



August 30, 2011

Dr. Donald Berwick  
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-1577-P: Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014: Proposed Rule**

Dear Administrator Berwick:

The non profit Northwest Kidney Centers is the oldest dialysis program in the world, based in the Puget Sound region of western Washington State. We are pleased with the manner in which CMS has implemented the first year of the PPS and the open communication with the community. We generally support many of the provisions of the proposed rule that maintain or improve the ESRD PPS for the next calendar year. However we have specific suggestions that will hopefully improve the rule.

### **BACKGROUND**

Last year in our 14 facilities and in 210 homes, Northwest Kidney Centers (NKC) provided 212,716 outpatient dialysis treatments. Today we serve 1420 individuals with kidney failure. Over 15% of our patients are on home therapy which includes 50 individuals on home hemodialysis and 170 peritoneal dialysis patients. We work closely with 40 nephrologists who practice in small and large group practices and academic settings. Because we provide care to 1/2 of 1% (0.5%) of US dialysis patients, we consider ourselves a Small Dialysis Organization (SDO). We opted to have all our facilities fully in the PPS in 2011. Our comments to you are submitted with the assumption that CMS shares our mission to promote the optimal health, quality of life and independence of beneficiaries who use dialysis. And as a non profit community owned organization, we share CMS's value of stewardship and seek to fulfill our mission in a cost effective, high quality manner in

service to the public.

## ESRD PROSPECTIVE PAYMENT SYSTEM

**Transition adjustment-** Northwest Kidney Centers supports the CMS proposal to maintain the zero percent transition adjustment for CY 2012. We appreciated CMS's decision earlier this year to base the adjustment on the actual number of facilities that opted into the PPS rather than estimates.

**Case mix adjustors-** NKC supports the CMS decision not to increase the number of co morbid case mix adjusters.

We urge CMS to work with the provider community to solve the problem of co morbidity capture by the dialysis facility. Dialysis facilities do not have access to the necessary supporting documentation required for claims submission for the six co morbid adjustors. We have assigned an experienced dialysis nurse to respond to alerts from nephrologists when they inform us that a patient may potentially have one of the six chronic or acute comorbidities. With great effort this nurse tracks down documentation from doctor offices, hospitals etc. for appropriate coding on our claims. This poses a significant burden and cost to the facility.

For example, this table presents the percent of NKC Medicare patients with the co morbid condition compared to the CMS contractor UM-KECC estimate (for July 2011):

Monoclonal Gammopathy:	NKC = 1.14%	KECC = 1.40%
Hemolytic or sickle cell anemia:	NKC = 0.19%	KECC = 2.40%
Myelodysplastic syndrome:	NKC = 0.95%	KECC = 1.10%
Pericarditis:	NKC = 0.00%	KECC: 0.40%
Bacterial Pneumonia:	NKC = 0.95%	KECC = 1.70%
GI Bleed:	NKC = 0.76%	KECC = 1.20%
Overall chronic conditions	NKC = 2.27%	KECC = 4.93%
Overall acute conditions:	NKC = 1.71%	KECC = 3.32%

Despite great diligence on behalf of our nephrologists and nurses we are identifying about half of the comorbidities compared to expected prevalence. When ICD 10 is implemented in 2013, the burden will increase to secure documentation to support the more granular ICD 10 level of coding. We support developing additional options, with CMS's help, to use hospital, doctor and other additional sources of information to secure co morbidity data.

## ESRD QUALITY INCENTIVE PROGRAM

**Elimination of Hg less than 10g/dL in Payment Year (PY) 2013 and 2014-** NKC understands that the hemoglobin less than 10 g/dL measure may not be an appropriate payment measure within the QIP at the current time given the June 2011 FDA Black Box

Warning culminating in a label change for ESAs, removing the target range of 10-12 g/dL. Reluctantly we agree with CMS's proposal to eliminate use of this measure for QIP in 2013 and 2014.

However, we believe it is important for CMS and the kidney care community to monitor changes in both upper and lower hemoglobin of patients to promote optimal care. This is a critical and potentially dangerous time for dialysis patient care in our country. PPS implementation encourages conservative use of expensive resources like Epogen which treats anemia as measured by hemoglobin. Yet right now there is a lack of clear scientific direction about a safe hemoglobin floor. Low hemoglobin is clinically important because data suggests an association between hemoglobin less than 10 g/dL and increased transfusions and morbidity with implications for transplantation and quality of life.

We recommend:

1. CMS should monitor and respond as appropriate to shifts of large numbers of patients to ranges of hemoglobin less than 10. Specifically we suggest that CMS should track and report all patients' hemoglobins between 8 and 12 g/dL, stratified by 1 gram decrements (e.g., percentage of patients with hemoglobin levels 9-9.9 g/dL, 8-8.9 g/dL, etc.) as well as the national average for each level. In this regard, each facility's Dialysis Facility Report Table 6 should be expanded to include more stratified information on hemoglobins less than 10g/dL. This information is only meaningful for reporting and national baseline creation if it is based upon contemporary data, specifically the monthly hemoglobin placed on the claim.
2. CMS should maintain the hemoglobin less than 10 g/dL threshold in Conditions for Coverage MAT which is required to be reviewed monthly by every dialysis facility, reported to the facility governing body, and monitored by Medicare surveyors.
3. CMS should monitor the number of blood transfusions in dialysis patients (in hospitals, dialysis units and other settings) and report results in Dialysis Facility Reports.
4. CMS should encourage ESRD Networks, who are knowledgeable about the hemoglobin controversies, to promote themselves as a resource for patients and others who have concerns about their care. The Networks can help identify current issues to be shared with CMS for action as needed. CMS commented to the General Accounting Office in their report on PPS oversight that CMS would use the Networks for that purpose. The Network Medical Review Boards may have a role in transfusion oversight as well as other monitoring.
5. To help explain the shifting and confusing situation to patients, CMS should include text in the QIP certificates to be posted in December 2011 to acknowledge the changing guidance in anemia management, so patients and caregivers are aware that the data are dated and not necessarily relevant in today's environment.

6. CMS should reinstate a low hemoglobin measure, as agreed upon by a consensus body, in PY 2014 or soon thereafter to establish a floor for patient safety and quality.

**Payment reductions for PY 2013-** NKC strongly opposes CMS's proposed structure for payment reductions. We urge CMS to use the existing structure that will be used for 2012: a five tier penalty structure that includes a range of 0.5 percent to 2.0 percent. For 2013, CMS proposes to reduce payment to facilities that receive a score of 29 or lower out of a maximum of 30. The proposed performance period for PY 2013 will be nearly complete by the time the final QIP rule is approved later this year. We object to raising the standard of performance to perfection-- or else penalty--when there is virtually no time to change practice and greater weight is applied to each of the two measures than in 2012. The payment reduction structure should remain the same in PY 2013 as in PY 2012.

Looking ahead, CMS has rectified the advance notice problem for PY 2014 by setting 2012 as the performance year and announcing measures before the performance year has started. However we continue to oppose in PY 2014 the proposed extremely stringent penalty model and advocate for continuation of the five tiers, 0.5 percent to 2.0 percent structure.

#### Clinical quality measures for PY 2014:

**Hemoglobin greater than 12g/dL-** We support continued inclusion of this measure in QIP.

**Kt/V as a quality measure-** NKC supports the move from URR to Kt/V as a better measure of adequacy. We recommend that CMS remove residual renal function from the hemodialysis Kt/V measure.

We strongly support continued exclusion of home hemodialysis and home peritoneal dialysis patients as well as those patients regularly dialyzing in a facility more or less than three times a week. Kt/V is measured differently for these categories of patients, which account for a small number of US dialysis patients. For those providers like NKC who have a large home dialysis population on frequent dialysis followed from one facility, it is important that the data be excluded to avoid inappropriate penalties.

**Vascular access type-** NKC supports use of this measure and asks CMS to place more emphasis on catheter reduction and less on fistula placement. Reduction in use of catheters is the most important measure associated in improving health and lowering costs. We propose that CMS weigh the catheter sub measure at two thirds of the value of the overall measure and the fistula measure at one third of the overall measure. This weighting will allow for more use of grafts as appropriate. Elimination of the fistula measure risks backsliding from the progress made through Fistula First, with the potential for too many grafts used as a solution to lowering catheters. We believe our proposal strikes the correct balance in incentives.

**Vascular access infections-** We do not support use of this measure. We recommend continued data collection and definition refinement before this measure is used for QIP.

There is lack of uniformity in defining a vascular access infection placed on the claim (V8). The initial results on V8 reporting as communicated in draft DFRs suggest underreporting of infections nationally, which would greatly skew the baseline year (July 2010-June 2011.) We have found from DFR analysis that there are many different results reported for peritoneal infections which are especially confusing to define. We strongly suggest that this measure is not ready for QIP. We note that our recommendation to assign heavy weighting to the catheter measure will help create conditions to reduce infections as well.

**Standardized hospitalization ratio-** We support the focus on reducing hospitalizations. Given variability across a single year, especially for smaller facilities, we urge CMS to use the four year SHR to be consistent with the results reported in Dialysis Facility Reports.

#### Reporting quality measures for PY 2014:

**NHSN reporting-** We do not support the NHSN reporting measure unless providers have the option to directly download data from facility electronic medical records. As we have communicated frequently via the CROWNWeb experience, manual data entry is burdensome, subject to error, and not appropriate for a QIP measure. If NHSN cannot be electronically linked, then we do not support this measure.

**CAHPS patient experience survey-** Per the Conditions for Coverage, all facilities already must conduct an annual patient experience survey. This QIP measure would require all facilities to use the CAHPS measure in place of, or in addition, to their own. CAHPS is quite long and costly and we believe would be more of a burden to patients than a help. We support current redevelopment of the CAHPS tool with input from the renal community including patients before it is made a QIP measure.

**Mineral metabolism reporting-** We support this measure.

#### Performance period for PY 2014:

**Performance year is 2012-** We support the proposal to use all of CY 2012 as the performance period for PY 2014. It is extremely important to know the measures before the performance period starts.

#### Weighting of measures in PY 2014

**Weighting of clinical measures-** We agree with CMS that clinical measures should compose 90% of performance score. Given the importance of vascular access to overall health and cost reduction, we propose weighting the access measure at 50% (2/3 catheter and 1/3 fistula); we propose the additional three measures (hemoglobin >12g/dL, Kt/V and SHR) compose the other 50%.

**Weighting of reporting measures-** The reporting of mineral metabolism should be weighted 100%, unless the NHSN can be implemented electronically in which case it would be included and the two measures would be weighted equally.

## Penalty structure in PY 2014

**Penalty structure-** As we described in our comments on PY 2013, we believe CMS should maintain a 0.5 – 2.0 percent reduction penalty range and have at least five tiers in the rate reduction scale. In addition to allowing comparisons between years, a five-tier rate reduction scale is more consistent with the literature supporting value-based purchasing programs.

## Technology Adjustment

The PPS structure should develop a mechanism for a new technology adjustor. Our field desperately needs innovation and research to advance patient care. That is why we founded the Kidney Research Institute three years ago. As new knowledge is developed the PPS should be adaptable so innovations in medications, diagnostic approaches, home therapy etc. can be implemented and not inappropriately held back by the PPS.

We appreciate the opportunity to comment on this proposed rule. I welcome your contact to discuss any aspects of this letter.

Sincerely,

A handwritten signature in cursive script that reads "Joyce F. Jackson". The signature is written in black ink on a white background.

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