August 7, 2008

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

Re: CMS-1403-P: Proposed Rule for Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009

Dear Administrator Weems,

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 and Other Revisions to Part B for Calendar Year (CY) 2009 (Proposed Rule).1 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 for individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).2 We appreciate the initiatives CMS has undertaken to ensure that ESRD beneficiaries have access to appropriate and high quality treatment services and would like to offer the following recommendations as additional steps to this end.

- CMS Should Recognize Congressional Intent and a Plain Reading of the Statute Supports only an Increase in the Drug Add-on Adjustment, and not a Decrease. In addition, CMS Should Not Change Its Methodology for Calculating the Growth in Drug Expenditures for Calculating the Drug Add-on Adjustment.

2 A roster of members of Kidney Care Partners is included as Attachment A.
CMS Should Promote Quality Care in the ESRD Program through the New Quality Incentive Program Authorized in the Medicare Improvements for Patients and Providers Act (MIPPA), rather than a Hospital-Acquired Conditions (HAC) Payment Policy.

CMS Should Provide the Community with the Opportunity to Comment on the New CPMs, Consistent with the Agency’s Quality Measure Development Overview Process.

Before CMS Eliminates the Geographic Wage Index Floor, It Must Ensure that Doing So Will Not Result in Beneficiary Access to Care Problems.

CMS Should Apply 2007 E&M Code RVU Increases to Inpatient Dialysis Services that Use Those E&M Services as Building Blocks, To Maintain Relativity in the E&M Code Family.

KCP looks forward to working with you to resolve these concerns before publication of the Final Rule.

I. CMS Should Recognize Congressional Intent and a Plain Reading of the Statute Supports only an Increase in the Drug Add-on Adjustment, and not a Decrease. In addition, CMS Should Not Change Its Methodology for Calculating the Growth in Drug Expenditures for Calculating the Drug Add-on Adjustment.

A. Interpreting the MMA Drug Add-on Requirement

KCP is concerned that the Agency implies it does not have to follow the plain meaning of the MMA by proposing a reading that the word “increase” actually would permit the Agency to reduce the drug add-on payment. The statutory term “increase” must be interpreted using the plain reading of the statute.

When Congress modified the methodology for reimbursing ESRD separately billable drugs, it required CMS to provide a drug add-on adjustment to the composite rate. 42 U.S.C. § 1395rr(b)(12)(B)(ii). Congress specified how CMS should calculate the adjustment. Id. Congress called for this calculation to be updated. Beginning in 2006, CMS must “annually increase” the basic case-mix adjusted payment amount by (1) “applying the estimated growth in expenditures” for separately billed drugs and (2) converting that estimated growth into “an increase applicable to the basic case-mix adjusted payment amounts.” Id. at § 1395rr(b)(12)(F).

As the Supreme Court has stated numerous times, when interpreting a statute, the interpreter must rely upon the plain meaning of the text. See Estate of Woart V. Nicklos Drilling Co, 112 S.Ct. 2589, 2594 (1992). The plain meaning of the word “increase” can be determined by consulting a dictionary. See Pittston Coal Group v. Sebben, 488 U.S. 105, 113 (1988). Webster’s dictionary defines increase as “1: to become progressively greater (as in size, amount, number, or intensity) 2: to multiply by the production of young[; as a] transitive verb 1: to make greater: augment.” Mirriam-Webster Online Dictionary (http://www.merriam-
webster.com/dictionary/increase). If Congress had wanted the drug-add on adjustment to be an increase or a decrease in the payment, it would have used the term “adjust” or some similar term as it did in other sections of the Social Security Act. Yet, Congress did not use such a term in this case. Therefore, the language must be interpreted in a manner that is consistent with the definition of the word “increase,” and CMS must annually update the adjustment by calculating this estimated growth in expenditures.

The legislative history also supports this conclusion. It indicates that Congress intended for CMS to update the drug add-on adjustment annually as well. The first year of the update was 2005. For following years, the Conference Report states that:

The system would be updated in 2006 for growth in drug spending for the portion of the basic case-mix adjusted payment amount that is represented by what is current spread on separately billed drugs and biologicals. However, the provision does not provide for an update to the composite rate portion of the base rate in 2006 and forward.

“Medicare Prescription Drug, Improvement, and Modernization Act of 2003” Conference Report, H. Rep. No. 108-391, 686 (emphasis added). The fact that Congress used the term “growth” and clarified that this “updated” payment would not provide for an “update to the composite rate” indicates that Congress clearly meant that the drug add-on adjustment would add to the existing dialysis payments. In addition, the conference report language clearly indicates that Congress envisioned the drug add-on adjustment to increase over time to remain consistent with increases in costs for drugs. Combined with the clear mandate in the text, there can be no doubt that CMS must provide for annual updates to the drug add-on adjustment. There is no textual or legislative history that supports the proposition that Congress intended that the drug add-on adjustment could result in lower payments to facilities.

This interpretation is also consistent with the Agency’s original interpretation of the statutory text. The CY2006 Physician Fee Schedule Rule indicates that CMS agrees the drug add-on adjustment must be updated annually. In its Final Rule for CY2006, CMS states:

[T]he statute does, in effect, provide for an annual update to the drug add-on to the composite payment rate. As discussed previously, the statute requires that we annually update the amount of the drug spread included in the composite payment rate, based on the projected growth in drug expenditure between 2005 and 2006.

70 Fed. Reg. 70116, 70166 (2005). Clearly, the Agency agrees that there must be an additional payment based upon the drug add-on adjustment statutory language.

Thus, the text, legislative history, and the Agency’s own previous interpretation clearly indicate that the drug add-on adjustment is to augment the dialysis payments. There is no evidence that the word “increase” as used by Congress was to be interpreted as also meaning “decrease.” When interpreting a statute, one must rely upon the words on the page. Thus, CMS’ broad interpretation outlined in the preamble would not withstand judicial review.
B. CMS Should Not Change Its Methodology for Calculating the Growth in Drug Expenditures for Calculating the Drug Add-on Adjustment

CMS should not change the methodology it uses for calculating the drug add-on adjustment. Beginning in 2006, the statute requires the Secretary to “annually increase the basic case-mix adjustment” by “applying the estimated growth in expenditures.” 42 U.S.C. § 1395rr(b)(12)(F). CMS has consistently stated that the Producer Price Index (PPI) is a viable proxy for determining changes in price. In the Notice of Proposed Rulemaking for the Physician Fee Schedule for Calendar Year 2008, the Agency specifically states:

As we indicated in the CY 2007 PFS final rule with comment period, we believe the PPI is a reasonable measure of drug pricing growth, and when used in conjunction with an estimate of per patient growth in drug utilization, this measure provides a simple and accurate approach to updating the drug add-on that could be readily used in subsequent years. Moreover, using the PPI significantly reduces any data bias that is inherent in using historical drug expenditure data that do not reflect current drug payment methodologies. Therefore, we established a mechanism for estimating the annual growth in expenditures for ESRD drugs and biologicals using the PPI for prescription drugs as a measure of price increases in conjunction with 2 years of historical data as a basis for estimating utilization growth at the per patient level.

72 Fed. Reg. 38122, 38165 (July 12, 2007). The Agency does not have similar experience with ASP. Additionally, KCP is concerned that the Agency’s proposal to use the combined Epogen/Procrit ASP does not reflect the cost facilities incur for Epogen because the ASP includes Procrit pricing as well to which facilities do not have access. Additionally, the enactment of the Medicare Improvements for Patients and Providers Act (MIPPA), Pub. L. No. 110-275, will lead to more changes to the reimbursement methodology. We encourage CMS to provide stability to the payment methodology for the interim, particularly given the fact that significant change is on the horizon.

If the Agency seeks to modify the methodology, it must do so in a manner that provides sufficient transition for dialysis providers and facilities. Given the changes to the Medicare ESRD program that are underway, it makes sense to provide some stability for the payment system. One way to ensure that there is no severe negative consequence to changing the methodology would be to establish the adjustment using a blended PPI/ASP calculation. CMS has used this type of transitional tool in other areas to ease in new payment methodologies, including the geographic wage index for dialysis facilities.

CMS should also take into account the fact that the 2007 data does not reflect future utilization growth trends. In 2007, the FDA issued a black box warning that resulted in changes to physician prescribing behavior. The warning impacted utilization in a manner that is not likely to be repeated in future years. The 2007 data is only one example of how utilization may change from year-to-year. CMS should revisit its utilization estimates each year and be cautious as to how it incorporates the 2007 – or any single year of data – into its calculations of the drug add-on adjustment.
II. CMS Should Promote Quality Care in the ESRD Program through the New Quality Incentive Program Authorized in the Medicare Improvements for Patients and Providers Act (MIPPA), rather than a Hospital-Acquired Conditions (HAC) Payment Policy

Generally, KCP supports efforts to link payment to quality. Dialysis facilities have been reporting quality data for more than a decade. Unlike other providers, dialysis facilities have reported this data without being paid for doing so and have contributed $0.50 per treatment since 1987 to support the ESRD network organizations that process much of the data that is sent to CMS. The kidney community supports the current CPM reporting, as well as efforts to measure the improvement in the quality of care dialysis patients receive. As part of our commitment to quality improvement, the KCP launched the Kidney Care Quality Initiative in 2005. The Initiative seeks to create a system for defining, assessing, monitoring, and rewarding quality care for patients with chronic kidney disease (CKD) and end-stage renal disease (ESRD). As part of its work under the Initiative, the KCP developed a proposal for implementing value-based purchasing in the Medicare ESRD program. It also created and supports the Kidney Care Quality Alliance (KCQA), a broader organization that develops measures for patients with kidney disease and kidney failure. To date, the KCQA has developed 17 measures, 5 of which are part of the new CPMs.

KCP also supports the quality provisions of the MIPAA. These provisions would establish a quality program that links payment to quality performance. This program will launch in 2012. The current CPMs will most likely serve as the baseline for determining quality performance under this program. Unlike other Medicare providers that are being paid to report quality metrics, dialysis facilities and providers will not only be reporting, but will also receive a cut of up to two percent if they do not meet the benchmarks established by CMS. Clearly, this program establishes the most rigorous quality performance incentives in the Medicare program since its inception. Given that such a groundbreaking program is scheduled to take effect in the near term, it simply does not make sense to try to roll out an additional program, such as an HAC payment policy.

KCP believes that tying payments to performance is an appropriate way to provide incentives for the delivery of high quality care. However, even if there were no quality incentive program already scheduled to take effect, implementing the hospital-specific HAC payment policy in the dialysis setting would not be an appropriate place to start. Unlike hospitals, dialysis facilities are responsible not only for the care of in-center hemodialysis patients, but also home hemodialysis and home peritoneal dialysis patients. CMS has consistently recognized the importance of home dialysis as a treatment option for patients with kidney failure. Applying an HAC payment policy with such a patient population would be extremely difficult because unlike hospitals, dialysis facilities do not have responsibility for 24 hours management of their patients. If CMS were to implement such a policy, it would create a disincentive to encourage patients to use home dialysis, contrary to CMS’ own initiatives.

In addition, the nature of the dialysis treatment – accessing a patient’s bloodstream through a catheter, synthetic graft, or AV fistula – leads to exposure to infection as a matter of fact. Even in the best care scenarios, patients whose natural barrier to infection – the integumentary system – will...
experience infections. Thus, it would be inappropriate to treat infections as “never” events. They are not medical mistakes, but rather a medical hazard associated with dialysis. That risk is greater when the patient has a catheter, the tip of which rests deep in their circulatory system. To implement such a policy in the dialysis setting could lead to a situation in which providers are reluctant to admit patients who have even a temporary catheter in place.

Another difference between the hospital and dialysis setting is that hospitals can treat their patients directly if a never event occurs. Dialysis facilities cannot. Thus, if the HAC policy were implemented in the dialysis setting, patients would be transferred to a hospital for treatment. CMS does not have authority to make dialysis facilities reimburse hospitals for the treatment of patient in such a case.

Therefore, KCP encourages CMS to focus on implementing the MIPPA quality program and refrain from applying the HAC payment policy in the dialysis setting.

III. CMS Should Provide the Community with the Opportunity to Comment on the new CPMs, Consistent with the Agency’s Quality Measure Development Overview Process

As you know, KCP strongly supports the development of quality metrics to measure performance for kidney failure and kidney disease. As noted, we have demonstrated this commitment by establishing a measure development organization – the Kidney Care Quality Alliance (KCQA). We were pleased that the KCQA measures endorsed by the National Quality Forum were included in the CPMs posted on the CMS website in April. However, based on the information released by CMS to date, it appears that the Agency has made some material changes to the measures and included four measures that were not endorsed by the NQF; KCP was disappointed that the Agency did not provide the community with the opportunity to comment on the new CPMs.

To resolve this concern, KCP encourages CMS to provide the community with an opportunity to comment – at a minimum – on the CPMs that were not endorsed by the NQF and those which the Agency modified. First, we are concerned that CMS adopted some measures, but provided no opportunity for community comment. Specifically, the four new measures adopted in April reflect neither NQF-endorsed measures nor KCQA developed measures. In addition, we are concerned that CMS did not work with the KCQA, as the owner of the measures, before making what appear to be changes to the KCQA measures that were endorsed by the NQF. For example, the vascular access CPM descriptions do not reference other surgeons qualified to provide vascular access-related services. This description appears to narrow the KCQA measure endorsed by NQF. Historically, CMS and KCP have had a positive working relationship. During comment periods, KCP has always sought to provide clear and concise comments with proposed workable solutions.

The four CPMs that did not receive NQF-endorsement are: (1) the measure for UUR for hemodialysis patients; (2) the measure for hemoglobin control for erythropoietin stimulating agents (ESAs) therapy; (3) the measure for hematocrit control for ESA therapy; and (4) the measure for monitoring of hematocrit levels below the target minimum, regardless of ESA use.
It is not clear why the Agency chose to forgo the comment process when adopting such an important component of the Medicare ESRD Program.

Additionally, the manner in which CMS adopted the CPMs is not consistent with the Agency’s commitment to an open process and is inconsistent with the manner by which it adopts measures for the Physician Quality Reporting Initiative (PQRI). Although CMS requests comments from physicians about the ESRD measures for PQRI, it does not provide a similar opportunity for the community to comment on the new CPMs. CMS should have used the Proposed Rule as an opportunity to gain input from the kidney care community on the dialysis-related anemia management CPMs, which were neither part of the KCQA consensus process nor endorsed by NQF, as well as any modifications to the NQF-endorsed measures. Therefore, we strongly encourage the Agency to issue the Final Rule as a Final Interim Rule with Comment to allow for a comment period on these CPMs.

In the future, we hope that CMS will continue to look to the kidney care community for input on measure development. In particular, we hope that CMS will work with KCQA to develop new measures, as well as to ensure smooth implementation of the CPMs. Community input into the measure development and adoption process will become more critical as the Medicare ESRD program moves to a value-based purchasing model. We are encouraged by the Agency’s measure development process outlined in the “Quality Measures Development Overview.” This process includes substantial opportunities for the kidney care community to work with the Agency collaboratively to ensure that measures adopted meet the needs of patients, providers, facilities, and policy-makers. We encourage CMS to continue to provide ample opportunities for input and look forward to working with the Agency in the future on measure development and adoption.

In addition, KCP is concerned that the amount of data CMS plans to collect to calculate the CPMs far exceeds the actual amount of information needed to do so. Under the HIPAA Privacy Rule (45 C.F.R. § 164.501 et seq.), CMS, as a health plan, may ask for only the minimum amount of data necessary to meet its purpose. The purpose of the data collection is to calculate the CPMs. CMS should not ask for additional data — in particular since many of the additional data elements support performance measures CMS submitted to NQF for possible endorsement but that were rejected during the consensus process and, further, were not listed as part of the new CPMs in the Conditions for Coverage. The request for additional data also places an unnecessary burden on providers and facilities, the majority of which will not be permitted to submit the data electronically. Given this practical reality, it also seems counterproductive to ask for extraneous data that will only slow down the manual collection process. Therefore, KCP strongly encourages the Agency to scale-back its data request to only such data as required to calculate the CPMs.

Finally, KCP is concerned that CMS proposes to drop the PQRI ESRD group measure. We understand the Agency is making this proposal because it plans to eliminate the anemia management measure. However, it is important that the ESRD group remain. Therefore, we recommend that CMS add the NQF-endorsed PD Adequacy individual clinician level measure (0308) and maintain the ESRD measure group in the final rule. Adoption of this measure would mean that the ESRD measure group would include an HD Adequacy measure, an Influenza Vaccine measure, a Vascular Access measure, and a PD Adequacy measure.
IV. Before CMS Eliminates the Geographic Wage Index Floor, It Must Ensure that Doing So Will Not Result in Patient Access Problems

KCP appreciates the smooth transition CMS undertook in shifting the Medicare ESRD program into a new geographic wage index system. The preamble notes that the Agency may seek to eliminate the floor to the geographic wage index in the future. Before CMS decides to take such action, we urge you to work with the community to evaluate the impact such a decision will have on patient access. Currently, the floor provides protection to facilities in areas that would otherwise not be able to support dialysis facilities. Eliminating the floor should only occur if CMS and the community determine that doing so will not create access to care issues for beneficiaries.

V. CMS Should Apply 2007 E&M Code RVU Increases to Inpatient Dialysis Services that Use Those E&M Services as Building Blocks, To Maintain Relativity in the E&M Code Family

In implementing the recommendations from the Five-Year Review of work relative value units (WRVUs) under the Medicare Physician Fee Schedule for the calendar year 2007 fee schedule, CMS increased the WRVUs for a majority of evaluation and management (E&M) codes. Further, the agency indicated in the 2007 proposed rule that it concurred with the recommendation of the AMA-Relative Value Update Committee (RUC) to incorporate the full increase for the E&M codes into the surgical global periods for each CPT code with a global period of 010 and 090.

While KCP does not argue with CMS' decision to apply these increases to the surgical global periods, we do support the position expressed by the Renal Physicians Association (RPA) that the use of E&M codes in surgical global packages is analogous to the use of E&M codes as building blocks for inpatient dialysis services. Accordingly, the increases in values for the E&M codes should also have been applied to the inpatient dialysis service codes using those E&M codes as building blocks (CPT codes 90935, 90937, 90945, and 90947). It is our understanding that in 2004 the reimbursement for CPT code 90935 was roughly equivalent to a level three subsequent hospital visit (CPT code 99233), and – if left unchanged – the proposed 2009 values will result in a reimbursement level that would be less than a level two subsequent hospital visit (CPT code 99232). KCP concurs with RPA’s previously stated position that such a change in relativity does not have face-value validity and if left unaddressed will create a major rank-order anomaly in the E&M service code family. We therefore recommend that CMS adjust the work RVUs for each inpatient dialysis code by applying the full increases for the appropriate building block codes in order to maintain both equity and relativity with the E&M code family.
VI. CONCLUSION

On behalf of KCP, I would like to express my gratitude for the Agency's willingness to consider our comments on the Proposed Rule. As I mentioned, we look forward to continuing to work with you to resolve these issues and ensure patient access to ESRD treatment and quality of care for Medicare beneficiaries. If you have any questions or would like additional information, please do not hesitate to contact Kathy Lester at 202-457-6562.

Sincerely,

Edward R. Jones, M.D.
Chairman
Kidney Care Partners
Abbott Laboratories
AMAG Pharmaceuticals
American Kidney Fund
American Nephrology Nurses’ Association
American Regent, Inc.
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