At this time, we are using the practice expense per hour for all physicians to establish the practice expense RVUs for medical nutrition therapy. We are not currently using the estimates of direct expenses for medical nutrition therapy because the services are valued in the no-work pool. However, we are researching alternatives to the no-work pool that would allow all no-work services to be priced under the top-down methodology. If we develop such an alternative, the estimates of direct expenses will be important in determining the RVUs for medical nutrition therapy. Indirect expenses are based on physician work and direct inputs. We believe that many of the costs identified by this commenter are indirect costs that would likely be included in practice expenses reported through the SMS survey. Since the commenter has suggested that practice expenses for private practice registered dietitians differ little from other

EXHIBIT "O"
PAGE 3 OF 4

practitioners, we believe the average practice expense per hour for all physicians is sufficient to use in the practice expense methodology.

Result of Evaluation of Comments

The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the rate for CPT code 97802. We are also changing the payment rate for CPT code 97804 using the assumption that the code will normally be billed for 4 to 6 patients with the average of 5. Using these revised values, the payment rate for group medical nutrition therapy will approximate the hourly rate paid for other medical nutrition therapy services.

F. Telehealth Services

Beginning October 1, 2001, the BIPA amended section 1834 of the Act to specify that we pay a physician (as defined in section 1861(r) of the Act) or a practitioner (described in section 1842(b)(18)(C) of the Act) for telehealth services that are furnished via a telecommunications system to an eligible telehealth individual.

The BIPA defined Medicare telehealth services as professional consultations, office or other outpatient visits, and office psychiatry services identified as of July 1, 2000, by CPT codes 99241 through 99275; 99201 through 99215, 90804 through 90809 and 90862 (and as we may subsequently modify) and any additional service we specify. The BIPA defines an eligible telehealth individual as an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

Section 1834(m) of the Act, as added by the BIPA, limited an originating site to a physician's or practitioner's office, hospital, critical access hospital, rural health clinic, or Federally qualified health center. Additionally, the BIPA specified that the originating site must be located in one of the following geographic areas:

- In an area that is designated as a rural health professional shortage area (HPSA) under section 332(a)(1)(A) of the Public Health Service Act.
- In a county that is not included in a Metropolitan Statistical Area (MSA).

However, an entity participating in a Federal telemedicine demonstration project that has been approved by, or receives funding from us as of December 31, 2000 would not be required to be in a rural HPSA or non-MSA.

The BIPA also required that we pay a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth beneficiary an amount equal to the amount that the physician or practitioner would have been paid under Medicare had the service been furnished without the use of a telecommunications system.

This section also provided for a facility fee payment for the period beginning October 1, 2001 through December 31, 2002, to the originating site of $20. For each subsequent year, the facility fee for the preceding year is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The BIPA also amended section 1833(a)(1) of the Act to specify that the amount paid must be 80 percent of the lesser of the actual charge or the amounts specified in new section 1834(m)(2) of the Act.

In order for us to have this benefit expansion implemented timely, we have used a program memorandum. The program memorandum was effective October 1, 2001. This final rule will be effective January 1, 2002.

The rule published on August 2, 2001 proposed to establish policies for implementing the provisions of section 1834(m) of the Act, as added by the BIPA, that change Medicare payment for telehealth services.

We proposed to revise § 410.78 to specify that Medicare beneficiaries are eligible for telehealth services only if they receive services from an originating site located in either a rural HPSA as defined by section 332(a)(1)(A) of the Public Health Services Act or in a county outside of a MSA as defined by section 1886(d)(2)(D) of the Act.

1. Definitions

Section 1834(m)(4)(F) of the Act, which was added by the BIPA and became effective for services beginning October 1, 2001, defined telehealth services as professional consultations, office and other outpatient visits, individual psychotherapy, pharmacologic management, and any additional service we specify. Additionally, this provision identified covered services by HCPCS codes identified as of July 1, 2000. We proposed to revise § 410.78 to implement this coverage expansion to include the following services (and corresponding CPT codes):

- Consultations (codes 99241 through 99275).
- Office and other outpatient visits (codes 99201 through 99215).
- Individual psychotherapy (codes 90804 through 90809).
- Pharmacologic management (code 90862).

We solicited comments regarding the guidelines that we should use to make additions or deletions of services. We also solicited comments about specific services that may be appropriate to be covered under the Medicare telehealth benefit.

In this final rule, we are specifying at § 410.78 that, except for the use of store and forward technology in the demonstration programs conducted in Alaska or Hawaii, an interactive telecommunications system must be used and the medical examination of the patient must be at the control of the physician or practitioner at the distant site. We are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and physician or practitioner at the distant site. We are also specifying that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

A patient need not be present for a Federal telemedicine demonstration program conducted in Alaska or Hawaii. We are specifying that for Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system. Additionally, we are specifying that the physician or practitioner at the distant site must be affiliated with the demonstration program.

We are defining asynchronous, store and forward technologies, as the transmission of the patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patient's medical condition and adequate for rendering or confirming a diagnosis or treatment plan. Finally, we are defining the originating site as the location of an eligible telehealth individual at the time the service being furnished via a telecommunications system occurs.

2. Conditions of Payment

The BIPA changed the telepresenter requirements. In accordance with section 1834(m)(2)(C) of the Act, a

EXHIBIT "D"
PAGE 4 OF 4

Provider Explanation of Benefits

PROVIDER NAME	PROVIDER NUMBER	STATEMENT DATE	TAX ID
MIDTOWN NUTRITION CARE	9203E	03/10/05	132845837

Empire BlueCross BlueShield

SITE NUMBER	CHECK NUMBER
100	0000026514400

Detail of Claims

PATIENT NAME	PATIENT ACCOUNT NUMBER	MEMBER ID	CONTRACT TYPE	CLAIM NUMBER
[redacted]	132171	[redacted]		50610214700 PSU CODE 15

			Submitted Charges	Charges Not Allowed	Allowed Amount
Service Information	Procedure Code: 97802 Service Type/Place: 6 OPC	Date(s): 02/25/05 - 02/25/05 No. of Units: 6	$300.00	$0.00	$300.00

Payment Calculation	Allowed Amount	$300.00
	Copayment	5.00
	Plan Payment for this Service:	$295.00
	Total Patient Responsibility:	*$5.00*
	Total Payment for this Claim:	*$295.00*

6 X $50.00

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

AUTHORIZED SIGNATURE

THE FACE OF THIS DOCUMENT HAS A BLUE BACKGROUND. IF NOT BLUE, DO NOT CASH.

⑈0026514400⑈ ⑆061209756⑆ 2079900411485⑈

EXHIBIT "E"
PAGE 1 OF 4

REMITTANCE ADVICE

Vendor Name: ROBERT L HOWARD
Vendor ID #: P2645837-P2679923
Member Name: [redacted]
Member ID: [redacted]
Patient Acct #: 12542-1

TIN: 132845837
Check Number: 28419702 01-12-2005
Provider Name: GROSSANO, DEBRA
Provider ID: P2679923
Claim #: 4357N16329

Serv Date	CPT Code	Description	QTY	Billed Amt	Max Amt	Withhold Amt	Deductible Amt	Copay/Co-ins Amt	Adj Code	COB Amt	Payment Amt
12-20-04	97802	MED NUTRIT TX INIT 1:1-PT EA 15	6	300.00	258.80			10.00			258.80
TOTAL CLAIM 4357N16329				300.00	258.80	0.00		10.00		0.00	258.80

	Billed Amt	Max Amt	Withhold Amt	Deductible Amt	Copay/Co-ins Amt	COB Amt	Payment Amt
Claim Payment Summary	300.00	258.80			10.00		258.80

Check Summary

Total Paid 258.80
Check Date..... January 12, 2005
Paid To ..... ROBERT L HOWARD
Check Number..... 28419702

6 X $44.80
FREEDOM PLAN

ATTENTION: THIS MAILING MAY CONTAIN DOCUMENTATION ON VARIOUS MATTERS

Oxford Health Plans (NY), Inc.

Please see last page for Appeals Rights

DETACH HERE DETACH HERE

Oxford Health Plans (NY), Inc.
7520 Main St. Trumbull, CT 06611

Chase Manhattan Bank Delaware
Wilmington, DE, 19801

62-26
311

28419702

4691-09

January 12, 2005

PAY:

Two Hundred Fifty Eight Dollars and 80 Cents********** 258.80

**********AUTO**3-DIGIT 100
N 038 9750
ROBERT L HOWARD
119W 57TH ST STE 1414
NEW YORK NY 10019-2401

Authorized Signature
(not valid after 180 days)

⑈28419702⑈ ⑆031100267⑆ 6301446914 509⑈

EXHIBIT "E" - PAGE 2 OF 4

[redacted]

REMITTANCE ADVICE

Vendor Name: ROBERT L HOWARD
Vendor ID #: P2845837-P442628
Member Name: [redacted]
Member ID: [redacted]
Patient Acct #: 12164-1

TIN: 132845837
Check Number: 28582141
Provider Name: GOLDFARB, BETH
Provider ID: P2586860
Claim #: 5022N17157

02-12-2005

[redacted]

Serv Date	CPT Code	Description	QTY	Billed Amt	Max Amt	Withhold Amt	Deductible Amt	Copay/Co-ins Amt	Adj Code	COB Amt	Payment Amt
01-20-05	97803	MED NUTRIT TX; F/U 1:1-PT EA 15	2	100.00	80.64			15.00			65.64
TOTAL CLAIM: 5022N17157				100.00	80.64	0.00		15.00		0.00	65.64

	Billed Amt	Max Amt	Withhold Amt	Deductible Amt	Copay/Co-ins Amt	COB Amt	Payment Amt
Claim Payment Summary	100.00	80.64			15.00		65.64

Check Summary

Total Paid 65.64
Check Date..... February 12, 2005
Paid To ..... ROBERT L HOWARD
Check Number..... 28582141

2 X 40.32
LIBERTY PLAN

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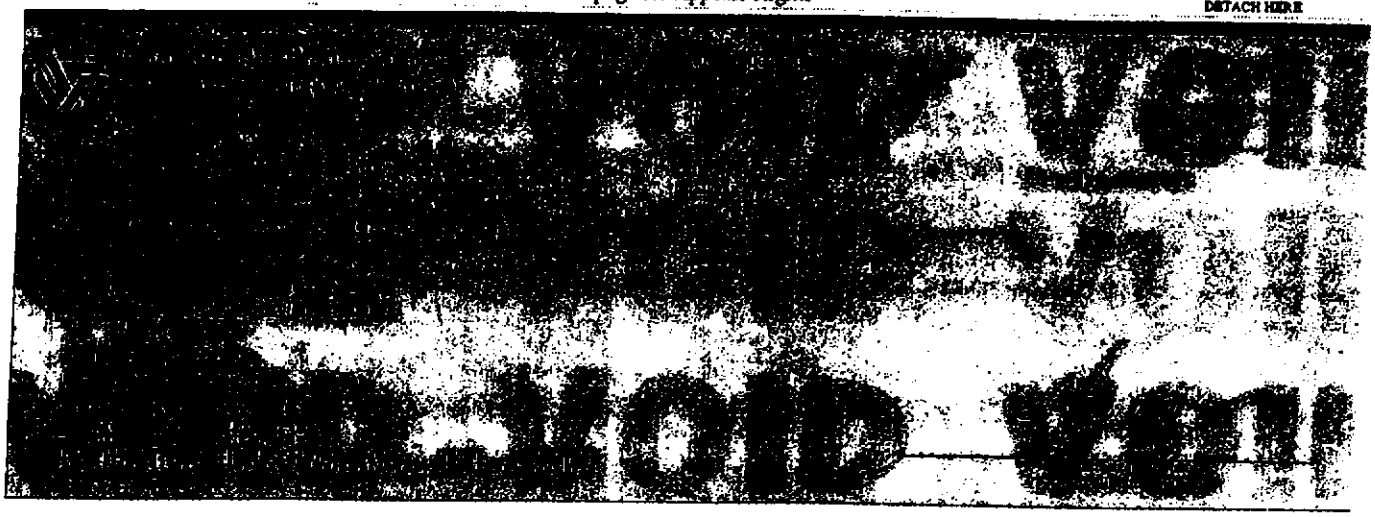
Oxford Health Plans (NY), Inc.

Please see last page for Appeals Rights

DETACH HERE DETACH HERE



⑈28582141⑈ ⑆031100267⑆ 6301446944 509⑈

EXHIBIT "E" - PAGE 3 OF 4

GHI
GROUP HEALTH INCORPORATED
P.O. BOX 2814
NEW YORK, N.Y. 10116-2814

PAY TO THE ORDER OF

DATE	CHECK NUMBER
[redacted]	

MIDTOWN NUTRITION CARE
119 WEST 57TH ST.
STE 1414
NEW YORK , NY 10019-2401

GROUP HEALTH INCORPORATED P.O. BOX 2814, NEW YORK, N.Y. 10116-2814 DETACH BEFORE CASHING EXPLANATION OF BENEFITS CHECK NUMBER

Check Date: 08/13/04 9582195

Provider: GOLDFARB BETH R RD

The information below summarizes GHI's claim settlement(s) for the service(s) and patient(s) listed.

Subscriber(s)/ Service(s)	Certificate(s)/ Service Date(s)	Claim Number(s)	Acct No(s)/ Patient(s)	Charge(s) Submitted	CoPayment(s) Applied	Benefit Payment(s)	Note(s)
[redacted]	[redacted]		11420-1				
PHYSICIAN EDUCAT SVC	07/31/04	EMC6171966	NEAL	$50.00	$15.00	$20.00	
PHYSICIAN EDUCAT SVC	07/31/04	EMC6171966	NEAL	50.00	15.00	20.00	
PHYSICIAN EDUCAT SVC	07/31/04	EMC6171966	NEAL	50.00	15.00	20.00	
PHYSICIAN EDUCAT SVC	07/31/04	EMC6171966	NEAL	50.00	15.00	20.00	
TOTALS				$200.00	$60.00	$80.00	

CALLED "PHYSICIAN EDUCAT SVC" BY GHI, BUT THIS NAME IS USED FOR CPT 97802, AS BILLED

Payment Summary

Basic Allowance	$140.00
Co-payment	60.00
Payment To You	$80.00

Note(s):

To report suspected fraud, call GHI's Fraud Hotline at 1-888-4-KO-FRAUD (1-888-456-3728) or e-mail kofraud@ghi.com

EXHIBIT "E"
PAGE 4 OF 4

3296475

8099870-99

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1502-P
PO Box 8017
Baltimore, Md. 21244-8017

We are commenting on proposed changes in the 2006 Physician Fee Schedule, specifically related to CPT codes 34101, 34111, 37204, 37205, 37607, 75710, 75827, 75894, 75898, 75960, 75962, 75978, 75827.

Item 1

The proposed 2006 Physician Fee Schedule has removed payment for the following codes in the non-facility setting:

34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision
37607	Ligation or banding of angioaccess arteriovenous fistula
37204	Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation.
37205	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel
75960	Transcatheter introduction of intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous and/or open, radiological supervision and interpretation, each vessel
75898	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion

All of these codes have been available for use in the non-facility setting in the past. They have been shown to be effective and safe in the free standing facility. They have been routinely used by Interventional Radiologists and Nephrologists.

If these changes take effect, it will materially interfere with medical care offered by Interventional Radiologists and Nephrologists, most of who operate in free-standing facilities. It will result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital medical services to CMS by requiring fragmentation of bundled procedures, duplication of services and a shift from an out-patient environment to the hospital.

Codes 34101 and 34111 are codes for procedures that are used to treat complications of other vascular access procedures, namely thrombectomy. The major complication of a percutaneous thrombectomy is the migration of an embolus to the feeding artery. When this occurs it blocks blood flow to the hand and to the digits. If not treated in a timely manner, it can have disastrous results. Fortunately, the complication is rare and fortunately, it can be treated in a timely manner resulting in a complete resolution. However, if the code is no longer included, there will be a tendency to delay treatment and refer to the hospital. This will result in increased risk to the patient, prolongation of the accompanying discomfort, duplication of services and a significant increase in cost. In these instances, instead of the patient being returned to the dialysis clinic for their regular dialysis, they will be sitting at the hospital in pain for several hours without dialysis waiting for a treatment at an alternative site.

Codes 37607, 37204, 75894, and 75898 all relate to the treatment of fistula failures by Interventional Radiologists and Nephrologists. The nephrology community and especially those involved with dialysis access intervention have seen the need for increasing the number of functioning fistulas in our dialysis patient community and have made a real commitment to this effort. A significant number of fistulas that are created have early or primary function. This means that they never develop adequately for use. It has been shown through a number of publications that a very large percentage of these failed fistulas can be salvaged. This effort is critical to the development of a fistula based strategy in the US. Interventional Radiologists and Nephrologists have and continue to take the lead in this effort. Since most work in free standing facilities, removing these codes will materially affect this effort.
Unfortunately, it is at times not obvious until the case is underway that such a procedure will be required. This means that if they are necessary for the success of the case, the procedure will be only partially done. The patient will then be referred to the hospital for a duplication of services and added expense, inconvenience and discomfort with no added benefit as it relates to success or safety.

Codes 37205 and 75898 are codes that relate to a procedure used to treat a complication. The major complication seen with venous angioplasty is rupture of the vein. Fortunately, this is not a common occurrence and fortunately, in the vast majority of cases it is a minor complication requiring no change in medical management. However; occasionally, this complication requires the placement of a stent. This can be easily done at the time and doing so saves a vascular access that would otherwise be lost. If it is not done at the time, a situation which deleting this

code would create, then it very likely can not be accomplished. In this instance the patient would lose their access, require a dialysis catheter with all of its complications, be referred to the hospital and require the placement of a new access.

Item 2

Additionally, the proposed 2006 Physician Fee Schedule has reduced the RVRBS unit value for the following codes in the non-facility setting:

75710 Angiography, extremity, unilateral, radiological supervision and interpretation
75827 Venography, caval, superior, with serialography, radiological supervision and interpretation
75962 Transluminal balloon angioplasty, peripheral artery, radiological supervision and interpretation
75978 Transluminal balloon angioplasty, venous (eg, subclavian stenosis), **radiological supervision and interpretation**

These are codes that are very commonly used by Interventional Radiologists and Nephrologists. Since most of these practitioners operate in the free standing, non-facility setting, they must support the facilities operation without the benefit of facility charges. This is accomplished through the use of the fees generated by these radiological supervision and interpretation codes. Since the cost of these facilities is continuing to rise, cutting the payment for these commonly used codes will jeopardize their economic viability. Simply stated, they will be required to close. This will result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital medical services to CMS by requiring a shift from an out-patient environment to the hospital for the patients currently being served and will slow the migration of patients currently locked into a hospital based environment to the out patient setting.

We do not feel that these changes are in the best interest of the patients that we serve.

Sincerely,

Gastone Crea

Dr. Gastone Crea, MD.

924

JCMG
JEFFERSON CITY MEDICAL GROUP
with Signature Care
Cardiology

Conrad S. Balcer, D.O.
John F. Sanfelippo, M.D., F.A.C.C., F.A.C.P
James F. Tritz, M.D.

Jane Vaughan, MSN, RN, BC, FNP
Arlene Woods, MSN, RN, BC, FNP
Sherry Rivas, MSN, RN, BC, FNP

September 27, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-P
Po Box 8017
Baltimore MD, 21244-8017

I am writing with regard to the 2006 Proposed Physician Fee Schedule Rule that was published in the August 8, 2005 Federal Register. Under the Proposed Rule, there are a number of CPT codes related to cardiac monitoring services which would suffer drastic payment reductions, including some cuts of up to 90%, and I encourage CMS to stop implementation of the new RVUs applied to these codes until a better assessment of their impact could be completed. The affected codes include the codes for holter monitoring, cardiac event monitoring, pacemaker monitoring and INR monitoring.

In reviewing these decreased RVUs, CMS should be mindful of the following points:

1. Cardiac rhythm abnormalities impact millions of patients each year, resulting in over a million hospitals annual admissions and an even greater number of emergency room visits.
2. Cardiac monitoring services are a critical measure in the prevention of serious cardiac conditions and allow doctors to treat a patient before his or her illness progresses to a stage requiring hospitalization or surgery.
3. Cardiac physicians rely heavily upon Independent Diagnostic Testing Facilities ("IDTF") to provide cardiac monitoring services (and other related services) to their patients. In fact, for some services, IDTFs are responsible for a substantial portion of the procedures performed on patients.
4. Due to the constant nature of cardiac monitoring, IDTFs must operate on a 24 hours a day, 7 days a week basis and maintain a complex infrastructure in order to accurately monitor patients.
5. The decreased payment rates currently proposed under the Rule will single-handedly drive IDTFs providing cardiac monitoring out of business, resulting in reduced accessibility of these important services for beneficiaries and increasing overall Medicare costs by hindering a physician's ability to stabilize and treat cardiac conditions before they require expensive surgeries and hospitalization.

Thanks you for considering my comments,

Sincerely,

James F. Tritz

James Tritz, M.D.

JCMG Medical Building • 1241 West Stadium Boulevard • #2100 • Jefferson City, MO 65109
Office 573/ 635-JCMG (5264) • Renew Prescription 573/ 556-5737 • Fax 573/ 761-4611 • www.jcmg.org

American Access Care

925

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1502-P
PO Box 8017
Baltimore, Md. 21244-8017

We are commenting on proposed changes in the 2006 Physician Fee Schedule, specifically related to CPT codes 34101, 34111, 37204, 37205, 37607, 75710, 75827, 75894, 75898, 75960, 75962, 75978, 75827.

Item 1
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75898	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion

All of these codes have been available for use in the non-facility setting in the past. They have been shown to be effective and safe in the free standing facility. They have been routinely used by Interventional Nephrologists.

If these changes take effect, it will materially interfere with medical care offered by Interventional Nephrologists, most of who operate in free-standing facilities. It will

300 Bailey Drive, Suite 107 • Stewartstown, PA 17363
Phone: 717.235.0181 • Fax: 717.235.4291
www.americanaccesscare.com

result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital medical services to CMS by requiring fragmentation of bundled procedures, duplication of services and a shift from an out-patient environment to the hospital.

Codes 34101 and 34111 are codes for procedures that are used to treat complications of other vascular access procedures, namely thrombectomy. The major complication of a percutaneous thrombectomy is the migration of an embolus to the feeding artery. When this occurs it blocks blood flow to the hand and to the digits. If not treated in a timely manner, it can have disastrous results. Fortunately, the complication is rare and fortunately, it can be treated in a timely manner resulting in a complete resolution. However, if the code is no longer included, there will be a tendency to delay treatment and refer to the hospital. This will result in increased risk to the patient, prolongation of the accompanying discomfort, duplication of services and a significant increase in cost. In these instances, instead of the patient being returned to the dialysis clinic for their regular dialysis, they will be sitting at the hospital in pain for several hours without dialysis waiting for a treatment at an alternative site.

Codes 37607, 37204, 75894, and 75898 all relate to the treatment of fistula failures by Interventional Nephrologists. The nephrology community and especially those involved with dialysis access intervention have seen the need for increasing the number of functioning fistulas in our dialysis patient community and have made a real commitment to this effort. A significant number of fistulas that are created have early or primary function. This means that they never develop adequately for use. It has been shown through a number of publications that a very large percentage of these failed fistulas can be salvaged. This effort is critical to the development of a fistula based strategy in the US. Interventional Nephrologists have and continue to take the lead in this effort. Since most work in free standing facilities, removing these codes will materially affect this effort.
Unfortunately, it is at times not obvious until the case is underway that such a procedure will be required. This means that if they are necessary for the success of the case, the procedure will be only partially done. The patient will then be referred to the hospital for a duplication of services and added expense, inconvenience and discomfort with no added benefit as it relates to success or safety.

Codes 37205 and 75898 are codes that relate to a procedure used to treat a complication. The major complication seen with venous angioplasty is rupture of the vein. Fortunately, this is not a common occurrence and fortunately, in the vast majority of cases it is a minor complication requiring no change in medical management. However; occasionally, this complication requires the placement of a stent. This can be easily done at the time and doing so saves a vascular access that would otherwise be lost. If it is not done at the time, a situation which deleting this code would create, then it very likely can not be accomplished. In this instance the patient would lose their access, require a dialysis catheter with all of its complications, be referred to the hospital and require the placement of a new access.

Item 2

Additionally, the proposed 2006 Physician Fee Schedule has reduced the RVRBS unit value for the following codes in the non-facility setting:

75710 Angiography, extremity, unilateral, radiological supervision and interpretation
75827 Venography, caval, superior, with serialography, radiological supervision and interpretation
75962 Transluminal balloon angioplasty, peripheral artery, radiological supervision and interpretation
75978 Transluminal balloon angioplasty, venous (eg, subclavian stenosis), radiological supervision and interpretation

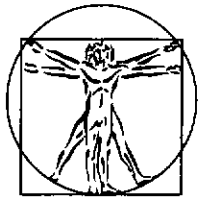
These are codes that are very commonly used by Interventional Nephrologists. Since most of these practitioners operate in the free standing, non-facility setting, they must support the facilities operation without the benefit of facility charges. This is accomplished through the use of the fees generated by these radiological supervision and interpretation codes. Since the cost of these facilities is continuing to rise, cutting the payment for these commonly used codes will jeopardize their economic viability. Simply stated, they will be required to close. This will result in a degradation of the quality of medical care and interfere with the patient's right to choose their medical care provider. Additionally, it will increase the cost of vital medical services to CMS by requiring a shift from an out-patient environment to the hospital for the patients currently being served and will slow the migration of patients currently locked into a hospital based environment to the out patient setting.

We do not feel that these changes are in the best interest of the patients that we serve.

Sincerely,

Raymond D. Figueroa
Chief Executive Officer

Barry J. Collins, D.O.
Adam J. Geller, P.A.-C



926

61 West Carleton Road
Hillsdale, MI 49242
Phone: (517) 439-5411
Fax: (517) 439-5418

The Bone & Joint Center
of Hillsdale County

September 28, 2005

Department of Health and Human Services
Attention: CMS-1502-P
PO Box 8017
Baltimore, MD 21244-8017

RE: File Code CMS-1502-P

To Whom It May Concern:

In response to a request from the American Osteopathic Academy of Orthopedics which I received (copy attached), I am submitting to you a summary of the casting supplies I use for the various surgical CPT codes which are being considered under the above-referenced file code. Pursuant to the instructions I received, one original and two copies are enclosed.

I am sending this information to you hard copy since it was prepared in the Excel format. For some reason, I am unable to transmit it to you electronically even though the information I received stated that Excel is an acceptable format.

I hope you find this information helpful.

Sincerely,

Barry J. Collins, D.O. /jlc

Barry J. Collins, D.O.

BJC/jlc

cc: Morton Morris, D.O., J.D.

Enclosures

926-A

The Bone & Joint Center of Hillsdale County

From: "Dr. Morris" <mmorris@nova.edu>
To: <AOAO@list.acast.nova.edu>
Sent: Monday, August 22, 2005 4:14 PM
Subject: Proposed Medicare fee change - Important for you to review.

This is information I just received. Please review and act accordingly.
Morton Morris, D.O, J.D.
Executive Director
American Osteopathic Academy of Orthopedics
(954) 262-1700

NEW MEDICARE PROPOSED FEE SCHEDULE NEGATIVELY IMPACTS ORTHOPEDICS

The new Medicare proposed fee schedule was released August 8 and is open for comment until 5 pm September 30, 2005.

In 2000, Medicare unbundled splint and cast supplies allowing them to be billed separately under HCPCS codes. The new fee schedule proposes to eliminate these HCPCS codes for billing cast and splint supplies and bundling cast and splint supplies under the surgery codes.

CMS is asking for feedback specifically as follows:
"For this reason, it is imperative that the relevant medical societies review the "Direct Practice Expense Inputs" on our website at www.cms.hhs.gov/physicians/pfs (under the supporting documents for the 2006 proposed rule) and provide us with feedback regarding the appropriateness of the type and amount of casting and splinting supplies. We are also requesting specific information about the amount of casting supplies needed for the 10-day and 90-day global procedures, because these supplies may not be required at each follow-up visit; therefore, the number of follow-up visits may not reflect the typical number of cast changes required for each service. The following cast and splint supplies have been reincorporated as direct inputs: fiberglass roll, 3 inch and 4 inch; cast padding, 4 inch; webril (now designated as cast padding, 3 inch); cast shoe; stockingnet/stockinette, 4 inch and 6 inch; dome paste bandage; cast sole; elastoplastroll; fiberglass splint; ace wrap, 6 inch; and kerlix (now designated as bandage, kerlix, sterile, 4.5 inch) and malleable arch bars. The cast and splint supplies have been added to the following CPT codes: 23500 through 23680, 24500 through 24685, 25500 through 25695, 26600 through 26785, 27500 through 27566, 27750 through 27848, 28400 through 28675, and 29000 through 29750."

To read the provision in the Federal register, go to:
http://www.cms.hhs.gov/providerupdate/regs/cms1502P.pdf . You may read the entire 302 page document or go to page 16 of the document, which is page 45778 of the Federal Register, first column with the heading "Payment for Splint and Cast Supplies."

If you comment, you must refer to file code **CMS-1502-P**. Facsimile comments will **NOT** be considered.

[redacted]owing information is taken directly from the Federal Register.

You may submit comments in one of three ways (only submit your comments once, CMS will eliminate duplicate submissions):

1. Electronically. You may submit electronic comments on specific issues in this regulation to http://www.cms.hhs.gov/regulations/ecomments. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. By mail. You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services,

Department of Health and Human Services
Attention: CMS–1502–P, P.O.
Box 8017
Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention:
CMS–1502–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your

comments to the Baltimore address, please call telephone number (410) 786– 7197 in advance to schedule your arrival with one of our staff members.

Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201;

or

426-B

Q-Code Summary for File Code CMS-1502-P

Barry J. Collins, D.O.
The Bone Joint Center of Hillsdale County
61 W. Carleton Rd.
Hillsdale, MI 49242
(517) 439-9377

Surgical Code	Global Period	Cast Type*	Total # Casts throughout Tx period	Total Stockinette Used				Total Webroll Used				Total Fiberglass Tape Used				Other Supplies
				2"	3"	4"	6"	2"	3"	4"	6"	2"	3"	4"	6"	
23500	90	0														
23505	90	0														
23515	90	0														
23570	90	0														
23600	90	0														
23605	90	0														
23615	90	0														
23620	90	0														
23630	90	0														
23655	90	0														
24500	90	LAC	2		36"			2	4	2			2	2		
24530	90	LAC	1		18			1	2	1			1	1		
24535	90	LAC	1		18			1	2	1			1	1		
24538	90	LAC	1		18			1	2	1			1	1		
24546	90	LAC	1		18			1	2	1			1	1		
24560	90	LAC	1		18			1	2	1			1	1		
24575	90	LAC	1		18			1	2	1			1	1		
24586	90	LAC	1		18			1	2	1			1	1		
24600	90	LAC	1		18			1	2	1			1	1		
24605	90	LAC	1		18			1	2	1			1	1		
24650	90	LAC	1		18			1	2	1			1	1		
24655	90	LAC	1		18			1	2	1			1	1		
24666	90	LAC	1		18			1	2	1			1	1		
24670	90	LAC	1		18			1	2	1			1	1		
24685	90	LAC	1		18			1	2	1			1	1		
25500	90	LAC	1		18			1	2	1			1	1		
25505	90	LAC	1		18			1	2	1			1	1		
25530	90	LAC	1		18			1	2	1			1	1		
25545	90	LAC	1		18			1	2	1			1	1		
25560	90	LAC	1		18			1	2	1			1	1		
25565	90	LAC	1		18			1	2	1			1	1		
25575	90	LAC	1		18			1	2	1			1	1		
25600	90	SAC/LAC	1 SAC/2LAC		48"			2	5	2			3	2		
25605	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25611	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25620	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25622	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25630	90	SAC	1		12"				1				1			
25650	90	SAC	1		12"				1				1			

Barry J. Collins, D.O.
The Bone Joint Center of Hillsdale County
61 W. Carleton Rd.
Hillsdale, MI 49242
(517) 439-9377

Q-Code Summary for File Code CMS-1502-P

	Global		Total # Casts throughout	Total Stockinette Used			Total Webroll Used			Total Fiberglass Tape Used			Other
26600	90	SAC	1	12"			1			1			
26605	90	SAC	2	24"			2			2			
26615	90	SAC	1	12"			1			1			
26720	90	SAC	1	12"			1			1			
26725	90	SAC	1	12"			1			1			
26727	90	0											
26735	90	SAC	1	12"			1			1			
26750	90	0											
26755	90	0											
26765	90	0											
26775	90	0											
27500	90	LLC	1		48"		2	4			3		
27502	90	LLC	1		48"		2	4			3		
27506	90	0											
27507	90	LLC	1		48"		2	4			3		
27508	90	LLC	1		48"		2	4			3		
27511	90	LLC	1		48"		2	4			3		
27514	90	LLC	1		48"		2	4			3		
27520	90	LLC	1		48"		2	4			3		
27524	90	LLC	1		48"		2	4			3		
27530	90	LLC	1		48"		2	4			3		
27535	90	LLC	1		48"		2	4			3		
27536	90	LLC	1		48"		2	4			3		
27540	90	LLC	1		48"		2	4			3		
27550	90	LLC	1		48"		2	4			3		
27552	90	LLC	1		48"		2	4			3		
27560	90	LLC	1		48"		2	4			3		
27750	90	LLC/SLC/SLWC	1of each	60"	48"		2	6	6		4	5	
27752	90	LLC/SLC/SLWC	1of each	60"	48"		2	6	6		4	5	
27756	90	LLC/SLC	1 of each	30"	48"		1	4	5		2	4	
27758	90	LLC/SLC	1 of each	30"	48"		1	4	5		2	4	
27759	90	SLC	2	60"			2	4	2		4	2	
27760	90	SLC	2	60"			2	4	2		4	2	
27766	90	SLC	2	60"			2	4	2		4	2	
27780	90	SLC	2	60"			2	4	2		4	2	
27781	90	SLC	2	60"			2	4	2		4	2	
27786	90	SLC	2	60"			2	4	2		4	2	
27788	90	SLC	2	60"			2	4	2		4	2	
27792	90	SLC	2	60"			2	4	2		4	2	
27808	90	SLC	2	60"			2	4	2		4	2	

926-C

Barry J. Collins, D.O.
The Bone Joint Center of Hillsdale County
61 W. Carleton Rd.
Hillsdale, MI 49242
(517) 439-8377

Q-Code Summary for File Code CMS-1502-P

Surgical Code	Global Period	Cast Type*	Total # Casts throughout Tx period	Total Stockinette Used				Total Webroll Used				Total Fiberglass Tape Used				Other Supplies
				2"	3"	4"	6"	2"	3"	4"	6"	2"	3"	4"	6"	
23500	90	0														
23505	90	0														
23515	90	0														
23570	90	0														
23600	90	0														
23605	90	0														
23615	90	0														
23620	90	0														
23630	90	0														
23655	90	0														
24500	90	LAC	2		36"			2	4	2			2	2		
24530	90	LAC	1		18			1	2	1			1	1		
24535	90	LAC	1		18			1	2	1			1	1		
24538	90	LAC	1		18			1	2	1			1	1		
24546	90	LAC	1		18			1	2	1			1	1		
24560	90	LAC	1		18			1	2	1			1	1		
24575	90	LAC	1		18			1	2	1			1	1		
24586	90	LAC	1		18			1	2	1			1	1		
24600	90	LAC	1		18			1	2	1			1	1		
24605	90	LAC	1		18			1	2	1			1	1		
24650	90	LAC	1		18			1	2	1			1	1		
24655	90	LAC	1		18			1	2	1			1	1		
24666	90	LAC	1		18			1	2	1			1	1		
24670	90	LAC	1		18			1	2	1			1	1		
24685	90	LAC	1		18			1	2	1			1	1		
			1													
25500	90	LAC	1		18			1	2	1			1	1		
25505	90	LAC	1		18			1	2	1			1	1		
25530	90	LAC	1		18			1	2	1			1	1		
25545	90	LAC	1		18			1	2	1			1	1		
25560	90	LAC	1		18			1	2	1			1	1		
25565	90	LAC	1		18			1	2	1			1	1		
25575	90	LAC	1		18			1	2	1			1	1		
25600	90	SAC/LAC	1 SAC/2LAC		48"			2	5	2			3	2		
25605	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25611	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25620	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25622	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25630	90	SAC	1		12"				1				1			
25650	90	SAC	1		12"				1				1			

Barry J. Collins, D.O.
The Bone Joint Center of Hillsdale County
61 W. Carleton Rd.
Hillsdale, MI 49242
(517) 439-9377

Q-Code Summary for File Code CMS-1502-P

	Global		Total # Casts throughout	Total Stockinette Used				Total Webroll Used				Total Fiberglass Tape Used				Other
26600	90	SAC	1		12"				1				1			
26605	90	SAC	2		24"				2				2			
26615	90	SAC	1		12"				1				1			
26720	90	SAC	1		12"				1				1			
26725	90	SAC	1		12"				1				1			
26727	90	0														
26735	90	SAC	1		12"				1				1			
26750	90	0														
26755	90	0														
26765	90	0														
26775	90	0														
27500	90	LLC	1			48"			2	4				3		
27502	90	LLC	1			48"			2	4				3		
27506	90	0														
27507	90	LLC	1			48"			2	4				3		
27508	90	LLC	1			48"			2	4				3		
27511	90	LLC	1			48"			2	4				3		
27514	90	LLC	1			48"			2	4				3		
27520	90	LLC	1			48"			2	4				3		
27524	90	LLC	1			48"			2	4				3		
27530	90	LLC	1			48"			2	4				3		
27535	90	LLC	1			48"			2	4				3		
27536	90	LLC	1			48"			2	4				3		
27540	90	LLC	1			48"			2	4				3		
27550	90	LLC	1			48"			2	4				3		
27552	90	LLC	1			48"			2	4				3		
27560	90	LLC	1			48"			2	4				3		
27750	90	LLC/SLC/SLWC	1of each		60"	48"		2	6	6			4	5		
27752	90	LLC/SLC/SLWC	1of each		60"	48"		2	6	6			4	5		
27756	90	LLC/SLC	1 of each		30"	48"		1	4	5			2	4		
27758	90	LLC/SLC	1 of each		30"	48"		1	4	5			2	4		
27759	90	SLC	2		60"			2	4	2			4	2		
27760	90	SLC	2		60"			2	4	2			4	2		
27766	90	SLC	2		60"			2	4	2			4	2		
27780	90	SLC	2		60"			2	4	2			4	2		
27781	90	SLC	2		60"			2	4	2			4	2		
27786	90	SLC	2		60"			2	4	2			4	2		
27788	90	SLC	2		60"			2	4	2			4	2		
27792	90	SLC	2		60"			2	4	2			4	2		
27808	90	SLC	2		60"			2	4	2			4	2		

Barry J. Collins, D.O.
The Bone Joint Center of Hillsdale County
61 W. Carleton Rd.
Hillsdale, MI 49242
(517) 439-9377

Q-Code Summary for File Code CMS-1502-P

	Global		Total # Casts throughout	Total Stockinette Used				Total Webroll Used				Total Fiberglass Tape Used				Other
27810	90	LLC/SLC/SLWC	1 of each		60"	48"		2	6	6			4	5		
27814	90	SLC	2		60"			2	4	2			4	2		
27818	90	SLC	2		60"			2	4	2			4	2		
27822	90	SLC	2		60"			2	4	2			4	2		
27823	90	SLC	2		60"			2	4	2			4	2		
27827	90	SLC	2		60"			2	4	2			4	2		
27828	90	SLC	2		60"			2	4	2			4	2		
27848	90	SLC	2		60"			2	4	2			4	2		
28400	90	SLC	2		60"			2	4	2			4	2		
28415	90	SLC	2		60"			2	4	2			4	2		
28430	90	SLC	2		60"			2	4	2			4	2		
28450	90	SLC	2		60"			2	4	2			4	2		
28470	90	SLC	2		60"			2	4	2			4	2		
28475	90	SLC	2		60"			2	4	2			4	2		
28476	90	SLC	2		60"			2	4	2			4	2		
28485	90	SLC	2		60"			2	4	2			4	2		
28490	90	SLC	2		60"			2	4	2			4	2		
28495	90	SLC	2		60"			2	4	2			4	2		
28505	90	0														Post-op Shoe
28510	90	0														Post-op Shoe
28515	90	0														Post-op Shoe
28615	90	SLC	2		60"			2	4	2			4	2		
28665	90	SLC	2		60"			2	4	2			4	2		
28675	90	SLC	2		60"			2	4	2			4	2		

* LAC Long-arm Cast
SAC Short-arm Cast
LLC Long-leg Cast
SLC Short-leg Cast
SLWC Short-leg Walking Cast

926-D

Barry J. Collins, D.O.
The Bone Joint Center of Hillsdale County
61 W. Carleton Rd.
Hillsdale, MI 49242
(517) 439-9377

Q-Code Summary for File Code CMS-1502-P

Surgical Code	Global Period	Cast Type*	Total # Casts throughout Tx period	Total Stockinette Used				Total Webroll Used				Total Fiberglass Tape Used				Other Supplies
				2"	3"	4"	6"	2"	3"	4"	6"	2"	3"	4"	6"	
23500	90	0														
23505	90	0														
23515	90	0														
23570	90	0														
23600	90	0														
23605	90	0														
23615	90	0														
23620	90	0														
23630	90	0														
23655	90	0														
24500	90	LAC	2		36"			2	4	2			2	2		
24530	90	LAC	1		18			1	2	1			1	1		
24535	90	LAC	1		18			1	2	1			1	1		
24538	90	LAC	1		18			1	2	1			1	1		
24546	90	LAC	1		18			1	2	1			1	1		
24560	90	LAC	1		18			1	2	1			1	1		
24575	90	LAC	1		18			1	2	1			1	1		
24586	90	LAC	1		18			1	2	1			1	1		
24600	90	LAC	1		18			1	2	1			1	1		
24605	90	LAC	1		18			1	2	1			1	1		
24650	90	LAC	1		18			1	2	1			1	1		
24655	90	LAC	1		18			1	2	1			1	1		
24666	90	LAC	1		18			1	2	1			1	1		
24670	90	LAC	1		18			1	2	1			1	1		
24685	90	LAC	1		18			1	2	1			1	1		
			1													
25500	90	LAC	1		18			1	2	1			1	1		
25505	90	LAC	1		18			1	2	1			1	1		
25530	90	LAC	1		18			1	2	1			1	1		
25545	90	LAC	1		18			1	2	1			1	1		
25560	90	LAC	1		18			1	2	1			1	1		
25565	90	LAC	1		18			1	2	1			1	1		
25575	90	LAC	1		18			1	2	1			1	1		
25600	90	SAC/LAC	1 SAC/2LAC		48"			2	5	2			3	2		
25605	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25611	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25620	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25622	90	SAC/LAC	2 SAC/1LAC		42"			1	4	1			3	1		
25630	90	SAC	1		12"				1				1			
25650	90	SAC	1		12"				1				1			

Barry J. Collins, D.O.
The Bone Joint Center of Hillsdale County
61 W. Carleton Rd.
Hillsdale, MI 49242
(517) 439-9377

Q-Code Summary for File Code CMS-1502-P

	Global		Total # Casts throughout	Total Stockinette Used				Total Webroll Used				Total Fiberglass Tape Used				Other
26600	90	SAC	1		12"				1				1			
26605	90	SAC	2		24"				2				2			
26615	90	SAC	1		12"				1				1			
26720	90	SAC	1		12"				1				1			
26725	90	SAC	1		12"				1				1			
26727	90	0														
26735	90	SAC	1		12"				1				1			
26750	90	0														
26755	90	0														
26765	90	0														
26775	90	0														
27500	90	LLC	1			48"			2	4				3		
27502	90	LLC	1			48"			2	4				3		
27506	90	0														
27507	90	LLC	1			48"			2	4				3		
27508	90	LLC	1			48"			2	4				3		
27511	90	LLC	1			48"			2	4				3		
27514	90	LLC	1			48"			2	4				3		
27520	90	LLC	1			48"			2	4				3		
27524	90	LLC	1			48"			2	4				3		
27530	90	LLC	1			48"			2	4				3		
27535	90	LLC	1			48"			2	4				3		
27536	90	LLC	1			48"			2	4				3		
27540	90	LLC	1			48"			2	4				3		
27550	90	LLC	1			48"			2	4				3		
27552	90	LLC	1			48"			2	4				3		
27560	90	LLC	1			48"			2	4				3		
27750	90	LLC/SLC/SLWC	1of each		60"	48"		2	6	6			4	5		
27752	90	LLC/SLC/SLWC	1of each		60"	48"		2	6	6			4	5		
27756	90	LLC/SLC	1 of each		30"	48"		1	4	5			2	4		
27758	90	LLC/SLC	1 of each		30"	48"		1	4	5			2	4		
27759	90	SLC	2		60"			2	4	2			4	2		
27760	90	SLC	2		60"			2	4	2			4	2		
27766	90	SLC	2		60"			2	4	2			4	2		
27780	90	SLC	2		60"			2	4	2			4	2		
27781	90	SLC	2		60"			2	4	2			4	2		
27786	90	SLC	2		60"			2	4	2			4	2		
27788	90	SLC	2		60"			2	4	2			4	2		
27792	90	SLC	2		60"			2	4	2			4	2		
27808	90	SLC	2		60"			2	4	2			4	2		

Barry J. Collins, D.O.
The Bone Joint Center of Hillsdale County
61 W. Carleton Rd.
Hillsdale, MI 49242
(517) 439-9377

Q-Code Summary for File Code CMS-1502-P

	Global		Total # Casts throughout	Total Stockinette Used				Total Webroll Used				Total Fiberglass Tape Used				Other
27810	90	LLC/SLC/SLWC	1 of each		60"	48"		2	6	6			4	5		
27814	90	SLC	2		60"			2	4	2			4	2		
27818	90	SLC	2		60"			2	4	2			4	2		
27822	90	SLC	2		60"			2	4	2			4	2		
27823	90	SLC	2		60"			2	4	2			4	2		
27827	90	SLC	2		60"			2	4	2			4	2		
27828	90	SLC	2		60"			2	4	2			4	2		
27848	90	SLC	2		60"			2	4	2			4	2		
28400	90	SLC	2		60"			2	4	2			4	2		
28415	90	SLC	2		60"			2	4	2			4	2		
28430	90	SLC	2		60"			2	4	2			4	2		
28450	90	SLC	2		60"			2	4	2			4	2		
28470	90	SLC	2		60"			2	4	2			4	2		
28475	90	SLC	2		60"			2	4	2			4	2		
28476	90	SLC	2		60"			2	4	2			4	2		
28485	90	SLC	2		60"			2	4	2			4	2		
28490	90	SLC	2		60"			2	4	2			4	2		
28495	90	SLC	2		60"			2	4	2			4	2		
28505	90	0														Post-op Shoe
28510	90	0														Post-op Shoe
28515	90	0														Post-op Shoe
28615	90	SLC	2		60"			2	4	2			4	2		
28665	90	SLC	2		60"			2	4	2			4	2		
28675	90	SLC	2		60"			2	4	2			4	2		

* LAC Long-arm Cast
SAC Short-arm Cast
LLC Long-leg Cast
SLC Short-leg Cast
SLWC Short-leg Walking Cast

927

Medical Oncologists / Hematologists
M.S. Murali, M.D.
Keith W. Logie, M.D.
Andrew R. Greenspan, M.D.
David M. Loesch, M.D.
Thomas L. Whittaker, M.D.
Hemachandra Venkatesh, M.D.
James K. Hwang, M.D.
Elsayed Aly, M.D.
Hillary H. Wu, M.D., Ph.D.
Sead Beganovic, M.D., Ph.D.
Jennifer K. Morgan, M.D.
Melody Sands, RN, CS, MSN

Radiation Oncologists
Nini M. Bermudez-Webb, M.D.
Morgan E. Tharp II, M.D.
John P. Jacobs, M.D.
G. Irene Minor, M.D.
Michael C. Hardacre, M.D.

Integrative Healthcare
K.C. Khemka, Ph.D.

Services
Clinical Hematology
Medical Oncology
Thrombosis & Hemostasis
Stem Cell Transplantation
PET Scanning
Conformal Radiation
IMRT
Specialized Brachytherapy
Cancer Research and Screening
Palliative Care
Integrative Healthcare

Executive Director
Christopher Achtien

Central Business Office
6330 East 75th Street, Suite 140
Indianapolis, IN 46250
317-594-6900
Fax: 317-594-6911

Cancer Center Locations
North
10212 Lantern Rd.
Fishers, IN 46038
317-841-5656
East
6845 Rama Dr.
Indianapolis, IN 46219
317-964-5200
Hancock
1 Memorial Sq., Suite. 50
Greenfield, IN 46140
317-467-7100
South
1346 E. County Line Rd.
Indianapolis, IN 46227
317-859-5500

CENTRAL INDIANA
CANCER CENTERS

September 21, 2005

Hon. Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

Attention: CMS-1502-P

P. O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

I am writing regarding solid compensator-based IMRT. I would like you to know that I support the CMS decision to crosswalk payment for 0073T to CTT77418. I would request that CMS issue a Medicare Program Transmittal to include compensator-based IMRT delivery code 0073T, and coding guidance for IMRT planning and delivery.

I believe without question the payments policy to allow use of compensator-based IMRT has allowed state-of-the-art quality radiotherapy to be delivered to patients who would otherwise not receive this care. I think that this reimbursement policy is essential to continue adequate care to Medicare patients.

I can tell you personally that this has been the case in Central Indiana. I am a radiation oncologist in a program that has multiple cancer centers. We have MLC-based IMRT available at one center only, and I have been delivering IMRT in this center utilizing very strict quality assurance guidelines. In the past year, we have incorporated compensator-based IMRT at one of our outlying centers that does not have MLCs. Patients in this area previously would either have to drive a long distance to receive this care, or receive lesser forms of radiation, with lower doses, which would lead to lower disease-control rates, yet with higher doses to critical organs yielding higher side effect rates. Most of my patients elected not to receive this care due to the longer drive. We have implanted compensator-based IMRT under extremely strict quality assurance guidelines, and have in fact verified that the treatment delivery is equal to what we give with the MLC-based program at our separate center. We are now able to deliver the same care to patients in different geographical areas, which would otherwise not be available.

Medical Oncologists / Hematologists
M.S. Murali, M.D.
Keith W. Logie, M.D.
Andrew R. Greenspan, M.D.
David M. Loesch, M.D.
Thomas L. Whittaker, M.D.
Hemachandra Venkatesh, M.D.
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Hancock
1 Memorial Sq., Suite. 50
Greenfield, IN 46140
317-467-7100
South
1346 E. County Line Rd.
Indianapolis, IN 46227
317-859-5500

CENTRAL INDIANA
CANCER CENTERS

I commend CMS and its staff for providing coverage and reimbursement for compensator-based IMRT. This policy decisions are provided for high-quality-cost-effective cancer treatment for Medicare beneficiaries to be given in a wider geographical distribution.

Sincerely,

Morgan E. Tharp II, M.D.

MET/Pradot/pre/roz

DD: 09/21/2005

Dictated, but not proofread.

928

JAMES L. POTH, M.D.
MICHAEL ALEXANDER, M.D., INC.
RICHARD M. SHAPIRO, M.D.
1668 DOMINICAN WAY
SANTA CRUZ, CALIFORNIA 95065

TELEPHONE 475-8800
FAX 475-8580

ONCOLOGY HEMATOLOGY

September 27,2005

Dear CMS staff,
As a physician practicing Medical Oncology in Santa Cruz County,California I have long been aware of the inequity of the designation of Santa Cruz as rural. This has recently been reinforced to me in our search for a new oncologist to join our practice. Every physician that we recruited was aware of the rural designation and the financial impact this would have on them. They were concerned that this would interfere with their ability to afford housing and the local cost of living since the low Medicare standard ratchets down all of our insurance payments. Thus, our county suffers de facto discrimination in terms of the quality of the physician it can attract.
By creating a new payment locality for Santa Cruz county you would help remedy this inequity. Our county is entitled to the same availability of quality physicians as other neighboring counties.
I appreciate your consideration and my opportunity to comment on this issue.

Michael Alexander MD

Michael Alexander,MD
Dominican Hospital Santa Cruz
Clinical Associate Professor of Medicine
Stanford University School of Medicine

929

August/September, 2005

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P. O. Box 8017
Baltimore, MD 21244-8017

Re: **File Code CMS-1502-P**

Issue: GPCIs / Payment Locality / Oppose Proposed Rule Change

To Whom It May Concern:

I am writing to comment on the Proposed Rule governing the Physician Fee Schedule Calendar Year 2006 as printed in the *Federal Register* of August 8, 2005.
I oppose the proposed removal of California's Santa Cruz and Sonoma counties from Medicare reimbursement Locality 99. Doing this does not address the problems of other counties within Locality 99 who suffer from significant cost disparities close to those of Santa Cruz and Sonoma counties. By proposing that these two counties be removed from Locality 99 into their own localities, exacerbates the problems of the remaining Locality 99 counties – especially those of Monterey, San Diego, and Santa Barbara.

I am also concerned that no where in the proposed rule is it mentioned that this "two-county fix" is the beginning of a greater effort to move all counties in the state and nation into payment localities that truly reflect their respective costs of providing medical services.

The Centers for Medicare & Medicaid Services should be responsible for calculating new Geographic Area Factors and Geographic Practice Costs Indices and making immediate locality adjustments to *all* counties exceeding the so-called "5% threshold".

Sincerely,

Signature: Patricia Wagenhals + Walter Wagenhals
Name: Patricia Wagenhals + Walter Wagenhals
Address: 7 Abinante Way
Monterey CA
93940

TOTAL P.01

930

TOWN OF
WINDSOR

Town of Windsor
9291 Old Redwood Highway
P.O. Box 100
Windsor, CA 95492-0100
Phone: (707) 838-1000
Fax: (707) 838-7349

www.townofwindsor.com

Mayor
Steve Allen

Mayor Pro Tempore
Sam Salmon

Council Members
Lynn Morehouse
Debora Fudge
Warin Parker

September 23, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
PO Box 8017
Baltimore, MD 21244-8017

Re: GPCIs

I understand that Medicare is proposing to create a new payment locality for Sonoma County, California. I would like to address some specific concerns from the perspective of the Town of Windsor, Sonoma County's fourth largest city.

- Santa Rosa now ranks with retirement destinations such as Clearwater, St. Petersburg, and Miami, Florida.
- Among cities with a population of 100,000 or more, Santa Rosa is sixth in the United States for the highest percentage of people 85 and older.
- The Town of Windsor is located just north of Santa Rosa.
- According to State of California Department of Finance, seniors 60 and older represent 16.6% of the total population in Sonoma County, with a projected rate of change of 196% by 2020.

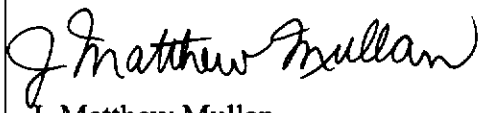
Amid the astounding growth in our elder population, Sonoma County is facing strains on the health care delivery network that are unacceptable to Medicare recipients:

- The number of practicing physicians in Sonoma County has not kept pace with local population growth. From 1995 to 2002, the population increased 13%, but the number of practicing physicians increased by only 4%.
- As of July 2005, 60% of Sonoma County primary care physicians were NOT accepting new Medicare patients.
- Many physicians are leaving our county to practice where reimbursement is more favorable. As a result, many specialties are under-supplied. For example, we have only two gerontologists in the county for more than 76,000 seniors.

Printed on recycled paper

The new locality would increase the Medicare reimbursement rate to more closely match actual practice expenses, helping Sonoma County physicians improve the quantity and quality of care they deliver to Medicare beneficiaries and other patients. The locality change would also aid efforts to recruit and retain physicians in the county, which has a large Medicare population. On behalf of the Windsor Town Council and our entire community we fully support your proposal to change Sonoma County's payment locality, and appreciate the opportunity to comment on this important issue.

Sincerely,



J. Matthew Mullan
Town Manager

c: Two copies attached
Windsor Town Council

I:\10 - Town Manager's Office\MULLAN\TOWN MANAGER\2005\09-26-05. Support Medicare Reimbursement..doc

Printed on recycled paper

931

9/28/05

Centers for Medicare and Medicaid Services
Dep't of Health and Human Services
Attention: CMS-1502-P
Baltimore, MD 21244

Re:GPCI

To Whom It May Concern:

I receive care from several great doctors—now and in the past. Unfortunately, they keep moving, because a few miles away they can be reimbursed at a higher rate for treating Medicare patients. There is a proposed rule before you that will take my county from the Rest of California payment designation. Passing this rule can certainly make things more equitable for our local doctors, so that their payment will be on a par with other counties in the San Francisco Bay area..

I truly support what you are doing and appreciate your attention to the proposed changes.

Yours truly

Roberta Bromberger
240 Mission St.
Santa Cruz, CA 95060

September 27, 2005

432

I am a resident of Sonoma County and a medicare beneficiary. the cost of living in Sonoma County has become increasingly expensive. Some physicians have, therefore, moved to other locations and some have chosen not to accept new medicare patients.

I fully support the proposal to change the reimbursement payments to our Sonoma County doctors.

Yours sincerely,

Betty Knight
60 Kingston Lane
Cotati CA 94931

Helen Mary McStravick

9/21/05

To: Medicare Decision Makers

From: Helen B. McStravick
Lodge at Paulin Creek
2375 Rosegloe #123
Santa Rosa Ca 95403

Re: Medicare Reimbursement

Please support the increase in the reimbursement rate for Sonoma County by 8%. I'm 81 yrs old, have had the same physician for over 20 yrs and now depend heavily on his excellent care. It would be a frightening loss if he now found it necessary to move out of the County because of financial reasons.

Thank you for your assistance

Helen B. McStravick

934

Connecticut Dietetic Association
"Serving the public through the promotion of optimal nutrition and well-being"
www.eatrightct.org

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September 27, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS-1502-P
Baltimore, MD 21244-8012

Dear Dr. McClellan:

The Connecticut State Dietetic Association (CDA) is pleased to comment on the Revisions to Payment Polices Under the Physician Fee Schedule for Calendar Year 2006. The CDA represents nearly 1,000 food and nutrition professionals who serve the public by providing Medical Nutrition Therapy and by promoting optimal health through nutrition.

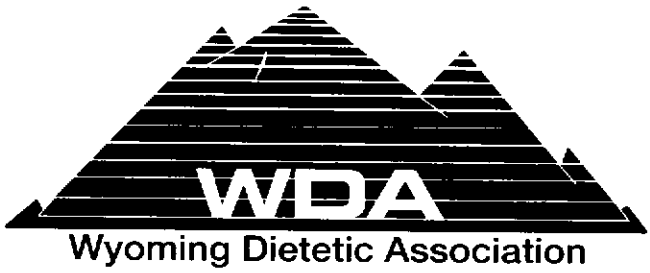
CDA has two main areas of interest with the proposed rule: (1) the agency's methodology for calculating practice expense for medical nutrition therapy (MNT) codes, and (2) the proposed changes for Medicare telehealth services. These two items impact the provision of MNT services, a covered Medicare service for eligible beneficiaries with diabetes and kidney disease.

Our specific comments follow:

1. **II.A. 2. —Practice Expense Proposals for Calendar Year 2006**
   The new methodology used to determine code values (RVUs) for non-physician practitioner services does not appropriately recognize the professional RD provider work effort within the practice expense (PE) values. We urge CMS to be receptive to approaches that deal with the work of non-physicians (e.g. registered dietitians) where the statute authorizes such services, such as MNT services. In addition, we request that CMS work with the American Dietetic Association to determine an alternative methodology for establishing PE for the MNT codes. While discussions of such alternatives occur, we suggest the agency delay implementation of the 2006 PE values for the MNT codes, and instead use the 2005 values until a satisfactory methodology is determined.

CDA, 18 Sakrison Road, Granby, CT 06035, Phone: 860/413-9355, Fax: 203/286-1677

935



September 23, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS-1502-P
Baltimore, MD 21244-8012.

Dear Dr. McClellan:

The Wyoming State Dietetic Association (WDA) is pleased to comment on the Revisions to Payment Polices under the Physician Fee Schedule for Calendar Year 2006. WDA represents nearly 100 food and nutrition professionals who serve the public by providing Medical Nutrition Therapy and by promoting optimal health through nutrition.

WDA has two main areas of interest with the proposed rule: (1) the agency's methodology for calculating practice expense for medical nutrition therapy (MNT) codes, and (2) the proposed changes for Medicare telehealth services. These two items impact the provision of MNT services, a covered Medicare service for eligible beneficiaries with diabetes and kidney disease.

Our specific comments follow:

1. **II.A. 2.—Practice Expense Proposals for Calendar Year 2006**
   The new methodology used to determine code values (RVUs) for non-physician practitioner services does not appropriately recognize the professional RD provider work effort within the practice expense (PE) values. We urge CMS to be receptive to approaches that deal with the work of non-physicians (e.g. registered dietitians) where the statute authorizes such services, such as MNT services. In addition, we request that CMS work with the American Dietetic Association to determine an alternative methodology for establishing PE for the MNT codes. While discussions of such alternatives occur, we suggest the agency delay implementation of the 2006 PE values for the MNT codes, and instead use the 2005 values until a satisfactory methodology is determined.

2. **II.D. Telehealth.**
   WDA supports CMS' recommendation to recognize individual medical nutrition therapy (MNT) as a Medicare telehealth service. We also support CMS' proposed rule to add registered dietitians and qualified nutrition professionals to the list of practitioners who are authorized to furnish and receive payment for telehealth services. We realize that this technology is currently used by certain authorized Medicare health professionals in rural health areas with a shortage of healthcare professionals. Including MNT in the list of approved telehealth services, and extending this to RD Medicare providers will improve access and services for patient/clients in remote areas where traditional MNT services may not be readily available. As a rural state, Wyoming suffers from getting access to health care. Patients and clients could greatly benefit by more accessible care.

Thank you for considering these comments in CMS' revisions to the 2006 Physician Fee Schedule.

Sincerely,

Judy Barbe, MS RD
WDA President

Post Office Box 1480
Mills, Wyoming 82644

307.472.1830

936

TEXAS DIETETIC ASSOCIATION

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Marilyn McGuire, CMP
12300 Ford Road, Ste. 135
Dallas, Texas 75234
(w) 972/755-2530
(f) 972/755-2561
TDA@nutrition4texas.org
http://www.nutrition4texas.org

2006 TDA Food and Nutrition Conference and Exhibition
April 6-8
The Woodlands Marriott Hotel
The Woodlands, Texas

September 23, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS-1502-P
Baltimore, MD 21244-8012.

Dear Dr. McClellan:

The Texas Dietetic Association (TDA) is pleased to comment on the Revisions to Payment Polices Under the Physician Fee Schedule for Calendar Year 2006. The TDA represents nearly 3,500 food and nutrition professionals who serve the public by providing Medical Nutrition Therapy and by promoting optimal health through nutrition.

TDA has two main areas of interest with the proposed rule: (1) the agency's methodology for calculating practice expense for medical nutrition therapy (MNT) codes, and (2) the proposed changes for Medicare telehealth services.

These two items impact the provision of MNT services, a covered Medicare service for eligible beneficiaries with diabetes and kidney disease.

Our specific comments follow:

1. **II.A. 2.—Practice Expense Proposals for Calendar Year 2006**
   The new methodology used to determine code values (RVUs) for non-physician practitioner services does not appropriately recognize the professional RD provider work effort within the practice expense (PE) values. We urge CMS to be receptive to approaches that deal with the work of non-physicians (e.g. registered dietitians) where the statute authorizes such services, such as MNT services. In addition, we request that CMS work with the American Dietetic Association to determine an alternative methodology for establishing PE for the MNT codes. While discussions of such alternatives occur, we suggest the agency delay implementation of the 2006 PE values for the MNT codes, and instead use the 2005 values until a satisfactory methodology is determined.

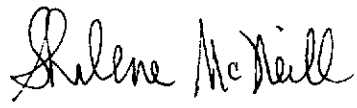
2. II.D. Telehealth.

TDA supports CMS' recommendation to recognize individual medical nutrition therapy (MNT) as a Medicare telehealth service. We also support CMS' proposed rule to add registered dietitians and qualified nutrition professionals to the list of practitioners who are authorized to furnish and receive payment for telehealth services. We realize that this technology is currently used by certain authorized Medicare health professionals in rural health areas with a shortage of healthcare professionals. Because Texas is a large state, there are areas that are underserved due to the distance and numbers of dietitians available to provide services. The ability to use available technology to connect with rural patients would be a great benefit and increase the availability of services to Medicare patients.

Including MNT in the list of approved telehealth services, and extending this to RD Medicare providers will improve access and services for patient/clients in remote areas where traditional MNT services may not be readily available

Thank you for considering these comments in CMS' revisions to the 2006 Physician Fee Schedule.

Best regards,



Shalene McNeill, PhD, RD
President, Texas Dietetic Association

cc: The American Dietetic Association
Policy Initiatives and Advocacy Group

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California Dietetic Association

7740 Manchester Ave., Suite 102, Playa del Rey, CA 90293-8499
Tel. (310) 822-0177 • Fax (310) 823-0264 • E-mail: CDAEP @aol.com • WebSite: www.dietitian.org

September 26, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS-1502-P
Baltimore, MD 21244-8012.

Dear Dr. McClellan:

The California Dietetic Association (CDA) is pleased to comment on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006. The CDA represents nearly 6,100 food and nutrition professionals who serve the public by providing Medical Nutrition Therapy and by promoting optimal health through nutrition.

CDA has two main areas of interest with the proposed rule: (1) the agency's methodology for calculating practice expense for medical nutrition therapy (MNT) codes, and (2) the proposed changes for Medicare telehealth services. These two items impact the provision of MNT services, a covered Medicare service for eligible beneficiaries with diabetes and kidney disease.

Our specific comments follow:

1. **II.A. 2.—Practice Expense Proposals for Calendar Year 2006**
   The new methodology used to determine code values (RVUs) for non-physician practitioner services does not appropriately recognize the professional RD provider work effort within the practice expense (PE) values. We urge CMS to be receptive to approaches that deal with the work of non-physicians (e.g. registered dietitians) where the statute authorizes such services, such as MNT services. In addition, we request that CMS work with the American Dietetic Association to determine an alternative methodology for establishing PE for the MNT codes. While discussions of such alternatives occur, we suggest the agency delay implementation of the 2006 PE values for the MNT codes, and instead use the 2005 values until a satisfactory methodology is determined.

2. **II.D. Telehealth.**
   CDA supports CMS' recommendation to recognize individual medical nutrition therapy (MNT) as a Medicare telehealth service. We also support CMS' proposed rule to add registered dietitians and qualified nutrition professionals to the list of practitioners who are authorized to furnish and receive payment for telehealth services. We realize that this technology is currently used by certain authorized Medicare health professionals in rural health areas with a shortage of healthcare professionals. Including MNT in the list of approved telehealth services, and extending this to RD Medicare providers will improve access and services for patient/clients in remote areas where traditional MNT services may not be readily available. In San Diego county, where I live, there are a limited number of RD Medicare providers and many patients must travel 1-1.5 hours one-way to see an RD and with the rising cost of fuel this further increases the health care costs to patients. In addition one RD in Southern California must travel by boat to Catalina Island once a month (a round trip of ~5 hours) to provide MNT services to patients on the island; it would be more efficient for the patients and RD to provide MNT over the phone. In summary, telephone counseling options would help many of our California Medicare recipients.

Thank you for considering these comments in CMS' revisions to the 2006 Physician Fee Schedule.

Sincerely,

Teresa Bush Zurn, MA, RD, FADA, CDE
President, California Dietetic Association

CC: The American Dietetic Association
Policy Initiatives and Advocacy Group

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BROOKS Pharmacy

ECKERD Pharmacy

September 30, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-1850

Subject: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

To Whom it May Concern:

Brooks/Eckerd Pharmacy is writing to provide comments on the proposed regulation that would change the supplying fees paid to pharmacies by Medicare Part B in 2006. Brooks/Eckerd Pharmacy has more than 1900 pharmacy locations in 18 states. All of our pharmacies are currently enrolled as providers of Medicare Part B drugs.

In summary, the supplying fees proposed for 2006 for supplier-provided Part B drugs, as well as the intention to reduce the dispensing fees for inhalation drugs, may well underpay pharmacies for their total cost of purchasing the drug and dispensing the drug.

MMA Changed Reimbursement Model for Part B Covered Drug

As you know, the Medicare Modernization Act (MMA) changed the basis of Medicare Part B drug reimbursement from an AWP-based system to an Average Sales Price (ASP)-based system. The ASP-based system significantly reduced pharmacy payment amounts for many Part B drugs, including those provided by community retail pharmacies. Some of these Part B drugs are very expensive, such as drugs to prevent organ rejection.

The use of ASP as a reimbursement method for retail pharmacies is problematic because ASP reflects manufacturer's revenues from sales to all "classes of trade". However, Brooks/Eckerd Pharmacy does not have access to the same discounts and other price concessions of these other purchasers, such as hospitals, nursing homes and HMOs. This places us at a disadvantage compared to other purchasers, since the ASP for a product may reimburse us at an amount lower than our costs of acquisition.

ASP is also outdated by several months, so we may have to absorb any manufacturer price increases for covered Part B drugs that occur before the ASP can be updated. As a result, we find that ASP reimbursement for some Part B drugs is significantly below our costs.

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Moreover, it generally costs Brooks/Eckerd significantly more to bill Medicare claims than other third party claims because of cumbersome Medicare billing requirements. Many Part B drug claims are rejected due to eligibility issues. Several claims are never paid because our stores cannot obtain the full or proper information. The bottom line is that we have enormous write offs in Medicare as compared to other third party on-line plans. Thus, the amount of the supplying fee established by CMS is critical to assuring that we are compensated for ASP-based product reimbursement that is not below costs, and to compensate for Medicare Part B's unusually burdensome billing requirements.

Establishment of Medicare Part B Supplying Fee

Brooks/Eckerd Pharmacy must assess the total amount of reimbursement paid by Medicare Part B when considering whether to provide Part B drugs to Medicare beneficiaries. The total reimbursement consists of the amount paid for the drug product dispensed (now based on ASP) as well as the fee paid to supply or dispense the drug.

As it moved to the ASP-based payment system in 2005, CMS established the current supplying fee for covered Part B drugs in its final Physician Fee Schedule Rule, dated November 15, 2004. This rule requires that "a supplying fee of $24 shall be paid to a pharmacy for each supplied prescription of drugs and biologicals...and a supplying fee of $50 is paid to a pharmacy for the initial supplied prescription of drugs and biologicals ...provided to a patient during the first month following a transplant." CMS does not currently pay a fee for Part B prescriptions for the same drug but a different strength supplied in the day.

Because the ASP-based reimbursement system was first introduced this year for Part B drugs, we didn't know what our total reimbursement would be, and whether we would financially be able to supply Part B drugs to Medicare beneficiaries. The uncertainty for us regarding the ASP-based payment rates for the drugs was somewhat mitigated by the amount of the supplying fees being paid by Medicare in 2005. The ultimate fees paid by CMS in 2005 helped to mitigate the impact of the move to an ASP-based system.

In theory, the supplying fees set by CMS in 2005 were to pay pharmacies for the supplying costs and the additional administrative costs of participating in Medicare Part B. In reality, these higher fees were to compensate us for the underpayments for drugs under the ASP-based system. This is because Brooks/Eckerd does not have access to the rebates, discounts and price concessions of other Part B purchasers, and therefore may buy at higher than the ASP plus 6 percent amount.

Thus, the proposal to reduce the supplying fee from $24 for each Part B prescription to $24 for the first prescription dispensed in a month to and $8 for each subsequent Part B prescription would represent a serious and significant reduction in total reimbursement.

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This reduction, when combined with the underpayment for the drug products on the ASP side, as well as the continuing additional costs of participating in Part B, could result in Brooks/Eckerd not being able to further provide Part B drugs.

In addition, because many Medicare beneficiaries come into the pharmacy at the end of the month to obtain their full prescription for next month, it would mean that a pharmacy could be paid only one full supplying fee for two full months worth of prescriptions. For example, if the beneficiary is only taking one Part B medication, the pharmacy would be paid $24 for the first prescription the first of the month. If the beneficiary seeks a refill on the 31st of the same month, the pharmacy would only be paid $8 for the next month's full prescription because the pharmacy dispensed it in the same month as the original prescription. Some beneficiaries might be asked to come back a few days later to obtain the prescription since the pharmacy would obtain their full supplying fee for the refill prescription by actually dispensing it in the next month. Thus, the dispensing fee should be based on a per prescription basis, not on a monthly basis.

Costs of Dispensing Medicare Part B Prescriptions

Pharmacies incur a significant amount of "bad debt" in Medicare Part B as compared to other third parties, which must be reflected in the supplying fee amount paid. If just one claim for an expensive Part B drug is rejected by the DMERC and eventually unpayable, it could eliminate or sharply reduce any margin that we might earn on Part B prescriptions. Thus, it is not clear where CMS obtained this $8 figure. These additional Part B costs can be significant when compared with traditional third party prescription plans.

First, CMS should know that a recent assessment by the University of Texas Center for Pharmacoeconomic Studies found in July 2005 that the average cost to fill a prescription was $9.62. Therefore, the proposal to use $8 as the new supplying fee for Part B prescriptions is below even a recent assessment of a retail pharmacy' costs to fill an average prescription, not a more-costly Medicare Part B prescription. Moreover, because of the many additional administrative tasks that have to be performed by the pharmacy in order to appropriately bill and receive payment for a Medicare Part B prescription, a fee of $8 does not adequately cover these additional costs.

We appreciate that CMS has decided to pay a fee for each prescription dispensed by the pharmacy or supplier for the same drug, but a different strength. However, even with the additional fees, this reimbursement, fails to meet our additional costs of processing claims.

Each group of Part B drugs has different coverage and billing issues that must be resolved before the pharmacy can submit a "clean" claim to the DMERC. The extent of the additional time involved depends on the category of drug and the willingness of the physician to work

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with the pharmacy to obtain the information necessary for billing. Transplant drugs tend to have the highest administrative costs, but the pharmacist must check that the other oral drugs (i.e., anticancer drugs and antiemetic drugs) are being used for an indication that is covered under Part B.

Even after "clean claims" are submitted to the DMERC, Medicare Part B has a higher rejection rate than traditional third party prescription plans because of the lack on an online claims adjudication system. This requires additional administrative tasks to resubmit the claim to Medicare. Some of the rejections for these clean claims are due to the fact that DMERCs still have issues with converting NDC codes for drugs to HCPCS codes.

In addition, Medicare Part B takes more time to pay pharmacies than traditional third party payers. This is due to a lack of the online claims processing system, which results in a higher rate of rejects.

We also have the additional costs of needing to contract with a separate billing entity – other than the standard third party billing contractor - to convert Medicare Part B claims from an NCPDP format to an ANSI X837 format so we can batch bill the DMERCs. This service costs Brooks/Eckerd an average of $2.00 per claim. This factor, in and of itself, requires that Medicare Part B pay pharmacies a significantly higher supplying fee to maintain beneficiary access to these Part B products.

Even if the online claims adjudication system were established, and some costs of participating were reduced, there are many other issues that have to be considered when determining providers' "costs" in filling Medicare Part B prescriptions that are not typical in other private or public third party prescription programs.

Administrative Issues Relating to Medicare Part B Participation

CMS proposed in the 2005 physician fee rule to make several administrative reforms to covered Part B drug billing that would have reduced the cost and administration of participation. However, the 2006 rule is silent on the progress made by CMS in making these administrative changes.

In fact, it appears to be taking an exceptionally long time to make some of these changes. These paperwork and other administrative requirements, which generally do not exist in other third party plans, simply make it more time consuming and costly for pharmacies to participate as suppliers in Medicare. We describe these below.

Assignment of Benefits Forms Not Yet Eliminated: We continue to be concerned that the Assignment of Benefits (AOB) form has not yet been eliminated for Medicare covered Part B drugs. We understand that CMS has begun the process to eliminate the AOB

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requirement – retroactive to January 1, 2005 – but that the entire process has not yet been completed. We urge CMS to move toward completing the elimination of this requirement for ALL Medicare Part B products, including diabetic supplies, as quickly as possible.

DIF Forms Not Yet Eliminated: Pharmacies currently have to complete a DMERC Information Form (DIF) to receive payment for immunosuppressive drugs. We believe that a pharmacy's costs of supplying Part B drugs to Medicare beneficiaries would be reduced with this change. Almost a year past since the October 2004 deadline, the DIF form has still not been eliminated, and as we understand it, may not be eliminated until 2006. In addition, CMS should not only eliminate the DIF form it should eliminate the requirement that pharmacies collect and submit the DIF form information. Most of the information required on the DIF form which pharmacies are required to submit can be obtained from other billing information submitted to Medicare by the institution in which the transplant was performed and the transplant physician.

Detailed Written Order Required Before Billing: Medicare requires that the pharmacy obtain a signed written order from the physician, with very specific directions for use, before the pharmacy can bill the DMERC for the Medicare Part B drug. That means that a pharmacy can accept a telephone order from the physician to fill the prescription, but must go back to the physician and obtain a signed written prescription before the order can be billed. This increases the paperwork requirements for the physician and the pharmacist. Almost all third parties, including Medicaid, allow filling and billing of a prescription drug based on verbal orders from the physician.

Diagnosis Codes Often Needed: Because some Part B drugs are only paid for when used to treat certain medical conditions, the pharmacy often has to contact the physician to assure that the Part B drug is being used for a covered Part B use (diagnosis codes are not a typical requirement on prescriptions billed to other third party plans). This results in an additional cost to the pharmacy to fill the prescription.

Crossover Claims: There are several issues regarding cross over claims for Medicare Part B drugs. While Medicare Part B is the primary payer for certain covered drugs, some third party payers, such as Medicaid and private employers, will wrap around the Part B coverage and pay all or part of the Medicare Part B cost sharing amount. Because of the lack of online claims adjudication, Brooks/Eckerd Pharmacy doesn't know if the claim has automatically "crossed over" to the other third party coverage, or whether to collect the 20 percent cost sharing amount (or some percentage of that amount) from the beneficiary. This information may only become known to us many months later after trying to reconcile the claims. In some cases, we have to refund the cost sharing amounts collected because the pharmacy didn't know when the prescription was being filled that another payer was paying for all or part of the cost sharing.

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Supplier Enrollment Procedures Cumbersome: The process used by Medicare to enroll and reenroll suppliers is incredibly involved and complex, more so than any other third party plans in which we participate. While this is a cost of doing business Brooks/Eckerd has personnel dedicated solely to the process of compiling and completing the paperwork necessary to maintain Medicare supplier billing status. These costs must be considered as part of the "costs of doing" business with Medicare, and should be reflected in the supplying fees paid.

Service Date/Billing Date Issues Remain: Almost all third party plans allow the pharmacy to use the date the prescription was filled as the date of service. In Medicare however, the date of service has to be the same as the date that the prescription was picked up by the beneficiary. Thus, if the pharmacy fills the prescription but the beneficiary does not pick it up on the same day, the pharmacist has to reverse the claim and fill the prescription again when the beneficiary comes in. It is often the case that many prescription refills are phoned in by patients, including Medicare beneficiaries, a day or two before they will be in to pick them up so that they don't have to wait at the pharmacy when they arrive. However, as stated above, if the pharmacist fills the prescription, not knowing that the beneficiary is coming in a day or two later, and the beneficiary doesn't pick it up on the day that the prescription is filled, the pharmacist has to reverse the claim and re-fill and re-bill the prescription when the beneficiary comes in to pick it up. This is burdensome and costly for the pharmacy. In essence, it means that the Brooks/Eckerd pharmacies have to incur the costs of preparing and dispensing the prescription twice.

Dispensing Fees for Inhalation Drugs

Brooks/Eckerd is very concerned that CMS is considering reducing the dispensing fees paid for Part B covered inhalation drugs. Under the current model, suppliers receive $57 for a 30-day supply of inhalation drugs and $80 for a 90-day supply of inhalation drugs. The same amount is paid regardless of the number of inhalation drugs provided over that 30-day period.

Brooks/Eckerd appreciates that CMS significantly increased on an interim basis the dispensing fees paid for these drugs in 2005. That is because payment for the drug product component decreased significantly under the ASP-based system for inhalation drugs. Therefore, it was critical that additional dispensing fee payments were provided to assure that the services associated with providing these drugs, as well as additional costs of processing Part B claims for these drugs, are being appropriately compensated. H

However, while $57 appears to be a high number for a dispensing fee, it must be remembered that many Medicare beneficiaries use more than one inhalation drug and that the pharmacy receives only one fee within a 30-day period of time regardless of the

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number of times that the beneficiaries receives those drugs within that period. For example, there are situations in which a beneficiary, taking 2 or sometimes three of these drugs, will obtain refills within the month or obtain the next month's supply in the same month that the original prescriptions were dispensed. As we have discussed throughout these comments, it costs suppliers significantly more to process non-adjudicated Part B claims than it does to process an online, real time adjudicated prescription claims.

If the beneficiary comes in at the end of the month for refills, the pharmacy could ask them to come back on the first of the month to obtain their refills so that the pharmacy would receive a full supplying fee. That is because under the current system, the pharmacy would receive no fees for inhalation drugs dispensed at the end of the month for which a fee was already paid earlier in the month. CMS may want to consider establishing a fee for each inhalation drug dispensed, rather than a single fee for a 30-day or 90-day period of time. This is similar to CMS proposal for Part B oral drugs – that is, a separate fee for each inhalation drug prescription, even if it is a prescription for the same drug but a different strength prescribed on the same day.

We are also concerned that, in some cases, the use of HCPCS codes for these drugs rather than NDC codes could underpay pharmacies for certain expensive inhalation drugs. That is because we have limited ability to interchange certain inhalation drugs that may have been prescribed by the physician. For example, CMS was not paying any additional amount for Xopenex (levoalbuterol), which was included in the HCPCS code for albuterol-based products, even though levoalbuterol was a more expensive drug. Thus, the payment amount for levoalbuterol was less than the pharmacy's cost of purchasing the drug. Recognizing this fact, levoalbuterol had been given its own HCPCS code in 2005, but we understand that this drug once again has been placed within the albuterol HCPCS code. This means that we are reimbursed well below the pharmacy's costs since the pharmacy is required to dispense the drug.

The same situation occurs when a physician writes "brand medically necessary" for other inhalation drugs. Branded multiple source drugs are usually included in the HCPCS codes for all versions of the drug, including generics, which drives down the reimbursement amount for this code. The pharmacy may have no choice but to dispense the higher cost brand if that is the desire of the physician, but the pharmacy is still paid at the lower HCPCS rate for that the brand name drug dispensed. The current dispensing fee paid does help compensate for the underpayment of the drug, but that leaves less of the supplying fee to pay pharmacies for the additional costs of processing Part B claims.

Brooks/Eckerd is willing to partner with CMS in the delivery of Part B drugs to Medicare beneficiaries. However, we are concerned with the reimbursement reductions experienced

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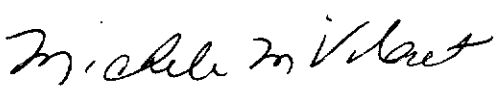
under the ASP-based system, the proposed reductions in the Medicare Part B supplying fees that will be paid in 2006, and the continuing administrative burdens of participating in Part B. We strongly urge that the supplying fees for 2006 be increased from their current levels, not decreased, and that CMS continue to work to enhance administrative efficiencies in the Part B program.

We thank you in advance for your attention to these issues and look forward to your response regarding their resolution. Please feel free to contact me directly with any questions.

Sincerely,



Michele M. Vilaret, R.Ph
Director of Government Programs

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The Cardiology Coalition
4812 Hickory Lake Lane • Matthews, North Carolina 28105
www.CardiologyCoalition.com

September 29, 2005

Mark McClellan, M.D., Ph.D.
Administrator, Centers For Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Mail Stop C4-26-05
Baltimore, MD 21244-8150

Dear Dr. McClellan:

I am writing to ask for your consideration of three substantially under valued services. Each of these services is provided in an effort to diagnose and treat the number one cause of death in our country. As prescribed by the current RVU assignment process, I have illustrated my concerns below by comparison to other medical services that have established relative value units. If more detailed information is necessary please let me know. However, the relative values assigned to these codes are so clearly inappropriate that it is hoped that a streamlined correction process might be implemented.

Diagnostic Heart Catheterization:

From a procedural perspective there are similarities and differences between heart catheterization and renal catheterization. In both situations the doctor advances the catheter to a selective position inside the arteries being studied, injects a contrast agent and interprets the resulting images. In most cases; the equipment utilized, catheterization laboratory and the access site are identical for both procedures.

By all measures, however, there is more skill, risk and work involved when performing a heart catheterization. The coronary arteries catheterized during a heart catheterization are twice as far from the typical access site as the renal arteries. This distance must be navigated with a guide wire and catheter prior to the procedure. Additionally, the coronary arteries are wrapped around the patient's heart which is beating faster than once each second. By comparison, the renal arteries are essentially stationary. During a typical heart catheterization the doctor will also position the catheter inside the patient's heart to perform left ventricular angiography. This work is in addition to the catheterization and angiography of the two coronary arterial families. The end organ involved when performing renal angiography is much less sensitive than the end organ involved when performing a heart catheterization and the doctor is exposed to much more radiation when performing a diagnostic heart catheterization than he/she would be during renal angiography.

Despite the fact that a full left heart catheterization is a more extensive procedure than renal angiography, cardiologists receive approximately 20% more reimbursement for performing renal angiography than they do for performing a full left heart catheterization. The national,

unadjusted Medicare rates for the 2005 calendar year are summarized below. These rates reflect the actual allowed amount for these procedures when performed in a facility setting.

Full Left Heart Catheterization

93510-26 (heart cath)	$257.32
93543 (inject LV)	15.54
93555-26 (S&I LV)	43.96
93545 (inject cors)	21.60
93556-26 (S&I cors)	44.72
TOTAL:	$383.14

Bilateral Renal Angiography

36245 (cath placement)	$253.16
36245-51 (cath placement)	126.58
75724-26 (renal S&I)	79.96
TOTAL:	$459.70

This data strongly suggests that cardiologists are substantially underpaid for heart catheterizations.

Internal Mammary Artery Angiography

When cardiologists visualize the left internal mammary artery during a diagnostic heart catheterization they must first perform a third order selective catheter placement. This is followed by contrast injection and visualization/interpretation of the images. This service, at the time of a heart catheterization, is reported with code 93539. This code generates just $21.60, unadjusted.

This is the exact same service as would be reported by codes 36247 and 75756-26 in the absence of a diagnostic heart catheterization. When these codes are reported, however, the doctor would receive $399.44. As you might notice, this would generate more revenue than the entire heart catheterization procedure discussed in the first concern above.

This information illustrates that arterial conduit angiography during a heart catheterization (93539) is considerably under valued. A similar discrepancy can be realized when looking at the reimbursement rate associated with venous bypass graph angiography (93540).

Multiple Coronary Interventions

Virtually all procedural codes in the current coding structure that are not "modifier 51 exempt" have a 50% "multiple procedure reduction" that applies. In short, a 50% reduction is applied to the lesser service when two procedures are performed at the same time. This presumably adjusts for the economies of scale achieved by the physician.

One exception to this rule is when cardiologists perform multiple coronary interventional procedures (angioplasty, atherectomy or stent placement). In these situations; the doctor will receive full reimbursement for the most intense procedure, which would be reported with code 92982, 92995 or 92980, respectively. The second/third intervention would be reported with the appropriate "additional vessel" code; 92984, 92996 or 92981, respectively. These multiple interventions in the coronary arteries receive a payment reduction of almost 75% when compared to the reimbursement amounts associated with the base vessel codes 92982, 92995 and 92980. These "additional vessel" codes appear to be under valued.

Conclusion

As you can see; these three discrepancies are all clear and substantial. Unrealistically low payment rates, such as these, have had a tremendously negative impact on the field of cardiology and the patients it serves. As a result, many gifted cardiologists have chosen to retire early and many potential candidates have chosen to pursue more lucrative specialties or professions.

I would be happy to share any additional information you need to further illustrate these concerns. These are possibly the most clear cut cases of under valued RVUs you will find. I hope that you realize the need to address this issue and that you will follow up with me as soon as possible.

Thank you for your consideration.

Sincerely,

Jim Collins, CPC, ACS-CA, CHCC

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IN BUSINESS FOR LIFE

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

September 30, 2005

Re: Comments to Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-P)

Dear Dr. McClellan:

Genentech, Inc. is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS') request for comments on the Proposed Rule entitled "Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006," published in the *Federal Register* on August 8, 2005. As you know, Genentech is a leading biotechnology company, headquartered in South San Francisco, California, with products available for serious and life-threatening medical conditions including cancer, asthma, and stroke. Many of our products are administered incident to a physician's service and are covered under Part B of the Medicare program. Hence, we have a sincere interest in ensuring that revisions to Medicare's physician fee schedule payment policies are implemented efficiently and effectively.

Genentech supports policies designed to ensure patient access to life-saving treatments as determined necessary by his or her physician. We remain committed to working with CMS and the provider and patient communities to maintain adequate reimbursement for these therapies and the services performed to administer them. We are concerned that potential decrease in reimbursement rates will have a negative impact on the care available to Medicare beneficiaries. We, therefore, encourage CMS to minimize these decreases, where possible, and allow physicians to choose the most appropriate therapy available while being reimbursed appropriately. Specifically, we urge CMS to adopt the following policy recommendations in the 2006 Physician Fee Schedule Final Rule:

- Eliminate proposal to require reporting, and calculation of price concessions, separately for "direct" and "indirect" sales;

- Provide more detailed definitions of components included in the proposed average sales price (ASP) calculation;

- Revise the existing ASP formula so a product's average ASP is calculated by billing unit [determined by Healthcare Common Procedures Coding System (HCPCS) code], not

National Drug Code (NDC) unit.

- Provide an extended timeframe or "trial period" to allow initial system adjustments and problem identification if proposed changes are implemented;

- Finalize proposal that requires manufacturers to report additional product-specific information;

- Find ways in which to minimize cuts to physician fee schedule payments, including a 4.3% decrease in the conversion factor, removing physician-administered drugs from the Sustainable Growth Rate (SGR) calculation, and continuation and expansion of demonstration projects that improve the quality of care delivered;

- Clarify methodology used by CMS to calculate projected decreases by physician specialty;

- Implement proposal to revise payment for separately billable drugs and biologicals furnished by free-standing end-stage renal disease (ESRD) facilities to be ASP+6%, consistent with payment rates for most other Medicare Part B drugs and biologicals; and

- Expand definition of "interactive telecommunications system" to include a one-way video used to diagnosis patients, particularly those in rural areas, with ischemic stroke in a timely manner.

Proposed Changes to ASP Reporting and Calculation

After performing a comprehensive analysis of the proposed changes to the ASP calculation, we believe that many of the changes will not result in more accurate payments, and will burden manufacturers unnecessarily as extensive revisions to data collection systems will be required. As a result, we recommend CMS does not implement the proposed changes, described in greater detail below, to the ASP methodology.

Reporting of "Direct" and "Indirect" Sales and Calculation of Price Concessions

Since implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), we have spent considerable time and effort developing processes to calculate and report correctly our ASPs. An analysis of our existing systems illustrates that CMS' proposal for manufacturers to report direct and indirect sales as separate components of the ASP calculation is complex and administratively burdensome, with minimal impact expected on the accuracy of ASPs reported. Moreover, in some cases, limitations inherent to the industry's, and our customers', reporting systems may prohibit capturing data at the level of detail required by the Proposed Rule, thereby actually jeopardizing the overall quality of data reported. As CMS indicates in the Proposed Rule that the effect of the new methodology on reported ASPs will depend on the extent to which the ratio of direct and indirect sales in the reporting quarter differs from the ratio of these sales for the 12-month period.[1] Based on our experience, the ratio

[1] 70 *Federal Register* 45843; Published August 8, 2005.

of direct to indirect sales for most manufacturers does not vary greatly among quarters and therefore is unlikely to produce a significant change in amounts reported.

The methodology in the Proposed Rule requires manufacturers to report lagged price concessions over the past 12 months for direct and indirect sales. The ASP calculation currently in use, however, already includes a rolling average of direct and indirect sales from the past 12 months. Therefore, as written, the proposed revision requires manufacturers to (re)-calculate separate price concessions for both direct and indirect sales over the past 12 months. As previously mentioned, the time and resources needed to complete two separate rolling average calculations for direct and indirect sales does not outweigh the minimal benefit anticipated.

Confusion Surrounding Components of ASP Calculation

Clear and concise definitions of the components required to perform pricing calculations are critical to ensure the accuracy of information reported. The Proposed Rule falls short of providing a specific definition of "direct" and "indirect" sales for the purposes of calculating ASP; indirect is defined as "sales to wholesalers, distributor and other similar entities" that sell to others while direct sales are defined as "sales directly from manufacturers to providers, i.e., hospitals or HMOs."[2] As written, these definitions do not encompass many types of sales that may occur in today's market. For example, if a manufacturer sells a Medicare Part B-covered product directly to a specialty pharmacy or home health infusion center, who then distributes the product directly to a Medicare beneficiary, should this sale be considered a direct or indirect sale? Similarly, if a manufacturer sells a Part B product directly to a specialty pharmacy or home health infusion center, who then distributes the product directly to a physician, should this be considered a direct or indirect sale? Finally, if a Part B product is sold only to wholesalers, would all sales to the wholesaler be considered indirect, regardless of to whom the wholesaler ultimately sells the product (i.e., physicians or a specialty pharmacy partner)? Unless CMS provides clarification on how manufacturers should classify the types of sales described above, the definitions' vagueness will cause additional confusion and will compromise the consistency of ASPs reported.

Formula for Determining Weighted Average for ASP Calculation

Genentech previously has notified CMS that the formula it uses to calculate ASP produces flawed results for many products, particularly those products that are available in multiple sizes with multiple NDCs but only one HCPCS code. Specifically, CMS' formula weights the ASP per billing unit by the total number of NDC units sold, *not* the total volume of the billing units sold, resulting in a weighted average ASP per NDC unit instead of a weighted average ASP for each billing code. This discrepancy in CMS' calculation does not allow for a true weighted average ASP for HCPCS codes encompassing multiple NDCs and causes inconsistencies in ASP as a method of reimbursement. Genentech encourages CMS to revise its formula so the average ASP for a product will be calculated by billing unit, not NDC unit.

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[2] *Ibid.*

Additional Time Needed to Implement Proposed Revisions

If CMS elects to pursue the changes described in the Proposed Rule, Genentech asks the Agency, at a minimum, for additional time to revise and update our data collection systems and processes to comply with the changes. We also will need time to review the implemented revisions and to verify our calculations for consistency and accuracy before using them to determine actual ASPs. When the transition from average wholesale price (AWP) to ASP reporting began after passage of the MMA, CMS recognized the importance of conducting a "trial period" with the new methodology to help identify and address initial concerns. We recommend that if CMS moves forward with its proposed revisions, a similar trial period is adopted for at least one full quarter to allow potential problems with the new method to be addressed as well.

Reporting of Additional Product-Specific Information

CMS proposes that beginning January 1, 2006, manufacturers must report wholesale acquisition cost (WAC) on the last day of the reporting period for all single-source drugs or biologicals. In addition to collecting ASP and WAC, CMS also proposes to begin collecting product-specific information such as the product's name, package size (strength, volume per item, and number of items per NDC); expiration date for last lot manufactured; and date the NDC was first marketed or sold, depending on the date of market entry. Genentech supports CMS' proposal to collect this additional product-specific data insofar as the information will help CMS calculate more accurate payments, including a true weighted average of ASPs for HCPCS codes encompassing multiple NDCs.

Reduction in Physician Fee Schedule Payments

Genentech is concerned that significant cuts to Medicare payments for physician administration services may decrease patient access to needed treatments. Specifically, the combination of the estimated 4.3% decrease in the annual conversion factor, the expiration of the transitional adjustment payment mandated by the MMA, the inclusion of physician-administered drugs in the current SGR formula, and the potential termination of the *Improved Quality of Care for Patients Undergoing Chemotherapy* demonstration project, will result in significantly lower payments for 2006 drug administration services than in 2005. The unintended consequence of such decreases may jeopardize Medicare beneficiaries' access to needed care.

Decreases by Physician Specialty

According to CMS' projections, the impact of the reimbursement decreases will vary by specialty. For example, CMS estimates that 2006 Medicare payment for oncology/hematology services will decrease by 5.2%, 5.4% for rheumatology, 5.3% for ophthalmology, and 3.5% for allergy/immunology. CMS also projects, however, that despite the expected decrease in oncology administration services, overall Medicare revenues for this specialty actually will increase by 8.1% if the use of oncology drugs and services increase at a similar rate in 2006 as in the past. Although Genentech supports this end result, it is unclear how CMS calculated the percent decreases, in particular the marketplace assumptions and methodology used to determine its projections.

To help the healthcare community better prepare for the anticipated decreases, the Biotechnology Industry Organization (BIO) requested further information from CMS in a letter dated August 20, 2005.[3] In the absence of a response to BIO's inquiry, we are unable to comment specifically on the projected decreases by physician specialty, and provide detailed suggestions for ways in which CMS can correct any flawed assumptions or calculations. Until a response to BIO's letter is obtained, we recommend that CMS delay any decreases in reimbursement in 2006.

Reforming the Physician SGR Payment System

The Medicare SGR payment formula for physicians has been the subject of significant debate since its development. Recently, Congress has initiated a new effort to discuss reforming the SGR and ensuring more appropriate reimbursement and widespread access to medically necessary physician services.

One of the largest concerns regarding the SGR is the inclusion of Part B drugs and biologicals in the formula. As patient are prescribed and use more physician-administered drugs, physicians overall payment will decrease according to the current SGR methodology. Under the current system, perverse economic incentives exist for physicians to inappropriately change their prescribing patterns to compensate for this reduction. Specifically, physicians may not prescribe injectable or infused drugs even when clinical most appropriate for their patients. In addition, they may prescribe other forms of therapy such as an oral outpatient drug, which may not be as effective as an injectable or infused product. Finally, physicians may feel pressured to move care currently provided in the physician office setting to the hospital outpatient department, which commonly is more expensive.

In order to improve the SGR methodology, Genentech recommends that CMS continue to work closely with providers and other relevant stakeholders to ensure appropriate actions are taken to improve the calculation, and ultimately reimburse physicians adequately and appropriately for care delivered. Genentech supports the position of the House Ways & Means Committee, and the 89 Senators who wrote the Administration to remove Part B covered drugs from the calculation of target spending for physicians under Medicare.

Continuation and Expansion of Demonstration Projects

When Congress drafted the MMA, important consideration was given to ensure significant changes to reimbursement for physician-administered drugs and biologicals and associated services would not negatively impact patient care. One tool CMS frequently employs to test and measure the likely effect of reimbursement changes on the quality of Medicare services provided is the implementation of demonstration projects.

[3] Letter sent from BIO to Herb Kuhn, Director, Center for Medicare Management at CMS, dated August 30, 2005 and entitled "Methodology Used to Calculate Values in Proposed Rule on Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006 (CMS-1502-P)."

Oncology Demonstration Project

CMS initiated a demonstration project in 2005 entitled *Improved Quality of Care for Patients Undergoing Chemotherapy* to measure and improve the quality of care provided to Medicare patients with cancer. By collecting data on three quality-of-life indicators for patients undergoing chemotherapy treatment, CMS has been able to build a database of "real-time" information to measure and better understand the symptoms of patients receiving chemotherapy. Such data will be useful to providers and patients alike to help better understand the quality of care provided to Medicare beneficiaries with cancer, adjust treatment practices as needed, and potentially reduce overall treatment costs.

Due to the widespread adoption and overwhelming support of the Demonstration by the oncology community, including House Resolution 261[4] and a bi-partisan letter signed by 39 Senators[5], Genentech strongly recommends that CMS continue the oncology Demonstration project throughout 2006. In the Proposed Rule, CMS outlines its intentions to continue working with the oncology community to collect data and to improve the care of patients with cancer. Genentech supports CMS' interest in continuing its data collection efforts regarding the relationships between patient-reported symptoms, hospitalizations, and emergency room visits for beneficiaries undergoing cancer treatment.

When developing plans to extend the Demonstration project into 2006, CMS should design the program with similar requirements and administrative responsibilities as in 2005, including the continuation of using the new billing codes specifically created to capture services provided under the demo. By continuing the Demonstration project, and expanding it as necessary, through cooperation with the oncology community, CMS will be able to build upon its baseline data with additional information needed to help answer the questions identified in the Proposed Rule.

Expanding Demonstration Project to Other Physician Specialties like Rheumatology

The success of the *Improved Quality of Care for Patients Undergoing Chemotherapy* demonstration has generated a great deal of interest among other physician specialties such as rheumatology, gastroenterology, urology, and infection disease, who also typically administer drugs and biologicals to beneficiaries under Part B of the program. These specialties recognize the value of data collection to improve the care delivered to all Medicare patients, not just those with cancer. Genentech recommends that CMS expand the current Demonstration project to include non-oncology medical specialists who provide similar services to patients, and for which equally useful quality data can be collected. Specifically, we would like CMS to develop a demonstration project studying the quality of care provided by rheumatologists.

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[4] House Resolution 261 entitled "Expressing the sense of the House of Representatives that the Centers for Medicare & Medicaid Services should be commended for implementing the Medicare demonstration project to assess the quality of care of cancer patients undergoing chemotherapy, and should extend the project, at least through 2006, subject to any appropriate modifications." Introduced by Representative Ralph Hall (R-TX) on May 5, 2005. Accessed at http://www.govtrack.us/congress/bill.xpd.

[5] Details of letter accessed at http://communityoncology.org/Default.aspx?tabid=68&ctl=Details&mid=390&ItemID=188 on August 36, 2005.

Rheumatologists treat Medicare patients with various conditions such as rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis using an infused drug that requires them to manage similar symptoms in their patients as those undergoing chemotherapy. The American College of Rheumatology (ACR) has spent considerable time and effort drafting standard and validated assessment measures to evaluate patient functionality when receiving treatment for the conditions mentioned above. The ACR presented their initial thoughts to CMS in late September and looks forward to working further with the Agency to discuss additional details and administrative necessities involved with creating a parallel demonstration project. By including rheumatologists and other medical specialties in a similarly-styled demonstration project as currently employed for oncology, it will provide valuable data that should improve care provided while reducing both short- and long-term medical costs for patients with rheumatic conditions.

Changes to Payment for Products Provided in ESRD Facilities

CMS proposes to revise payment for separately billable drugs and biologicals furnished by free-standing ESRD facilities to be more consistent with payment rates for most other Medicare Part B drugs and biologicals. Beginning in 2006, CMS proposes to pay for products billed separately from the dialysis composite rate at ASP+ 6% instead of average acquisition price. (CMS proposes to continue payment for separately billable drugs and biologicals administered to dialysis patients in hospital-based facilities on a cost basis.) Genentech supports the Agency's proposal to reimburse separately billable products administered in free-standing ESRD facilities at ASP+6% in order to maintain consistency within the Part B payment system, and because CMS already collects ASP data on a quarterly basis. Moreover, ASP-based reimbursement more accurately captures provider's costs than outdated acquisition data.

In addition to changes in payment for separately billable drugs and biologicals, CMS also proposes a drug add-on adjustment of 8.9% to the dialysis composite rate payment in 2006 for freestanding dialysis facilities. Such an adjustment was mandated in the MMA to help facilities transition from the AWP based payment methodology to a composite rate payment methodology. As such, we support the adjustment to ensure facilities are able to continuing offering important services to patients in need.

recommends that the Agency revise its definition to telehealth services because doing so would increase access to the most favorable treatment options available, particularly for patients residing in rural areas.

CMS outlines some reasons in the Proposed Rule as to why the Agency does not want to change the definition of an interactive telecommunications system. Genentech believes, however, that due to the severity and time-sensitive nature of this condition, the ability for the treating physician to make a timely diagnosis and treatment decision for a patient in need outweighs potential unknowns with the technology. Specifically, the suggested additional clinical value of two-way interactive video compared to a one-way video is not enough in and of itself to justify the unmet clinical need for providing this service in a timely manner. Nonetheless, additional research should be conducted to determine whether the use of a one-way video telecommunications system that permits the physician at the distant site to examine the patient in real-time is clinically adequate for a range of specialty consultations besides stroke, particularly those in which an immediate decision is not paramount to patients' outcomes.

Conclusion

Genentech appreciates the opportunity to comment on the Physician Fee Schedule 2006 Proposed Rule, and urges the Agency to make the policy recommendations described above. We look forward to working with the Agency and all interested stakeholders to ensure payment for administration of drugs and biologicals under Part B of the Medicare program is appropriate and does not compromise beneficiary access to care

Please contact me or Heidi Wagner at (202) 296-7272 if you have any questions about our comments or need additional information.

Sincerely,

Walter Moore
Vice President, Government Affairs

cc: Herb Kuhn, Director, Center for Medicare Management

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September 30, 2005

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Re: Medicare Program; *Revisions to Payment Policies Under the Physician fee Schedule for Calendar Year 2006;* Proposed Rule; 70 *Fed. Reg.* 45,764 (Aug. 8, 2005)

Dear Administrator McClellan:

The Association of American Medical Colleges (AAMC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule concerning *Revisions to Payment Policies Under the Physician fee Schedule for Calendar Year 2006;* Proposed Rule; 70 *Fed. Reg.* 45,764 (Aug. 8, 2005).

The AAMC is a national association representing the 125 accredited U.S. Medical schools, the 16 accredited Canadian medical schools, nearly 90,000 full-time clinical faculty, approximately 400 major teaching hospitals and health systems, 90 academic and professional societies, and the nation's medical students and residents.

Clinical faculty provide a variety of services to Medicare beneficiaries, ranging from primary care to subspecialty care. On a national basis, the median amount of service provided to Medicare patients is 24% of total services across all specialties; there are fifteen specialties for which the median amount of service provided to Medicare patients is greater than 30%. Some individual departments report that as much as 49% of their clinical services are provided to Medicare patients. Further, also on a national basis, the median amount of service provided to Medicaid patients is 16%, compared to just 4% for nonacademic multispecialty group practices. Academic medical centers serve the particularly vulnerable dually eligible Medicare-Medicaid patients as well.

Updates to the Conversion Factor under the Sustainable Growth Rate (SGR) System

Stable and adequate Medicare physician payments are critical to ensure that seniors have continued access to the professional services provided by academic physicians. Nearly one-sixth of all physicians providing Medicare services are academic physicians. Medicare reimbursements to academic physicians represent up to one-third of faculty

practice revenues. In light of the fact that faculty practice revenues, on average, represent about 36% of a medical school's total revenue, unstable Medicare payments could jeopardize beneficiary access to faculty professional services, as well as academic medicine's core missions of medical education, research, clinical services, and community services (including charity care).

The 2006 physician fee schedule proposed rule projects a 4.3% decrease to the conversion factor (CF). Under the current flawed SGR system, this will be the first in a series of reductions that are projected to total approximately 26% over the next six years. The physician community has long commented on problems with the SGR system, particularly the volatile and steep negative updates to the conversion factor resulting from the need to meet expenditure targets. CMS' annual calculations of the Medicare Economic Index (MEI) have identified the MEI to be approximately 3% each of the past several years. However, the CF, even with legislative relief, has not kept pace with this rate of increase in practice related expenses. The impact of the proposed decrease in the 2006 CF, and thus physician payments, is even more disconcerting given CMS' prediction that once again costs to deliver medical care will grow by 2.9%.

AAMC analyses conducted in prior years when the CF was cut dramatically, such as 2002, demonstrated that the vast majority of faculty practice plans stood to lose more than -5.4% of their Medicare revenue (the CY 2002 reduction in the Conversion Factor). In fact, Medicare revenue for some plans was projected to decline by as much as 7.5%. Further analysis of the impact by specialty demonstrated that some specialties, because of the CY 2002 changes in Relative Value Units (RVUs), were projected to experience Medicare revenue declines of 10% or greater. AAMC is concerned that the projected cut of 4.3%, combined with proposed changes to the Practice Expense Relative Value Units (PERVU) will once again have differential and greater impact on faculty practice groups.

Physician practices are also businesses and it is difficult to maintain any business that experiences continuously declining revenue in the face of continuously increasing expenses. Decreasing payments to physicians at a time when costs are increasing places a financial burden on physicians who care for Medicare beneficiaries. This trend could potentially have an adverse impact on beneficiary access to care.

In March 2005, AMA released results of a survey in which physicians were asked whether they plan to make changes to accepting new Medicare patients, or to treating established Medicare patients, if Medicare payments are reduced by 5% in 2006. The AMA report includes the following findings:

Almost 40% of physicians plan to decrease the number of new Medicare patients they accept if Medicare payments are cut by 5% in 2006. Furthermore, almost 20% of physicians say they fear such cuts may force them to reduce the number of established Medicare patients they treat if Medicare payment rates are cut by 5% in 2006.

Physicians were asked whether they plan to make any changes to their practice if Medicare payments are reduced by 5% in 2006 and by 31% in 2006-2013. If Medicare payments are reduced by 5% in 2006, more than half of physicians will make patient care

changes within their practice, including reducing time spent with Medicare patients, increasing the referral of complex cases and ceasing to provide certain services.

In addition, more than half of physicians will not make investments in their practice, including deferring the purchase of new medical equipment and the purchase of information technology. Furthermore, if Medicare payments are reduced by 31% in 2006-2013, more than two-thirds of physicians will make these types of significant patient care changes and cease important investments in their practice. (Source: Member Connect®: Physicians' Reactions to the Projected Medicare Physician Payment Cuts, American Medical Association, Division of Market Research and Analysis. March 2005)

Many academic medical centers (AMCs) and their faculty serve as safety net providers in their community and are committed to providing the best possible care to Medicare beneficiaries. However, the current proposed payment reduction, and the potential impacts noted above, would weaken the financial stability of academic medical centers.

Specifically, as safety net providers, AMCs treat Medicare beneficiaries as both primary and referral providers. If physicians nationally begin to limit their number of new and/or established patients, or begin to refer complex and other types of cases, such patients are likely to be referred to AMCs or other groups that continue to accept Medicare patients. Also, if physicians nationally do not invest in equipment and technology, it is possible that the rate of diffusion of new treatment technologies from academic centers into the community will be slowed, thus also resulting in more patients being treated at AMCs than would otherwise if physicians did not make such choices. If these potential responses by physicians occur, and negative conversion factor updates continue, the financial impact will likely place ever-increasing strain on academic medical centers' ability to fulfill their multiple missions and serve as safety net providers.

As you stated, when the proposed rule was released, "the current system of paying physicians is simply not sustainable." There also has been acknowledgement from Congress and MedPAC that the SGR must be replaced with a new formula that reflects increases in the cost of practicing medicine and provides stable updates. Thus, we urge CMS to take all administrative actions that will facilitate enactment of a new payment methodology by Congress.

- <u>Administrative Actions to Address Issues with the Medicare Physician Payment Formula</u>

The SGR could be adjusted by CMS to take into account many factors beyond physicians' control, including changes due to law and regulation, which promote Medicare spending on physicians' services. The two most notable of these are spending on drugs covered under Part B and changes due to National Coverage Decisions (NCDs).

- <u>Removing Drugs from SGR Calculations</u>

Between the 1996 SGR base year and 2004, the number of drugs included in the SGR pool rose from 363 to 444. Further, actual spending on physician-administered drugs rose from

$1.8 billion to $8.7 billion, an increase of 365% per beneficiary, compared to an increase of only 63% per beneficiary for actual physicians' services. As a result, drugs have consumed an ever-increasing share of SGR dollars and have gone from 3.7% of the total in 1996 to 10% in 2004.

Ideally, a permanent solution to the SGR problems will be achieved by the combined efforts of CMS, Congress and the physician community. Unfortunately, congressional relief alone will result in costs that will be significant and perhaps prohibitive. However, if the Administration exercises its authority to assist with achieving this goal, a solution may be more readily adopted.

The physician community believes that CMS has the authority to make administrative changes to its calculation of the formula that would lower the cost for Congress to enact a new Part B payment methodology by retroactively removing the costs of drugs and accounting for NCDs.

Members of Congress share this opinion. House Ways and Means Chairman Thomas and Health Subcommittee Chairman Johnson, as well as Senate Finance Chairman Grassley, Ranking Member Baucus (and 87 additional Senators) recently sent written correspondence to CMS and to OMB Director Bolton, respectively, requesting that increases in Medicare spending due to physician-administered drugs be removed retroactively from calculations of the SGR. Chairmen Thomas and Johnson also requested that steps be taken to ensure that the SGR accurately reflects spending increases due to such matters as expanded Medicare benefits and national coverage decisions.

The AAMC encourages CMS to use its administrative authority to remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996, for the 2006 physician fee schedule rule. Removing drugs will significantly reduce the cost of legislation to address the projected Medicare pay cuts. Earlier this year CMS indicated to Congress that removing drugs prospectively is worth about $36 billion, while removing them from the base-year forward is worth $111 billion.

- Impact of Expanded Benefits and National Coverage Decisions

Congress and CMS have initiated a variety of changes to the Medicare program which are very beneficial to patients and can assist with improving the health status of America's seniors. However, as discussed above relative to coverage of drugs under Part B, these changes will also result in greater use of physician and other services covered under Part B, which will ultimately penalize physicians under the current SGR methodology. Although the impact of the increased expenditures could be removed from the SGR expenditure target, they often are not adequately accounted for and removed from the SGR calculations.

Under the MMA several new benefits became effective on January 1, 2005. Some of these benefits included such things as: initial preventive physical examinations; diabetes

screening tests; cardiovascular screening blood tests; coverage of routine costs of Category A clinical trials; and additional ESRD codes on the list of telehealth services. These services will result in increased spending due to increased physician office visits and related medically necessary services such as laboratory tests to monitor or treat chronic conditions that will now be identified. CMS has not provided details of how these estimates were calculated, and certain questions remain. Further, CMS should examine past experience with out-year increases of new benefits when projecting expenditures due to MMA enactment. Specifically, BBA-related changes, including pelvic and breast exams to screen for breast or cervical cancer were still increasing at a rate of about 10% a few years after implementation, as were colorectal cancer screenings of high-risk patients. These impacts should be taken into account in revising the 2005 and 2006 SGR.

Practice Expense Relative Value Units

The proposed rule includes CMS' plan to revise the current methodology for establishing practice expense relative value units (PE RVUs) for physicians' services. The proposed rule states that the new methodology and its impact on some PE RVUs, could cause financial burden on medical practices, especially in combination with projected Medicare physician pay cuts. CMS, therefore, is proposing a four-year phase-in of the new PE RVUs, beginning in 2006. CMS has identified that the new methodology will cause largest increases of PE RVUs for the specialties of dermatology, urology, radiation oncology, gastroenterology, pathology, and physical therapy while anesthesiology, neurosurgery, cardiac surgery, thoracic surgery, ophthalmology, rheumatology and some non-physician practitioners face the steepest cuts.

As mentioned above, AAMC data analyses indicate that there are fifteen specialties for which the median amount of service provided to Medicare patients by faculty practice groups is greater than 30%. Initial analyses by AAMC of the impact of the proposed CF update of –4.3% and PE RVU changes indicate that the decrease in revenue across faculty practice groups will exceed –6%. This results from the type and mix of services that are typically provided by academic medical centers.

The significant impact of the changes in PE RVUs under this proposal warrants further consideration and review by the medical community and CMS. Review could include CMS' publication of: examples of how the new values were calculated, the actual new practice expense values for each code (in addition to the values for the first year of the transition included in the proposed rule); the practice expense per hour and source of the data for each specialty, and the budget neutrality adjuster applied as a final step to the calculations.

Supervisory Anesthesiologists in a Teaching Setting

The AAMC encourages CMS to revise Medicare policy to allow supervising anesthesiologists in a teaching setting to be paid 100% of Medicare payment when supervising two concurrent resident cases, similar to payment for teaching physicians involved in two overlapping surgeries. Establishment of payment parity among

anesthesiologists and surgeons under the Medicare program will assist with continuing to provide adequate access to services for Medicare patients.

Multiple Imaging Procedure Reduction

The AAMC encourages CMS to reconsider its position on applying multiple imaging procedure payment reductions. If CMS does apply reductions as the proposed rule indicates, AAMC recommends that savings from any new policies related to multiple imaging procedure reductions be applied to practice expense relative values only, rather than to all relative values. Physician work relative values should be maintained and remain stable and thus should not be subject to budget neutrality adjustments.

Quality

On page 308 of the proposed rule, CMS requests comments "that build on recent progress on payment reforms to promote higher quality and avoid unnecessary costs, and that are consistent with the President's budgetary goal of paying for better value in Medicare without increasing overall Medicare costs." Previous AAMC testimony to PPAC noted that AAMC supports the CMS quality agenda for both physicians and hospitals. All AAMC Council of Teaching Hospital and Health System members that were eligible to submit data for COMPARE quality reporting did so. Several AMCs are actively involved in current CMS quality demonstration projects including the Physician Group Practice and Care Management for High Cost Beneficiaries demonstration projects.

AAMC has also advocated, as have several other physician organizations, that physician pay-for-performance programs need to be based upon clear design principles and goals for which there is broad agreement. AAMC believes that key among these are:

- Improved quality of care and safety should be the primary objective of initiatives. It is well recognized that improved quality and implementation of some preventive measures can decrease health care utilization and thus also decrease costs in the long-run. However, improved quality and safety should be the primary objective of activities.

- Performance measures must be evidence-based, broadly accepted, clinically relevant, continually updated and developed with the physician community.

- Data must be fully adjusted for case-mix, sample size, age/sex distribution, severity of illness, number of co-morbidities, and patient population characteristics that may influence results.

- Fair and accurate models for attributing care when multiple physicians treat patients must be implemented.

- Initiatives need to be flexible enough to assess performance at both the individual level or the group level, as appropriate.

- Physicians must have the ability to review and correct performance data.

- Quantity of Measures

In addition, the implementation of quality programs should be fair and equitable to all physician specialties and groups, without placing additional undue administrative burdens on a particular specialty or practice type. As CMS, specialty societies, and quality consensus building organizations examine multiple measures for different specialties, CMS should consider the feasibility of implementing large numbers of multiple measures simultaneously or at a rapid pace.

Specifically, current and foreseeable Medicare reimbursement systems will pay physicians on a service code level basis. CMS needs to be mindful of the potential unintended negative consequences of implementing pay-for-performance systems on a service code basis, whether for actual discrete payments or for metrics factored into overall payments. CMS appears to recognize that such an approach could lead to inequitable payment among specialists, and thus has initiated work to gather measures from all specialties.

However, if multiple performance measures are implemented for multiple specialties simultaneously, physicians/physician groups might have to report on all relevant performance measures to be eligible for payment and recognition. This could result in an abruptly increased administrative burden on multispecialty group practices.

AAMC data show that the median number of clinical departments and physicians at AMCs are 16 and 500 respectively and thus AMCs have physicians in essentially all specialties. Depending upon the structure of a performance improvement system, AMCs could be required to implement *all* measures. Compared to single specialty practices, large multispecialty practices would need incrementally more resources to implement, track and validate a large number of measures.

Although such practices may have information technology resources to assist with quality improvement efforts, current information technology (IT) alone cannot produce quality improvement. Quality improvement efforts also require workflow redesign for physicians and support staff, organizational system redesign, and often, IT system modifications. Despite recent increases in electronic health record systems on the market, these systems are exactly that–electronic health record systems–and do not necessarily include the functionality of ready-to use patient registries, a key building block to population management and quality improvement.

Thus, we believe that CMS needs to consider carefully its implementation of pay-for-performance (or reporting) programs with respect to the volume of measures required to be eligible for recognition and/or payment. Most private payers implementing pay-for-performance programs have begun with a modest number of measures and increased them steadily over time. Even the current Medicare PGP demonstration project is phasing in measures for one disease state per year. Again, AAMC strongly encourages the adoption of quality standards, but requests that CMS use it's administrative authority to ensure that

quality programs are designed in a flexible manner to accommodate the many structures of physician practices and groups.

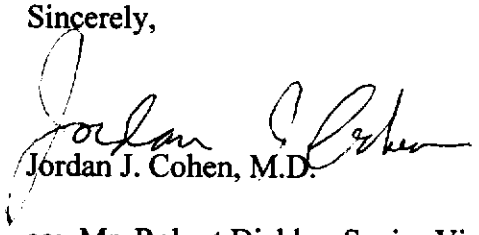
- Attribution of Care

Careful consideration needs to be given to the methodology used to attribute care to individual physicians or groups when more than one physician/group treats a patient. This is an issue that CMS and participants in the Physician Group Practice demonstration have strived to address in order to utilize an attribution model that is fair, can be implemented, and is consistent with patient care practices and preferences.

A patient may be followed by more than one provider, both of whom have accountability around one disease state or who have distinct accountability around separate disease states. If a primary care physician and a consulting endocrinologist do not share or have access to treatment history and results for a patient with diabetes, duplicative services could be provided. An unwanted result could be that a patient receives more than the medically-necessary number of foot or eye exams each year or undergoes duplicate lab tests. An equally unwanted result could be that a patient does not receive an indicated test because one provider assumed or was erroneously told that it was arranged. In either circumstance, these examples highlight the need for correct attribution of responsibility and delivery of care.

AAMC appreciates the opportunity to comment on the Medicare Program, Revisions to Payment Policies Under the Physician fee Schedule for Calendar Year 2006, Proposed Rule. We would be pleased to provide clarification or additional comments. Please contact me or Mr. Robert Dickler or Ms. Denise Dodero at (202) 828-0490.

Sincerely,



Jordan J. Cohen, M.D.

cc: Mr. Robert Dickler, Senior Vice President
Ms. Denise Dodero, Associate Vice President

(FORM LETTER #1)
942
Received 1616

Date: 8/30/05

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Attention: CMS-1502-P
PO Box 8017
Baltimore, MD 21244-8017

Re: GPCIs

I understand that Medicare is proposing to create a new payment locality for Sonoma County, which is an increasingly expensive place to live and work. In the new locality, the Medicare reimbursement rate would be more closely matched to actual practice expenses than it is now.

The new locality would help Sonoma County physicians improve the quantity and quality of care they deliver to Medicare beneficiaries and other patients. The locality change would also benefit efforts to recruit and retain physicians in the county, which has a large Medicare population.

I fully support your proposal to change Sonoma County's payment locality, and I appreciate the opportunity to comment on this important issue.

Sincerely,

Bennett Wren

Name: Bennett Wren
Address: 104 Plumeria Court
City, State, ZIP Cloverdale CA. 95425

cc: Two copies attached

943
(FORM LETTER #2)
Received 4655

Date: 8-25-05

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
PO Box 8017
Baltimore, MD 21244-8017

Re: GPCIs

I am a Medicare beneficiary who receives medical care from a physician in Sonoma County, California. I understand that Medicare is proposing to create a new payment locality for Sonoma County, which is an increasingly expensive place to live and work. In the new locality, the Medicare reimbursement rate would be more closely matched to actual practice expenses than it is now.

The new locality would help Sonoma County physicians improve the quantity and quality of care they deliver to me and other Medicare beneficiaries. The locality change would also benefit efforts to recruit and retain physicians in the county, which has a large Medicare population.

I fully support your proposal to change Sonoma County's payment locality, and I appreciate the opportunity to comment on this important issue.

Sincerely,

Name: Edith Drew
Address: 798 Corona Rd
City, State, ZIP Petaluma, Calif. 94954

cc: Two copies attached.

944
(FORM LETTER #3)
Recieved 345

Date: AUG. 25, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
PO Box 8017
Baltimore, MD 21244-8017

Re: GPCIs

As a physician practicing medicine in Sonoma County, California, I strongly support your proposal to create a new payment locality for Sonoma County. The new locality would lessen the disparity between practice expenses and Medicare reimbursements.

This disparity has adversely affected our local health care system for several years. In many cases, Medicare reimbursements don't cover expenses, and a significant number of local physicians have stopped taking Medicare patients or have simply left the county. The disparity has also hampered efforts to recruit new physicians to Sonoma County.

By creating a new payment locality for Sonoma County, you will help ensure the viability of physician practices in the county and will improve access to care for local Medicare beneficiaries. Your proposal will correct existing payment inequities and will help you achieve your goal of reimbursing physicians based on the cost of practice in their locality.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Name: RALPH P. HOYAL
Office Address: 1041 FOURTH ST.
City, State, ZIP SANTA ROSA, CA 95404

945
(FORM LETTER #4
Received 195

Paul, Susan
122 Library Lane
Santa Cruz, Ca 95062

August 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

RE: File Code CMS-1502-P
Issue Identifier: GPCI's/ Payment localities

I am writing to comment on the proposed rules governing physician fee schedule for calendar year 2006 published in the Federal Register this summer. I **strongly support** the proposed rules changes regarding physician payment locality revisions in California involving Santa Cruz and Sonoma Counties because they correct inadequacies in reimbursement to these two counties, both of which currently remain in Locality 99 even though their GAF's have exceeded the 5% threshold(105% rule) over the national 1.000 average.

In particular, the County of Santa Cruz, when broken out from Locality 99, would otherwise reflect a 1.125% GAF. The boundary payment difference between Santa Cruz and its neighboring County of Santa Clara(Locality 9) is a whopping 25.1% for the same medical service. The status quo is unfair and discriminatory to the citizens of Santa Cruz.

Access to medical care suffers because Santa Cruz remains in Locality 99. The imbalance between physician reimbursement and geographic practice costs has many serious health consequences for us. Physicians are leaving the area, retiring early or moving away. It is difficult to recruit new physicians to replace those who die, retire, or relocate. Those new physicians who do come here usually stay only 1-2 years before moving to other parts of the state or country where they can afford to live and work. Medicare recipients then have immense difficulty finding new doctors because few primary care physicians can afford to take on new Medicare patients. When patients do not have primary care doctors, they have to use our overcrowded emergency rooms for primary care. Many more patients are admitted to the hospital for acute and severe medical diseases that might have been prevented or managed as outpatients. Furthermore, sometimes critically ill patients must be transported out of our county altogether because the hospitals do not have the necessary medical specialists on staff for emergencies.

During my working career, I have paid all required taxes, and as a citizen living in Santa Cruz County, I deserve the same access to quality health care as those residents of Santa Clara. I vigorously applaud CMS in taking action now to correct this unfair situation, which has existed far too long. Placing Santa Cruz in a separate Locality with physician reimbursements appropriate to the current geographic practice costs is the right thing to do.

Thank you for your efforts to create an equitable solution in 2006.

Sincerely yours,

Claire Paul

946
(FORM LETTER #5)
Received 146

August 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: File Code CMS1502-P - Issue Identifier: GPCIs / Payment Localities

To whom it may concern:

I am writing to strongly support your proposed revision to physician payment localities in California recently published in the referenced rule. The great difference between the cost of medical practice in Santa Cruz County as measured by GAF cost values and the low rate of reimbursement due to being assigned to Locality 99 has made recruitment and retention of physicians willing to serve Medicare beneficiaries very difficult.

We were pleased to see that your proposed rule would alleviate this problem by removing Santa Cruz and Sonoma Counties from Locality 99 and placing them into unique localities. We laud your efforts to rectify this long-standing inequity. Your proposal will be of great help in ensuring access to necessary health care services. The proposed rule is fair. Neighboring counties to Santa Cruz and Sonoma have some of the highest payment levels for physicians in the nation. The adjustment you propose appropriately addresses this payment imbalance. This revision would bring you closer to your goal of reimbursing physicians based on the cost of practice in their locality.

Sincerely,

E. Brown

Edie Brown, RN, MPH

947

(FORM LETTER #6

Received 509

Date 8/21/05

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: File Code CMS 1502-P

Issue Identifier: GPCI's/Payment Localities

Dear Sirs,

I strongly support your proposed change to the physician payment localities in California, which is stated on page 92 in your recently published Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006. This refers to your proposal to move Santa Cruz and Sonoma Counties from Locality 99 to their own unique localities. As you know, the cost of medical practice here in Santa Cruz county is more than 10% above the average cost of medical practice in Locality 99. Because of the relatively low rate of Medicare reimbursement, it is difficult to recruit new physicians and to retain established physicians in this area. Especially since our neighbor, Santa Clara county, has a 24% higher reimbursement rate for the same medical services, luring physicians to move to that area. Your proposed change appropriately addresses this payment imbalance and will help develop an adequate physician base in our area. This will improve access to health care services for all people, especially the senior population. I applaud your recommendation to correct this long-standing inequity.

Sincerely,

Mrs. Barbara O. Reed
360 Blackstone Dr.
Boulder Creek, CA 95006

948
(FORM LETTER #7)
Received 79

To:
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1502-P
PO Box 8017
Baltimore, MD 21244-8017

re: GPCI
Geographical Price Cost Index

To Whom It May Concern:

This letter is to strongly urge you to support the change proposed administrative change regarding the Geographical Price Cost Index for Santa Cruz and Sonoma Counties.

Santa Cruz County is designated a rural county and the physicians here receive payments that are considerably lower than our neighboring counties that are designated urban. However, Santa Cruz County is one of the most expensive places to live in the state and in the whole country.

The local medical providers have found it increasingly difficult to attract and retain qualified physicians due to the lower Medicare reimbursement rate and the high costs of living in this county. We are experiencing a crisis of not enough Medicare-assigned physicians in the area.

Again, please support this proposal, as it would make a huge difference to the Medicare beneficiaries in these areas.

Sincerely,

Signature Kathryn A. Huckaby 8/27/05

Name Kathryn A. Huckaby

Address with zip 241 Forest Ave
Santa Cruz, CA 95062

949

(FORM LETTER #8)

Received 89

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: GPCI

To Whom It May Concern:

We strongly support the proposed revision to the physician payment localities in California that you published in the reference rule.

You are to be commended for addressing an important issue for physicians and Medicare beneficiaries in the San Francisco Bay Area. You have addressed the two most problematic counties in the state, and you have made an important change that will go a long way to ensuring access to care for health care services in our county.

We understand this also to be a fundamental issue of fairness. Neighboring counties to Santa Cruz and Sonoma Counties have some of the highest payment levels for physician services in the nation. The adjustment that you propose appropriately addresses the current inequitable payment problem.

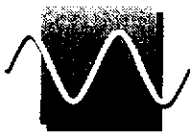
CMS acknowledges that they have the responsibility to manage physician payment localities. We understand that there have been not been revisions to the localities since 1996. You have selected the most important area in our state to begin to correct this problem.

Sincerely,

Christine M Lean PCT
Satellite Dialysis
40 Penny Ln #1
Watsonville CA 95076

950
(FORM LETTER #9)
Received 25

PACIFIC HEARING SERVICE



September 2, 2005

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

Re: CMS-1502-P

Dear Dr. McClellan:

As an audiologist, I am writing to express my concern about the Centers for Medicare & Medicaid Services' (CMS) proposed Medicare Physician Fee Schedule, which would reduce Medicare reimbursement for audiology services by as much as 21 percent over a four-year period beginning in 2006. No other specialty is as dramatically affected by the proposed elimination of the non-physician work pool (NPWP) and the new methodology to calculate the practice expense relative value units. Simply stated, audiologists may not be able to continue to offer services to Medicare beneficiaries unless CMS develops an equitable reimbursement rate for these services.

Adequate and fair reimbursement rates for audiology services are essential for covering the expenses audiologists incur in performing hearing and vestibular services for Medicare beneficiaries. Hearing loss is a common malady of the aging population. As the lifespan of America's seniors increases, a greater need for audiology services will develop. For these Medicare patients, the benefits of having qualified and licensed audiologists who are trained to evaluate and care for them are immeasurable.

I respectfully request that you work with the audiology community and the American Academy of Audiology to develop solutions to address the negative impact of the elimination of the non-physician work pool. Working together, we can develop a fair and equitable reimbursement rate for audiology procedures and ensure Medicare beneficiaries' access to these vital services.

Thank you for your consideration.

Respectfully,

Jennifer Fargo Lathrop

Jennifer Fargo Lathrop, M.A., Audiologist

Cc: Mr. Herb Kuhn, Director, Center for Medicare Management

Jennifer Fargo Lathrop, M.A., FAAA • Jane H. Baxter, M.S., FAAA
Board Certified in Audiology
496 First Street, Suite 120 • Los Altos, CA 94022 • (650) 941-0664
3351 El Camino Real, Suite 100 • Atherton, CA 94027 • (650) 366-9605

951
(FORM LETTER #10)
Received 349

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

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare and Medicaid Services (CMS) to change the Medicare anesthesiology teaching payment policy.

Medicare's discriminatory payment arrangement, which applies only to anesthesiology teaching programs, has had a serious detrimental impact on the ability of programs to retain skilled faculty and to train the new anesthesiologists necessary to help alleviate the widely-acknowledged shortage of anesthesia providers -- a shortage that will be exacerbated in coming years by the aging of the baby boom generation and their need for surgical services.

Under current Medicare regulations, teaching surgeons and even internists are permitted to work with residents on overlapping cases and receive full payment so long as the teacher is present for critical or key portions of the procedure. Teaching surgeons may bill Medicare for full reimbursement for each of the two procedures in which he or she is involved. An internist my supervise residents in four overlapping office visits and collect 100% of the fee when certain requirements are met.

Teaching anesthesiologists are also permitted to work with residents on overlapping cases so long as they are present for critical or key portions of the procedure. However, unlike teaching surgeons and internists, since 1995 the teaching anesthesiologists who work with residents on overlapping cases face a discriminatory payment penalty for each case. The Medicare payment for each case is reduced 50%. This penalty is not fair, and it is not reasonable.

Correcting this inequity will go a long way toward assuring the application of Medicare's teaching payment rules consistently across medical specialties and toward assuring that anesthesiology teaching is reimbursed on par with other teaching physicians.

Please end the anesthesiology teaching payment penalty.

Name Dr Mara Matuszczak (Matuszczak)

Address 2248 Colquitt
Houston TX 77098

952
(FORM LETTER #11)
Received 8

August 10, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Colleagues,

It has come to my attention that Medicare is considering changing the teaching physician policy for anesthesiologists. As a member of the American Association of Nurse Anesthetists (AANA), I have significant concerns with any changes that would create further inequities in how the Medicare system treats teaching Certified Registered Nurse Anesthetists (CRNAs) and anesthesiologists, and, more importantly, present possible negative impacts on Medicare beneficiaries' access to safe anesthesia care.

CMS has already twice rejected a proposal to change the anesthesia teaching rules so that teaching anesthesiologists would be paid a full fee for each of two overlapping cases involving medical residents, a manner similar to certain teaching surgeons. Such a proposal provides major new incentives to teach anesthesiology residents, and severe disincentives to teach nurse anesthetists, and is not based on a consensus process that treats both nurse anesthetists and anesthesiologists equally.

I appreciate that Medicare is considering its options on this important policy issue. Nurse anesthesia is a success story. With anesthesia 50 times safer than 20 years ago, CRNAs' patient safety record is shown to be indistinguishable from that of physicians providing anesthesia. CRNAs assure patients access to safe anesthesia care, and predominate in rural and medically underserved America and the Armed Forces. Further, it has been shown CRNAs are educated more cost-effectively than are our colleagues and competitors. Yet, while Medicare Direct GME payments to residents and medical direction payment rules already discriminate against educating CRNAs, the nurse anesthesia profession has been successful at increasing the number of accredited educational programs and graduates to meet growing demand for safe anesthesia care for patients. Thus, changing the anesthesia teaching rules to further dramatically favor one type of anesthesia provider over another creates negative impacts against educating safe anesthesia providers such as CRNAs, harming the healthcare system and patients' access to healthcare services.

So that patients anywhere in the country will continue to have access to the safe anesthesia care that they need, I am requesting that CMS work with both nurse anesthetists and anesthesiologists in developing a consensus proposal to address issues in the anesthesia teaching rules.

Sincerely,

Melanie Bigler
Signature

Print name: MELANIE BIGLER

Street address:

City/State/ Zip: HOT SPRINGS AR

953
(Form Letter #12)

OPPOSITION to File Code CMS-1502-P
Medicare Payment Localities – "Rest of California"

Received 155

August/September, 2005

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P. O. Box 8017
Baltimore, MD 21244-8017

To Whom It May Concern:

I am a Medicare beneficiary who receives care from a knowledgeable and dedicated physician. I understand that the Proposed Rule CMS-1502-P will remove Santa Cruz and Sonoma counties from Medicare's payment Locality 99 in California, at the expense of the remaining Locality 99 counties, including my own county, Monterey.

My physician will be expected to take yet another cut in Medicare reimbursement, putting my continued care in jeopardy. I'm worried that my physician may decide to stop seeing Medicare patients altogether.

There is no doubt that the Medicare system needs to be fixed and that the physician payment formula needs to be improved, but you're not solving any problems by this piecemeal approach. In fact, you're jeopardizing the continued participation of your current Medicare providers in the remaining Locality 99 counties.

I appreciate your consideration of my opposition to CMS-1502-P.

Sincerely,

Signature: Florence W. Ferriss
Name: Florence W. Ferriss
Address: 9335 Holly Oak Way
Salinas, Ca. 93907

954

Form letter #13 (TA)

Received 11

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Department of Anesthesiology and Critical Care

August 29, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

RE: Teaching Anesthesiologists

To Whom It May Concern:

I am writing in reference to the current Medicare teaching anesthesiologist's payment rule, which is unwise, unfair, and unsustainable. Quality medical care, patient safety, and an increasingly elderly Medicare population demand that the United States has a stable and growing pool of physicians trained in anesthesiology. There is a national priority on reducing surgical complications by 25% over the next five years. Many of these strategies involve anesthesiologists, both in the operating room and outside of the operating room. They require subspecialty trained physicians, including intensivists, who are exclusively derived from the physician pool. Additionally, chronic pain is increasingly common in the Medicare population, and anesthesiology is one of the primary routes by which physicians are further trained in pain management.

Currently, slots in anesthesiology resident programs are going unfilled because of an ill-conceived Medicare policy that shortchanges teaching programs, withholding 50% of their funds for concurrent cases. The Department of Anesthesiology and Critical Care at the University of Pennsylvania School of Medicine currently trains 72 residents and approximately 10 additional fellows in critical care, chronic pain management, and cardiovascular anesthesiology. We have a faculty of over 62 physicians, with several faculty openings.

As outlined above, the Medicare teaching anesthesiologist rule significantly impacts our academic departments and their ability to sustain economic viability. This has driven most research and advancement out of the academic departments. As the Institute of Medicine report has recently emphasized, anesthesiology is a field which has shown the greatest improvement in patient safety. As CMS is well aware, quality of care is usually cost effective, and although adverse intraoperative events directly attributable to anesthesiology have decreased, anesthesiologists continue to perform research which would effect the entire perioperative continuum and decrease overall complication rates, including such interventions as appropriate antibiotic timing, perioperative glucose control, and numerous interventions to reduce pulmonary complications. Again, many of these strategies are targeted to the highest risk and most vulnerable patients who seek teaching hospitals as the most appropriate venue for care. Therefore, this arbitrary Medicare payment reduction, which is not in line

3400 Spruce Street • Philadelphia, PA 19104-4283

with the surgical fee schedule (in which the surgeon receives 100% of the fee for each case in Medicare), will lead to stagnation in perioperative advancements which could improve patient care and theoretically reduce overall healthcare costs.

CMS must recognize the unique delivery of anesthesia care, and pay Medicare teaching anesthesiologists on par with their surgical colleagues. The Medicare anesthesia conversion factor is less than 40% of prevailing commercial rates. Reducing that by 50% for teaching anesthesiologists results in revenue grossly inadequate to sustain the service, teaching, and research missions of academic anesthesia training programs. The net result will be a reduction in advancements in quality of care that have been the hallmark of academic anesthesia during the last 50 years. If you have any questions, please feel free to contact me.

Sincerely,

John G. Augoustides, M.D.
Assistant Professor of Anesthesia

JGA/irk

3400 Spruce Street • Philadelphia, PA 19104-4283

955

Form Letter #14 (GPCI)

Received 26

August 15, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P. O. Box 8017
Baltimore, MD 21244-8017

Re. File Code CMS1502-P

Issue Identifier: GPCI's / Payment Localities

Dear Sirs:

I am writing on behalf of Santa Cruz Orthopaedic Institute, Drs. Nicholas A. Abidi and Peter M. Reynolds, to strongly support your proposed revision to physician payment localities in California recently published in the reference rule. Our organization has previously written to express our concern about the viability of the health care system which serves our residents. The great difference between the cost of medical practice in Santa Cruz County as measured by GAF cost values and the low rate of reimbursement due to being assigned to Locality 99 has made recruitment and retention of physicians willing to serve Medicare beneficiaries very difficult.

We were pleased to see that your proposed rule would alleviate this problem by removing Santa Cruz and Sonoma Counties from Locality 99 and placing them into unique localities. We applaud your efforts to rectify this long-standing inequity. Your proposal will of great help in ensuring access to necessary health care services. The proposed rule is fair.

Neighboring counties to Santa Cruz and Sonoma have some of the highest payment levels for physicians in the nation. The adjustment you propose appropriately addresses this payment imbalance. This revision would bring you closer to your goal of reimbursing physicians based on the cost of practice in their locality.

Sincerely,

Cheryl Tuesenberg

Name: _____

Address: 210 Rolofson
Santa Cruz, CA 95060

956

Form letter # 15(GPCI)

Received 4/7

P. O. Box 8017
Baltimore, MD 21244-8017

Re. File Code CMS1502-P

Issue Identifier: GPCI / Payment Localities

8-11-05

Dear Sirs:

I am writing on behalf of the citizens of Santa Cruz County, California, regarding revision of Physician payment localities published in the reference rule. We have written to you previously regarding our concerns that under-reimbursement of physicians in our county places our residents in jeopardy of experiencing a deterioration of our health care system. We believe that your proposed revision of payment localities would address those concerns and we laud your efforts at rectifying the current damaging situation. Your proposal would make an important change that would substantially help in ensuring access to health care services in our county.

We understand this to be a fundamental issue of fairness. Neighboring counties to Santa Cruz and Sonoma have some of the highest payment localities in the nation. The adjustment you propose is appropriate and fair in achieving your goal of reimbursing physicians based on the cost of practice in their locality.

Sincerely ,

Laurey Shumaker
831 335-0125

Laurey Shumaker
550 Water St
Santa Cruz, CA 95060

957

Form letter #16 (GPC

Received 98

Date: SEPT 26/05

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore MD 21244-8017

Re: File Code CMS1502-P

Issue Identifier: GPCI's / Payment Localities

Dear CMS Staff:

I am writing to strongly support the proposed revision to physician payment localities in California that you published earlier this month. I hope that you adopt this rule as final in November. As an employee of Dominican Hospital, I am very concerned that as our physicians age and retire, we as a community are able to attract new physicians to take their place. I have followed the issues surrounding the inclusion of Santa Cruz County within Locality 99 for California and welcome the opportunity to support your proposed solution to the current inequitable payment policy. I believe adoption of your proposed rule will go a long way to ensuring ongoing access to high quality care for community residents.

As you know, physicians in Santa Cruz receive reimbursement at levels 25% less than physicians in two of our neighboring counties. Current payments are about 10% less than they should be, given the county's current GAF. They do not reflect the high cost of practice in our community.

You are to be commended for proposing a rule that would address this problem for physicians in Santa Cruz and Sonoma Counties, the two most problematic counties in California. I believe this to be fair and appropriate. Thank you for considering my comments.

Sincerely,

Name: Mary-Pat Pumfrey

Address: 8695 Empire Grade
Santa Cruz CA 9506

958

Form letter #17

Received 7

Cardiovascular Care

MICHAEL H. GOLDMAN, M.D., F.A.C.C.

1635 NORTH GEORGE MASON DRIVE
SUITE 150
ARLINGTON, VIRGINIA 22205

3028 JAVIER ROAD
SUITE 500
FAIRFAX, VIRGINIA 22031

TELEPHONE (703) 698-5556

FACSIMILE (703) 807-0082

September 21, 2005

1

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: File Code CMS-1502-P

Proposed Centers for Medicare and Medicaid Services ("CMS") rule for the Medicare Program regarding Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 – NUCLEAR MEDICINE SERVICES

Dear Administrator McClellan:

I am a cardiologist in private practice and wish to comment specifically on that part of the proposed rule that would reclassify nuclear medicine services as Designated Health Services (DHS) for purposes of the Stark physician self-referral law. I am concerned that this proposal would unfairly penalize those physicians who have invested in entities providing such services in reliance upon the statute and CMS' prior interpretation of the statute. I further believe that this proposed rule would significantly limit beneficiary access to nuclear services particularly in rural areas. I request that this proposed change not be included in the final rule on the grounds that Congress did not intend for the physician self-referral law to apply to nuclear medicine services and that nuclear medicine is a distinct and separate field from radiology. In the event that CMS reclassifies nuclear medicine services as DHS, I further respectfully request that the final rule should grandfather prior ownership arrangements entered into in good-faith based on the existing regulations.

It is clear from the statutory text, legislative history, and CMS's own long-standing interpretation of the physician self-referral law that nuclear medicine was not intended to be included in the definition of DHS. Section 1877(h)(6) of the Social Security Act specifically includes only the following services as DHS:

> *clinical laboratory services; physical therapy services; occupational therapy services; radiology services, radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics,*

orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.[1]

Congress further specifically defines radiology services as: "***magnetic resonance imaging, computerized axial tomography, and ultrasound services.***"

As nuclear medicine is not in the statute as a DHS, CMS would need to determine that nuclear medicine is encompassed in one of the congressionally enumerated categories of DHS. CMS proposes to accomplish this by re-designating nuclear medicine procedures under what it calls "*radiology and certain other imaging services.*"[2] This proposal is beyond the scope of the statutory language.

Importantly, the words *"certain other imaging services"* do not even appear in Section 1877(h)(6) and, in fact, Congress previously rejected statutory phrasing virtually identical to language in the proposed rule. The original statutory provision included the extremely broad category "*radiology, and other diagnostic services*" as DHS in Section 1877(h)(6)(D) of the Omnibus Budget Reconciliation Act of 1993.[3] The following year, however, in the Social Security Act Amendments of 1994, Congress narrowed that broad language by striking the phrase "*other diagnostic services*" and replacing it with a far more precise description of the covered services. The new, narrowly drawn category of DHS consisted of "*radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services.*"[4] This language does not mention nuclear medicine.

CMS now seeks to rely on language Congress has previously rejected. If Congress had intended to broaden the scope to a "radiology service," it would have retained the earlier, broadly drawn category or would have listed nuclear medicine services with MRI and CT. Rather, in amending the statute, Congress affirmatively defined the scope of radiology services to omit nuclear medicine.

Moreover, this interpretation of Section 1877(h)(6)(D) conforms to CMS's own long-standing and well-considered view that nuclear medicine is not a radiology service for the purpose of the physician self-referral law. After carefully considering the statutory text and legislative record, CMS, in its January 4, 2001 final rule, decided to "*exclude[] nuclear medicine [from DHS] because those services are not commonly considered to be radiology.*"[5] This judgment was based on a specific factual finding with respect to the proper classification of nuclear medicine.

Nuclear medicine services are clinically and technically distinct from the services that Congress enumerated in defining the scope of "radiology services" under Section 1877(h)(6)(D). The American Board of Nuclear Medicine (ABNM), the primary certifying organization for the practice of nuclear medicine in the United States, defines nuclear medicine as "*the medical specialty that employs radionuclides to evaluate metabolic, physiologic and pathologic*

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[1] 42 U.S.C. § 1395nn(h)(6) (2005).
[2] 70 Fed. Reg. 151 (Aug. 8, 2005).
[3] Public Law 103-66, Sec. 13,562 (Aug. 10, 1993).
[4] Public Law 103-432, Sec. 152 (October 31, 1994).
[5] 66 Fed. Reg. 927 (Jan. 4, 2001).

conditions of the body for the purposes of diagnosis, therapy and research."[6] In a typical procedure, a physician trained as a nuclear medicine specialist supervises the administration of a radioactive material into a patient. The distribution of this administered material is determined by special device that detects the radioactivity coming from the patient. The nuclear medicine physician makes a diagnosis based on that distribution.[7]

The injection of radioisotopes into patients distinguishes nuclear medicine from radiology. Although radiologists sometimes do inject "contrast agents," these agents are biologically inert, and their function is entirely different from that of radioisotopes in a nuclear medicine procedure. As noted in the ABNM definition, some of the procedures performed in nuclear medicine are for therapeutic purposes, and therefore, specialized training, such as that obtained in programs leading to certification by the ABNM, is a prerequisite for clinically appropriate use.

CMS also relies on a letter from the American College of Radiology (ACR) claiming that nuclear medicine is "a part of the specialty of radiology" and noting that the American Board of Radiology's (ABR) process of certifying diagnostic radiologists includes examination in nuclear medicine. This position is directly contradicted by the Americal Board of Medical Specialties (ABMS), the body that officially sanctions all medical residency training programs in the United States. It is physicians trained in ABMS-approved programs, rather than the ABR, that define the specialty of nuclear medicine.[8] According the ABMS, Nuclear Medicine and Radiology each posses "primary" (that is, fundamental and independent) board status as medical specialties. Nuclear Medicine, like Radiology, is one of only 26 distinct medical disciplines subject to Primary Board Certification. Services such as CT and MRI, by contrast, have "affiliate" status, and are among the many subspecialty groups within radiology. Moreover, the ABMS oversees separate specialty training programs in both diagnostic radiology and nuclear medicine. Although some nuclear medicine training is incorporated into the diagnostic radiology training program, and the ABR does include questions on nuclear medicine in its certification examination, only after successfully completing a nuclear medicine residency program do physicians become eligible to take the American Board of Nuclear Medicine examination.

I am also concerned that CMS states in the proposed rule, that nuclear medicine services "*pose the same risk of abuse that the Congress intended to eliminate for other types of radiology, imaging, and radiation therapy services and supplies.*"[9] CMS has not considered that, unlike most radiology services, nuclear medicine imaging introduces potentially harmful radioactive material directly into the body. As a result, no physician would use nuclear procedures in clinically inappropriate circumstances.

The proposed rule also relies on the fact that since the publication of the Phase I final rule excluding nuclear medicine services from DHS, "many more nuclear medicine procedures have been performed in physician offices or in physician-owned freestanding facilities." The

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[6] http://www.abnm.org/

[7] *See, e.g.*, http://www.radiochemistry.org/nuclearmedicine/definition.htm.

[8] In addition, for a physician to be eligible for a dual certification in nuclear medicine and radiology under the ABNM program, she must first obtain separate approval for her proposed training program from both the ABNM and the ABR. After completing her training, she must then pass a certifying examination in radiology and a certifying examination in nuclear medicine, each administered by their respective certifying boards.

[9] 70 Fed. Reg. 151 (Aug. 8, 2005).

proposed rule reports that while physician services grew 22 percent between 1999 and 2003, imaging services grew 45 percent, and nuclear medicine grew an impressive 85 percent. The suggestion is that the absence of self-referral restrictions on nuclear medicine services referrals has made such services subject to over-utilization. This implication is unwarranted. CMS appears to have failed to consider that as nuclear medicine represents only a tiny fraction of all diagnostic imaging, even modest numerical growth can appear dramatic when it is presented in the form of a percentage increase.

Many physicians have entered into ownership and other arrangements in good-faith reliance on the existing regulations, as well as CMS's express exclusion of nuclear imaging from DHS. Accordingly, CMS recognizes in the proposed rule that it may be necessary to extend special consideration to physicians who have pre-existing ownership interests. The rule specifically requests comments on whether to specify a delayed effective date or grandfathering certain arrangements. I respectfully request that CMS exempt existing physician ownership interests from reclassification as DHS.

When Congress established an 18-month moratorium on physician self-referrals to specialty hospitals, it chose, as a matter of basic fairness, not to apply the new prohibition to physicians who had already made substantial investments in such hospitals.[10] Accordingly, Congress provided for the "grandfathering" of existing facilities and those under development as of the date that the specialty hospital bill was passed by both houses. The case for grandfathering is even more compelling with respect to nuclear medicine services, because physicians have relied on CMS's express declaration that nuclear medicine is not a subspecialty of radiology and I urge CMS to similarly grandfather existing nuclear medicine arrangements.

I appreciate your attention to my request that in the final rule CMS maintain its present policy that nuclear medicine is not a DHS or in the alternative, grandfather existing arrangements.

Very truly yours,

Michael Goldman, M.D., F.A.C.C.

[10] See CMS Transmittal No. 62, March 19, 2004, available at http://www.cms.hhs.gov/manuals/pm_trans/R62OTN.pdf.

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Form Letter #16
(SGR)
Received 14

East Memphis Anesthesia Services, PLC

6005 Park Ave., Suite 905B • Memphis, TN 38119
Phone (901) 682-2872 • Fax (901) 682-9316

September 27, 2005

Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

This letter is in response to the planned cut in Medicare reimbursements for the upcoming year. This cut, along with the financial pressures that are consistently placed on my practice could force me to make some very difficult decisions. Given the fact that a large portion of my practice is elderly this will drastically affect my reimbursement. The choice must be made, do I continue to participate in the Medicare program or not? How many practitioners will make the decision not to participate any longer? How many patients will be affected by this discontinued service?

I would ask you to strongly reconsider this move and not make this deep cut in Medicare reimbursement.

Sincerely,

Jivan Dalsania

Jivan Dalsania, M.D.

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(Form letter # 19)
Received 104

August 10, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1502-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Colleagues,

It has come to my attention that Medicare is considering changing the teaching physician policy for anesthesiologists. As a member of the American Association of Nurse Anesthetists (AANA), I have significant concerns with any changes that would create further inequities in how the Medicare system treats teaching Certified Registered Nurse Anesthetists (CRNAs) and anesthesiologists, and, more importantly, present possible negative impacts on Medicare beneficiaries' access to safe anesthesia care.

CMS has already twice rejected a proposal to change the anesthesia teaching rules so that teaching anesthesiologists would be paid a full fee for each of two overlapping cases involving medical residents, a manner similar to certain teaching surgeons. Such a proposal provides major new incentives to teach anesthesiology residents, and severe disincentives to teach nurse anesthetists, and is not based on a consensus process that treats both nurse anesthetists and anesthesiologists equally.

I appreciate that Medicare is considering its options on this important policy issue. Nurse anesthesia is a success story. With anesthesia 50 times safer than 20 years ago, CRNAs' patient safety record is shown to be indistinguishable from that of physicians providing anesthesia. CRNAs assure patients access to safe anesthesia care, and predominate in rural and medically underserved America and the Armed Forces. Further, it has been shown CRNAs are educated more cost-effectively than are our colleagues and competitors. Yet, while Medicare Direct GME payments to residents and medical direction payment rules already discriminate against educating CRNAs, the nurse anesthesia profession has been successful at increasing the number of accredited educational programs and graduates to meet growing demand for safe anesthesia care for patients. Thus, changing the anesthesia teaching rules to further dramatically favor one type of anesthesia provider over another creates negative impacts against educating safe anesthesia providers such as CRNAs, harming the healthcare system and patients' access to healthcare services.

So that patients anywhere in the country will continue to have access to the safe anesthesia care that they need, I am requesting that CMS work with both nurse anesthetists and anesthesiologists in developing a consensus proposal to address issues in the anesthesia teaching rules.

Sincerely,

E. T. R, RN, SRNA

Signature

Print name: Eric T. Riley

Street address: 2001 Petersen Dr. NW

City/State/ Zip: Stewartville, MN 55976