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;

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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;\(^6\)


\(^3\)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 percent7) 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.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Jan’05 Payment Limit</th>
<th>Apr’05 Payment Limit</th>
<th>Jul’05 Payment Limit</th>
<th>Oct’05 Payment Limit</th>
<th>Oct’05 vs. Jul’05</th>
<th>Oct’05 vs. Jan’05</th>
<th>2002 Wgts Non-Epogen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epogen</td>
<td>$9.317</td>
<td>$9.250</td>
<td>$9.307</td>
<td>$9.313</td>
<td>0.1%</td>
<td>(0.0%)</td>
<td>67.9%</td>
</tr>
<tr>
<td>Zemplar</td>
<td>$4.017</td>
<td>$3.971</td>
<td>$3.871</td>
<td>$3.809</td>
<td>(1.6%)</td>
<td>(5.2%)</td>
<td>15.9% 49.5%</td>
</tr>
<tr>
<td>Venofer</td>
<td>$0.362</td>
<td>$0.365</td>
<td>$0.365</td>
<td>$0.359</td>
<td>(1.6%)</td>
<td>(0.8%)</td>
<td>5.0% 15.6%</td>
</tr>
<tr>
<td>Hectorol</td>
<td>$2.797</td>
<td>$2.784</td>
<td>$1.501</td>
<td>$1.684</td>
<td>12.2%</td>
<td>(39.8%)</td>
<td>1.3% 4.0%</td>
</tr>
<tr>
<td>Ferrlecit</td>
<td>$4.829</td>
<td>$4.726</td>
<td>$4.713</td>
<td>$4.699</td>
<td>(0.3%)</td>
<td>(2.7%)</td>
<td>6.0% 18.8%</td>
</tr>
<tr>
<td>Infed</td>
<td>$11.060</td>
<td>$11.218</td>
<td>$11.223</td>
<td>$11.344</td>
<td>1.1%</td>
<td>2.6%</td>
<td>0.7% 2.0%</td>
</tr>
<tr>
<td>Carnitor</td>
<td>$14.649</td>
<td>$11.122</td>
<td>$12.174</td>
<td>$11.270</td>
<td>(7.4%)</td>
<td>(23.1%)</td>
<td>1.7% 5.2%</td>
</tr>
<tr>
<td>Alteplase</td>
<td>$30.152</td>
<td>$30.089</td>
<td>$30.772</td>
<td>$31.436</td>
<td>2.2%</td>
<td>4.3%</td>
<td>0.2% 0.6%</td>
</tr>
<tr>
<td>Calcitriol</td>
<td>$0.710</td>
<td>$0.859</td>
<td>$0.623</td>
<td>$0.817</td>
<td>31.1%</td>
<td>15.1%</td>
<td>1.2% 3.8%</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>$2.419</td>
<td>$3.188</td>
<td>$2.983</td>
<td>$3.200</td>
<td>7.3%</td>
<td>32.3%</td>
<td>0.2% 0.6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wgtd Avg ASP+6%</th>
<th>Total</th>
<th>Non-Epogen</th>
</tr>
</thead>
<tbody>
<tr>
<td>$7.69</td>
<td>$4.27</td>
<td></td>
</tr>
<tr>
<td>$7.58</td>
<td>$4.06</td>
<td></td>
</tr>
<tr>
<td>$7.60</td>
<td>$4.00</td>
<td></td>
</tr>
<tr>
<td>$7.59</td>
<td>$3.94</td>
<td></td>
</tr>
<tr>
<td>(0.2%)</td>
<td>(1.5%)</td>
<td></td>
</tr>
<tr>
<td>(0.1%)</td>
<td>(2.8%)</td>
<td></td>
</tr>
</tbody>
</table>

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-

7Please 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. 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

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8OIG, “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. 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”). 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 different. 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. Combined with the 2005 windfall, the impact would be a decrease of approximately $2.00 per treatment for independent facilities and an increase of approximately $11 per treatment for hospital-based providers. 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 all 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

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9See supra, note 3 at 11.
settings\textsuperscript{10} and the collection of data on acquisition cost and payment per unit for drugs from hospital-based providers.\textsuperscript{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

\textsuperscript{10}MedPAC, “Report to the Congress: Issues in a Modernized Medicare Program” 91 (June 2005).

\textsuperscript{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,

[Signature]

Kent J. Thiry
Chairman of the Board
Kidney Care Partners
Abbott Laboratories
American Kidney Fund
American Nephrology Nurses’ Association
American Regent, Inc.
The American Society of Nephrology
The American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
Fresenius Medical Care North America
Gambro Healthcare/USA
Genzyme
Medical Education Institute
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Care Group
Renal Physicians Association
Renal Support Network
Satellite Health Care
Sigma-Tau Pharmaceuticals, Inc.
U.S. Renal Care, Inc.
Watson Pharma, Inc.