



September 24, 2010

Dr. Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 314G
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1418-F: End-Stage Renal Disease Prospective Payment System Final Rule

Dear Dr. Berwick,

I am writing on behalf of Kidney Care Partners (KCP) in reference to the "End-Stage Renal Disease Prospective Payment System" Final Rule (Final Rule).¹ KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both chronic kidney disease (CKD) and irreversible kidney failure, known as End Stage Renal Disease (ESRD).

Overall, KCP is pleased that the Agency clearly reviewed our comments, as well as those of our members, on the proposed rule and took important steps to address many of the concerns we raised. We especially appreciate the efforts of Marilyn Tavenner, Jonathan Blum, Laurence Wilson, and the other members of the CMS team that work on the Medicare ESRD program. They were extremely generous with their time and carefully considered the comments that they received.

We are writing to highlight a few remaining issues, including our technical concerns with the Final Rule. Specifically, we encourage CMS to:

Ensure that the calculation of the transition adjustment amount for Calendar Year (CY) 2011 is based upon the actual number of facilities that opt out of the transition period rather than on the assumption noted in the Final Rule and that the recalculation is implemented for January 2011 dates of service;

¹75 Fed. Reg. 49030 (2010).

Work with KCP to resolve a series of technical issues identified by The Moran Company; and

Provide additional guidance as quickly as possible so that facilities can appropriately prepare for implementation on January 1, 2011.

- I. CMS should ensure that the calculation of the transition adjustment amount for Calendar Year (CY) 2011 is based upon the actual number of facilities that opt out of the transition period rather than on the assumption noted in the Final Rule and that the recalculation is implemented for January 2011 dates of service.

Of the four priority issues KCP described to CMS earlier this year, the issue that remains of heightened concern for us after promulgation of the Final Rule is the calculation of the transition adjustment amount for CY 2011. We strongly urge the Agency to revise this amount using the actual data it collects as to the number of facilities that opt out of the transition before the January 1, 2011, implementation date. This change is critically important to avoid a substantial and unintended cut in the Medicare ESRD Program.

CMS should base the calculation for the transition adjustment amount on the actual number of facilities that opt out of the transition. In the Final Rule, CMS estimates that approximately 43 percent of dialysis facilities will opt out of the transition period. While we appreciate that the Agency must rely upon estimates until such time as it has actual data (which will be November 1, 2010), we are concerned that the Final Rule considerably underestimates the actual number of dialysis facilities that will elect to be paid under the PPS beginning on January 1, 2011. For example, if three of the larger dialysis organizations fully opted out of the transition, it would mean that more than 70 percent of facilities would be paid under the PPS. If this percentage is used instead of the estimate of 43 percent, the adjustment should be 0.59 percent rather than 3.1 percent.²

Resolving this issue is critically important to the entire kidney care community. If left unchanged, one of our members estimates that approximately \$240 million will be removed from the Medicare ESRD Program. As MedPAC has historically recognized, dialysis margins are already tight.

On the basis of 2008 payment and cost data, we project that the 2010 aggregate margin will be 2.5 percent. This estimate reflects the 1 percent composite rate update in MIPPA, effective January 1, 2009, and January 1, 2010. This projection for 2010 does not take into account the 2 percent reduction in total spending that MIPPA mandated to begin in 2011 under the new dialysis payment method.³

²Internal analysis prepared by The Moran Company (available upon request).

³MedPAC, "Outpatient dialysis services: Assessing payment adequacy and updating payments," Report to the Congress Medicare Payment Policy 133 (March 2010).

MedPAC's analysis did not include an assessment of the impact of an additional 3.1 percent transition adjustment. Removing 3.1 percent (or the approximately \$240 million) from the system could create economic instability within the kidney care community. Some facilities could end up operating with negative margins. Congress never intended for such a reduction. In fact, it clearly stated that CMS should maintain the overall spending on the Medicare ESRD program at 98 percent of current levels.⁴

In addition, we are concerned that if not modified to reflect the actual percentage of facilities selecting to be paid under the PPS, there will be a strong disincentive for facilities to opt out of the transition and into the PPS. In the proposed rule, CMS indicated that the transition adjustment "should not change facilities' incentives with respect to whether or not to opt out of the transition."⁵ The transition adjustment should be calculated so that it does not incentivize facilities to stay in the transition.

We believe CMS has sufficient authority to make this change without going through notice and comment rulemaking. The request does not seek to change the methodology used to calculate the adjustment, only the assumption of the number of facilities that would opt into the bundle. Thus, we believe a revision to this number could be published as a technical correction so that the final adjustment is consistent with Congressional intent. If rulemaking were required, we would argue that this change does not trigger the 60-day rulemaking requirement in the Social Security Act and, thus, it could be effectuated on an expedited basis.

While we appreciate that the language in the preamble implies that the Agency will re-examine the issue for CY 2012, the loss of dollars to the program is significant and there is no guarantee that CMS will be in a position to return them to the system. Rather than wait a year, we ask CMS to revise the adjustment based upon the actual number of facilities opting into the bundle immediately after receiving facilities' transition elections. We would welcome the opportunity to assist the Agency in finding a way to address this concern for services provided January 1, 2011, and thereafter.

II. CMS should work with KCP to resolve a series of technical issues identified by The Moran Company.

KCP appreciates the Agency's ongoing willingness to work with us and The Moran Company to address a series of technical issues. In coordination with the Kidney Care Council, we have through The Moran Company provided CMS with a memorandum that sets forth a series of technical issues that we hope to discuss with CMS in the short-term. A copy of the memorandum is attached to this letter. Among other things, The Moran Company has raised the following concerns:

⁴42 U.S.C. § 1395r(b)(14)(A)(ii).

⁵74 Fed. Reg. at 49945.

There is a discrepancy in the number of patients identified, the treatment counts, and the payments per treatment for purposes of calculating the base rate. In each case, The Moran Company's analysis resulted in higher counts/amounts than those reported in the Final Rule and impact file.

The Moran Company found an additional \$1.54 per treatment when it tried to replicate the Medicare allowable payments using 2007 claims, which provides the basis for the 2011 base rate set forth in the Final Rule.

The Moran Company found an additional \$0.44 per treatment in laboratory test payments to facilities in the claims files. It is also concerned that the use of a monthly capitated payment (MCP) list to identify laboratory test payments understates the payments for the published list of laboratory services paid for patients on dialysis.

It appears that HCPCS code Q 4081 (injectable E poetin alfa, 100 units) has inadvertently been left out of the analysis.

It also appears that Iron Dextran has not been included in the Final Rule, with one exception. This exclusion would result in approximately \$850,000 (using 2007 SAF data) being inadvertently taken out of the system.

Although the Final Rule states that pediatric patients and facilities are not eligible for low volume adjustments, the impact analysis continues to include them, which means that the standardization adjustment may be overstated.

We believe most of these issues can be resolved informally and look forward to working with the Agency to do so.

- III. CMS should provide additional guidance as quickly as possible so that facilities can appropriately prepare for implementation on January 1, 2011.

In addition, the KCP has been reviewing the Final Rule in an effort to identify and try to resolve any implementation questions so as to allow for a smooth implementation. We appreciate the Agency's recent guidance documents, but we continue to have questions about implementation. We hope that CMS will work with the kidney care community to resolve these as quickly as possible. We have outlined our questions below.

A. Scope of Bundle

KCP has identified the following questions related to drugs, laboratory tests, and supplies. We appreciate the Agency's ongoing efforts to answer our questions and have identified the following as priority areas that we hope CMS clarify and provide further guidance on in the near future. Specifically, we request clarification or guidance as to:

Intravenous (IV) drugs, including: (1) will ESRD-related IV drugs will be recorded on the claim and (2) how non-ESRD IV drugs will be recorded on the claims and whether facilities will be paid at ASP+ 6 percent for them;

Oral drugs with IV equivalents, including: (1) how will drugs outside of Part B that do not have HCPCS codes be assigned such codes; (2) whether CMS plans to provide a cross-walk (HCPCS and NDC) for these drugs; and (3) how facilities should report acquisition costs;

How blood transfusions and blood products are recorded on the claims;

How supplies will be recorded on the claims (distinguishing between those paid separately and those that historically were part of the composite rate);

How the "AY" modifier is to be used for non-ESRD supplies (eg, those used in blood related products); and

How facilities that transition into the bundle will bill and be paid for services in the bundled that they have not had to bill in the past.

B. Adjustors

KCP has identified the following questions related to the age/BSA/BMI, co-morbidity, and low volume adjustors. Specifically, we request that CMS clarify and provide further guidance as to:

Whether the age, BSA, and BMI adjustors will or will not be applied with the new patient adjustor;

How facilities should report the co-morbidity adjustors using ICD-9 codes if they do not have sufficient information about a patient's co-morbid condition;

How facilities should resubmit claims for a correct payment when a co-morbidity condition is identified after a claim has been submitted;

The level of verification that will be required to support the use of diagnosis codes (eg, physician verification in chart, family or self-reporting);

How to define when comorbid conditions identified as case-mix adjustors start and end for purpose of billing and if there is a recurrence how the recurrence should be billed;

How CMS will ensure that the criteria for the low volume adjustor are clear and applied in the same way by all Medicare Administrative Contractors; and

How the new patient adjustor will be applied in light of the fact that facilities have 45 days to submit the 2728 form.

Additionally, we urge the Agency to continue working with the kidney care community on the development of an adjustor that takes into account a beneficiary's race. As we described in our comment letter on the ESRD PPS proposed rule, we believe CMS should implement a case-mix adjustor for race because of the strong correlation between race and costs, which CMS recognized in the preamble to the proposed rule.⁶ We would welcome the opportunity to work with the Agency to develop appropriate criteria to verify race in a way that such data could be collected with reasonable reliability; however, we are confident that the current Medicare database is sufficient to support the use of a race adjustor as other criteria are developed. Most importantly, we remain concerned that the higher costs associated with certain racial and ethnic minority groups, as noted in the recent report by the Government Accountability Office (GAO),⁷ are not recognized by the PPS as finalized. As we have described to CMS previously, facilities that disproportionately care for more minority patients may face economic challenges that could lead to access problems in some areas of the country. Again, we hope to work with the Agency to address this important issue in the near future.

Finally, we urge the Agency to follow the model of the Medicare Advantage plans and provide facilities with the information necessary to establish the co-morbidity adjustors. This exchange of information would allow for verification and straight-forward documentation.

C. Outlier Policy

KCP requests that CMS clarify and provide further guidance about the outlier policy. We encourage the Agency to work with KCP to prevent as much money as possible from leaking out of the Medicare ESRD Program under this policy. We also request clear and detailed guidance outlining the specific responsibility of facilities to identify outlier services. Finally, we hope to work with the Agency to develop and distribute the promised list of items that will qualify for outlier payments.

D. Medicare/Medicaid Overlap

KCP appreciates the willingness of CMS to assist us with engaging with the Centers for Medicaid, CHIP, and Survey and Certification to help ensure that the Medicaid program appropriately implements the PPS. It is imperative that States appreciate the changes outlined in the Final Rule. We encourage you to continue your current efforts to assist the

⁶74 Fed. Reg. 49922, 49962 (Sept. 2009).

⁷Government Accountability Office, "END-STAGE RENAL DISEASE: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System" (March 2010).

State Medicaid Agencies in properly interpreting the Final Rule and with incorporating the PPS into their payment structures.

E. Changes in Revenue Coding

CMS has made two changes to revenue coding for reporting dialysis treatments. However, it is important to move to revenue coding that fits the full range of dialysis services delivered today, including different dialysis modalities and pediatric care. Any service that may be substantially affected by recalibration of the payment system in 2014 should be tracked at the revenue code level so that accurate data are available for 2011 and 2012 when the recalibration analytics take place in 2013 using these data. Tracking modalities, pediatric care, and training at the revenue code level will also improve the evaluation of quality data associated with these different patient populations. KCP would welcome the opportunity to work with CMS on this issue.

F. Monitoring

Finally, we hope that the Agency will work with KCP to develop and implement a monitoring plan. The process should be open and transparent with the opportunity for public input. As part of this endeavor, we encourage CMS to create tracking codes to assist in monitoring features of patient care.

IV. Conclusion

We appreciate the opportunity to share our questions and recommendations with you. Please do not hesitate to contact Kathy Lester at 202-457-6562 if you would like to discuss them in detail or have any questions.

Sincerely,



Kent Thiry
Chairman
Kidney Care Partners

Abbott Laboratories
Affymax
AMAG Pharmaceuticals
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Diagnostic and Interventional Nephrology
American Society of Nephrology
American Society of Pediatric Nephrology

Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
California Dialysis Council
Center for Dialysis Care
DaVita, Inc.
DCI, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Genzyme
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage
Mitsubishi Tanabe Pharma America
Renal Advantage Inc.
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
sanofi-aventis
Satellite Healthcare
U.S. Renal Care
Watson Pharma, Inc.