August 29, 2011

Donald Berwick, MD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1577–P
P.O. Box 8010
Baltimore, MD 21244–8010

Dear Dr. Berwick:

As President of the National Kidney Foundation (NKF), I am pleased to provide these comments on behalf of the National Kidney Foundation Patient and Family Council as well as the National Kidney Foundation Council of Advanced Practitioners, Council of Nephrology Nurses and Technicians, Council on Renal Nutrition, and Council of Nephrology Social Workers. In all, these NKF constituencies constitute 50,000 members residing in all parts of the country. We are responding to the Proposed Rule, 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 [CMS–1577–P], Federal Register, July 8, 2011.

A. PROPOSED POLICY CHANGES FOR PAYMENT YEAR 2012 ESRD PROSPECTIVE PAYMENT SYSTEM

1. CMS proposes to apply ESRD market basket (minus productivity adjustment) to update payment for the oral equivalent of injectable drugs. We are concerned that this approach could set a precedent that might affect access to care for preferred agents when additional oral drugs are included in bundle in 2014. In our letter (dated December 11, 2009) in response to the Proposed Rule for the ESRD Prospective Payment System that had been published in the Federal Register on September 29, 2009, we expressed doubts that the add-on that had been proposed for oral drugs would be sufficient to enable dialysis facilities to provide newer, alternative oral drugs to most patients. An inadequate update formula would accentuate those concerns. The factors used in the productivity adjustor, which are mostly derived from capital and labor related economic measures, are not appropriate for use to modify the market basket costs of drugs, which are consumable items.

2. CMS is proposing to exclude all thrombolytic drugs from calculation of outlier services. We object to that proposal. There should be a longer experience

with the use of thrombolytics under a bundled payment system before excluding them from the outlier payments. When used properly, these agents may help avoid unnecessary (and expensive) access procedures and interventions and payment policy that could adversely impact their proper use could lead to a greater number of invasive vascular access procedures outside the dialysis unit, and could be detrimental to patients' outcomes.

3. CMS is proposing to recognize testosterone and anabolic steroids (used in anemia management) as outlier services. We recommend against this. The forthcoming KDIGO Clinical Practice Guideline for Anemia and CKD reviewed the evidence for use of androgens as adjuvants to ESA therapy, and makes a strong (level 1B) recommendation that they not be used. The rationale states, "The risks of androgen therapies and their uncertain benefit on Hb concentration or clinical outcomes argues against their use as ESA adjuvants." Given that this is not recognized standard of care, we would discourage against any potential financial incentive associated with their use.

4. In order to maintain and facilitate beneficiary access to all modalities of kidney replacement therapy, CMS should update the home hemodialysis and home peritoneal dialysis training add-on so as to keep pace with increasing costs, such as nursing salaries, that facilities and providers incur to provide these services.

5. We reiterate our concern that CMS has failed to provide a case-mix adjuster for race/ethnicity. As stated in our letter of December 11, 2009:

"We are concerned that the Proposed Rule includes no case-mix adjuster for race. Hemoglobin (Hb) values vary significantly between races, with African-American individuals consistently showing Hb concentrations 0.5- to 0.9- g/dL lower than Caucasian or Asian/Pacific Islander populations. African-Americans also have a greater prevalence of anemia at every stage of chronic Kidney Disease (CKD) compared with whites. (NKF Kidney Disease Outcomes Quality Initiative, Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease, ***Am J Kidney Dis***, Vol 47, No 5, Suppl 3, May 2006, p. S26-27.) Mean Hb levels at the initiation of dialysis are highest in whites and lowest in African Americans, at 10.3 and 9.8 g/dl, respectively. (United States Renal Data System, 2007 ***Annual Report***, p. 104.) The USRDS has reported that African-American patients require greater doses of Erythropoiesis Stimulating Agents to achieve Hb levels similar to white patients. (Excerpts from the United States Renal Data System 2006 ***Annual Report***, ***Am J Kidney Dis,*** Vol 49 No 1, Suppl 1, January 2007, p. 121.) Information from the USRDS shows that African Americans on hemodialysis have lower hemoglobin levels and require higher doses of erythropoietin compared with other races (USRDS 2006 ***Annual Data Report***, Vol. 1, p. 121). Ishani and colleagues have shown that African Americans begin dialysis with lower hemoglobin levels and require higher

ESA doses to reach hemoglobin levels similar to those of other races (Ishani et al. ***J Am Soc Nephrol*** 2009; 20:1607-13).

"In addition a higher relative percent of African Americans are prescribed expensive, brand-name only medications (cinacalet, IV vitamin D) for bone and mineral metabolism disorders (St. Peter WL et al. ***Clin J Am Soc Nephrol*** 4: 354–360, 2009, St. Peter WL et al. ***Pharmacotherapy*** 2009;29:154-164.) Moreover, a higher percentage of African Americans than other races receive IV vitamin D. (St. Peter et al. ***Pharmacotherapy*** 2009;29(2):154–164) and require higher doses of Vitamin D for mineral and bone disorders. (Gutierrez OM, Isakova T, Andress DL, Levin A, Wolf M: Prevalence and severity of disordered mineral metabolism in blacks with chronic kidney disease. ***Kidney International***, 73: 956-962, 2008.) African Americans also are more likely to receive cinacalcet for treatment of secondary hyperparathyroidism compared with Caucasians. (St. Peter et al. ***Clin J Am Soc Nephrol*** 4: 354–360, 2009.). The fiscal constraints of a prospective bundled payment system might make it difficult for those dialysis facilities that provide care to a predominantly African American population to provide optimal treatment for anemia and bone and mineral disorders in this patient population without a risk adjustor for race."

Finally, it was recently recognized that the previously described "survival advantage" enjoyed by African-Americans with ESRD is actually only present among older patients. In fact, younger African-Americans have a greater risk of mortality which the authors hypothesize may be related to decreased access to care (Kucirka LM, Grams ME, Lessler J, Hall EC, James N, Massie AB, Montgomery RA, Segev DL**:** Association of race and age with survival among patients undergoing dialysis**.** ***JAMA,*** 2011 Aug 10;306(6):620-6) It is our concern that failure to include race as an adjuster may exacerbate access to care and differential outcomes seen in this vulnerable population.

B. ESRD QUALITY INCENTIVE PROGRAM (QIP) FOR PAYMENT YEAR 2013

1) Performance Measures

For payment year 2013 CMS proposes to retire the following measure that will be utilized in the QIP for 2012: "Percentage of Medicare patients with an average Hemoglobin Less Than 10g/dL."

NKF urges CMS to address the potential unintended consequences that could result from its proposal to retire this measure, such as an increase in the use of transfusions to ameliorate anemia in dialysis patients. CMS maintains that removing this measure is consistent with the new labeling approved by the Food and Drug Administration (FDA) for erythropoeisis stimulating agents (ESAs) used to treat anemia. The package insert for ESA products now recommends that patients with

chronic kidney disease and their physicians should weigh the possible benefits of using ESAs to decrease the need for red blood cell transfusions against the increased risks for serious adverse cardiovascular events. The challenge is to minimize the risk for the subgroup at heightened risk for cardiovascular complications while maximizing the benefit of ESAs for the majority of patients. This requires careful consideration of the risk profile of individual patients. We still need a mechanism for monitoring low hemoglobins, so that any adverse clinical consequences of under-treatment of anemia can be detected and corrected.

There are many reasons why transfusion avoidance for kidney patients should be a prime public policy focus. Red blood cell transfusions carry many risks that are specific to kidney patients, in addition to the well-known danger of exposure to blood borne pathogens. In the presence of severe chronic anemia, transfusions may lead to congestive heart failure, particularly in the elderly. Iron overload can develop with the administration of frequent red blood cell transfusions over a prolonged period. In addition, transfusions carry a risk of potassium overload which can be fatal for individuals with permanent kidney failure. Finally, red blood cell transfusions can also induce antibodies that interfere with kidney transplantation; and, for this reason, transfusions should be avoided in patients awaiting a kidney transplant.

Additional factors to consider for anemia therapy in dialysis include the relationship between hemoglobin level and quality of life, rehabilitation and employment, risk of hospitalization, and the impact on health care disparities. As of February 2011, the prevalence of having hemoglobin levels less than 10g/dL was 28% higher in African Americans patients than non-African American patients. Finally, low hemoglobin levels might cause some patients to skip dialysis sessions, and this could compromise dialysis adequacy, leading to increased risk of morbidity and mortality.

Since practice patterns for anemia therapy are in flux as a result of the change in FDA label for ESA products, it may not be appropriate to continue the QIP measure with payment consequences. On the other hand, there are other options available to the agency to ensure patient safety, for example, a QIP measure for Hemoglobin Less Than 10g/dL, based on data that are no more than 6 months old, that would be used only to keep patients and their loved ones informed about trends in anemia therapy in individual clinics, in the broader community, and in the nation at large.

We are concerned about individuals on dialysis with hemoglobin levels below 10g/dL who are not receiving ESAs. For that reason, we believe that reporting

should include all dialysis patients and not be limited to those being treated with ESAs.

Finally, we would encourage the development of outcome measures for anemia therapy that are not focused on hemoglobin levels, such as measures based on transfusion avoidance.

CMS proposes to carry over a Hemodialysis Adequacy Measure from Payment Year 2012 (Percentage of Medicare patients with an average Urea Reduction Ratio equal to or greater than 65 percent) while signaling the agency's intent to replace the URR Adequacy Measure with a Kt/V Adequacy Measure in 2014. NKF urges the agency to accelerate plans to move to a Kt/V Adequacy measure or permit dialysis facilities/providers to elect the measure on which they wish to be evaluated. The URR standard does not allow providers and physicians to individualize the dialysis prescription for patients with significant residual renal function or recognize the clearance related to ultrafiltration thereby underestimating actual delivered dialysis to a degree that is not consistent among patients.

2) Methodology for Calculating the Total Performance Score for the PY 2013 ESRD QIP

The ESRD QIP for PY 2012 provides payment reductions of 0.5 percent, 1.0 percent, 1.5 percent, or 2.0 percent, if a clinic achieves a total performance score less than 26 (out of a total of 30 points) with the level of reduction corresponding to the clinic's total performance score. However, for PY 2013, CMS is proposing a more rigorous sliding scale of payment reductions. (The minimum reduction proposed is 1.0 percent.) It is also proposing to require a total performance score of 30 that providers/facilities would need to achieve in order to avoid a reduction. We have two concerns about this proposal. First of all, it appears that most dialysis clinics would be subject to a reduction in reimbursement if the proposed 2013 QIP scoring methodology is implemented. This would result in draining resources for patient care from the Medicare ESRD Program. Secondly, the change in scoring methodology will confuse patients. That confusion will be compounded if CMS adopts a scale for PY 2014 that is similar to the scale for PY 2012, as is proposed in the draft regulation. With different scales for each year, it will be impossible for patients to evaluate trends in the quality of care they receive.

C. ESRD QIP FOR PY 2014

1) Clinical Measures

a. Dialysis Adequacy

The National Kidney Foundation urges CMS to stimulate the development of an adequacy measure for hemodialysis patients who dialyze more than 3 times per week, either at home or in a clinic.

b. Vascular Access Type Measure

A vascular access measure is important because choice of vascular access affects many of the other parameters of care that CMS has proposed to emphasize in the Quality Incentive Program, e.g. adequacy of dialysis, infection, hospitalization. Nevertheless, the proposed measure is flawed because it ignores the many patients who are not candidates for placement of an AV fistula but whose outcomes could be enhanced by the placement of a synthetic graft. Similarly, the measure should not be limited to dialysis patients who are Medicare beneficiaries. The "Fistula First" program, which tracks progress in choice of vascular access, is not limited to Medicare beneficiaries, nor is the CMS Clinical Performance Measure project. Furthermore, decisions about vascular accesses should be made before a beneficiary becomes entitled to Medicare because of ESRD. We note that the proposed measure could discriminate against new dialysis clinics that might have a large proportion of patients who are initiating dialysis, and therefore, who may not yet have permanent vascular access. Finally we are concerned that for the catheter component of the Vascular Access Type measure, CMS is only be able to provide example performance standards from October 1, 2010 through November 30, 2010. We believe that performance measures should be based upon a full year of data.

c. Vascular Access Infections Measure

The National Kidney Foundation's Vascular Access Guidelines, which are part of the Kidney Disease Outcomes Quality Initiative (KDOQI), recommend different target rates for infection control with different kinds of vascular access. (Please see Guideline #32, which recommends less than 1% per year for fistulas, less than 10% per year for grafts and less than 50% for catheters. ***American Journal of Kidney Diseases***, Vol 48, no 1, Suppl 1, July 2006.) Hence, depending on the case-mix of accesses in particular units, there will be markedly different risks for bacteremia. Some providers have used percentage of infections per patient-year at risk as a quality improvement measure. The United States Renal Data System uses the measure of hospital admissions per 1000 patient-years for bacteremia and sepsis. However, we are not aware of any precedent for the metric that CMS has proposed for the Vascular Access Infections Measure

d. Standardized Hospitalization Ratio (SHR) Admissions measure

According to the latest Annual Report from the United States Renal Data System, there were 1.9 hospital admissions per patient year for hemodialysis patients in 2008. Hospital days per patient year for hemodialysis patients were 12.8 in the same period. This is obviously an area for concern. On the other hand, because the SHR measure proposed by CMS could lead to "cherry picking" of patients, and resulting deficiencies in access to care for sicker individuals with multiple chronic conditions, NKF suggests that the measure be focused on admissions that could be prevented by interventions by dialysis facilities/providers. Examples of such causes for admission are: congestive heart failure, fluid overload, hyperkalemia. Because of the problems with this measure, we suggest that it not be given the same weight as the other clinical measures.

2) Reporting Measures

The three "reporting" measures that CMS proposed are: patient experience of care; bone mineral metabolism reporting; and National Health Safety Network (NHSN) dialysis event blood stream infection reporting

a. Patient Experience of Care

The NKF Patient and Family Council applauds the agency's desire to enhance efforts for evaluating the experience of care of dialysis patients. On the other hand, the NKF Council of Nephrology Social Workers questions the assumption that the ICH CAHPS is the only acceptable tool for measuring patient satisfaction. The members of the CNSW Executive Committee are concerned about the number of questions in the CAHPS survey. Patients may be reluctant to complete a survey that has more than 20 questions. As a result, we are concerned that the response rate to the CAHPS survey would be so low that it would not provide meaningful direction for quality improvement initiatives. As an alternative, CMS could revise the measure so that dialysis clinics could report the administration of any validated survey for patient experience of care.

b. Bone Mineral Metabolism

We recommend that the measure for bone mineral metabolism reporting be expanded to include PTH. Ideally a composite measure that would incorporate PTH, calcium and phosphorus could be used to encourage the maintenance of an appropriate balance in which all three are close as possible to the normal range, but we recognize that this may be difficult to formulate. Due to the morbidity and mortality risks associated with extreme PTH values, we believe it is important to

monitor the number of patients with PTH below 100 pg/mL, and above 400 pg/mL who are not on therapy.

D. FUTURE QIP MEASURES

1. Iron Measures: An overarching principle is that patients whose iron is too low should be supplemented and patients whose iron is too high should not be supplemented. According to the 2006 KDOQI Anemia guideline, patients should have a minimum TSAT of 20 % and a minimum ferritin of 200 ng/mL. The public review draft of the forthcoming KDIGO Clinical Practice Guideline for Anemia in CKD suggests that IV iron be administered in adult patients in whom an increase in hemoglobin concentration is desired, if their TSAT is < 30% and ferritin is < 500 ng/mL. The exact tradeoff between more iron and less ESA is not known, but hemoglobin response to additional iron is lower at higher ferritin levels. With little evidence for a specific upper ferritin limit, a measure for trends in ferritin may be of some value.

2. Serum Phosphorus Upper Limit. From a patient safety perspective, there is evidence linking hyperphosphatemia to poor outcomes. Observational data show that there is a strong association in dialysis patients of high serum phosphorus levels with mortality and cardiovascular events. The threshold above which risk is increased varies across studies from 5.0-7.0 mg/dL. An upper limit of 6.0 mg/dL might be a place to start.

3. NKF supports a QIP measure for proportion of patients with hypercalcemia, such as Measure #1454 , recently endorsed by the National Quality Forum Board of Directors: Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL. This is consistent with the Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease – Mineral and Bone Disorder (CKD-MBD) developed by the Kidney Disease Improving Global Outcomes (KDIGO) initiative and published in ***Kidney International***, Volume 76, Supplement 114, August 2009.

4. For the reasons mentioned above with regard to reporting measures for the QIP in 2014. NKF supports the development of Clinical Measures for PTH.

E. FINAL COMMENTS

In the Proposed Rule for the ESRD Prospective Payment System (Federal Register, September 29, 2009) CMS provided examples of items and services, such as time on machine, nutritional services, social work services, and nursing services, for

which additional data are needed to predict cost. In the Final Rule for the ESRD Prospective Payment System, the agency stated that further direction in this regard will be provided in the future. These components of patient care are of high concern to NKF constituents. Therefore, we urge CMS to proceed with its examination of these items and services. Lastly, as stated in our letter of December 11, 2009, we are concerned that there would be little incentive towards innovation from the medical products industry for new diagnostic tools and/or new therapies for this relatively small market if a product is placed under the bundle. Dialysis providers will not have the financial resources to acquire and use such new products. Pharmaceutical manufacturers will have little inducement to develop new medications targeting appropriate needs of dialysis patients. This will be particularly true for managing anemia and bone and mineral metabolism disorders in kidney failure. By potentially stifling innovation, and clinical research, bundling could reduce the likelihood of future improvements in patient care. CMS should explore a mechanism like the transitional pass-through payment for drugs, biologicals, and radiopharmaceutical agents under the Medicare hospital outpatient prospective payment system (OPPS). Such a mechanism is an essential aspect of other prospective payment systems and the ESRD Bundled Prospective Payment System should be no exception.

Thank you for your attention to the comments of the National Kidney Foundation.

Sincerely,

Lynda A. Szczech

Lynda A. Szczech, MD
President
National Kidney Foundation, Inc.