September 30, 2011

The Honorable Max Baucus
United States Senate
Washington, DC 20510

Dear Senator Baucus:

In the current bundled prospective payment environment for kidney dialysis services, the Centers for Medicare and Medicaid Services (CMS) must continue to protect individuals on dialysis who need anemia therapy. Therefore, we urge you to join the National Kidney Foundation (NKF), America's oldest and largest kidney patient organization, in urging CMS to address the potential unintended consequences that could result from its proposal to retire an anemia measure in the Medicare End Stage Renal Disease (ESRD) Quality Incentive Program (QIP). Those unintended consequences could include an increase in the use of transfusions to ameliorate anemia in dialysis patients.

In the Federal Register for July 8, 2011, and with regard to payment year 2013, CMS proposed to retire a measure for percentage of Medicare patients with an average Hemoglobin Less Than 10g/dL (a measure of low red blood cell count or anemia) while continuing plans to utilize that measure in the QIP for 2012. 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. 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, CMS could develop a QIP measure for Hemoglobin Less Than 10g/dL for reporting purposes only. Such a measure should be based on data that are no more than 6 months old, and 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.

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. Given that need for transfusion at the population level increases when hemoglobin falls below 10, using the percentage of patients with hemoglobin < 10 g/dL as a quality indicator would appear to be both clinically meaningful and consistent with FDA labeling. In fact, for dialysis patients with anemia, the package insert recommends that ESA treatment be initiated when the

hemoglobin level is less than 10 g/dL and that the dose of ESA should be reduced or interrupted only if the hemoglobin level approaches or exceeds 11 g/dL. **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. According to the University of Michigan DOPPS Practice Monitor, the percentage of black dialysis patients having hemoglobin levels less than 10g/dL rose from 8.7% to 11.1% after three months of bundling while there was little to no change in non-blacks.

Finally, there has been a decrease in the mortality rate of dialysis patients since ESAs were made available for anemia therapy in this population in 1989. As indicated in the U.S. Renal Data System 2010 Annual Report, the five-year probability of survival among patients who developed chronic kidney failure or End Stage Renal Disease during the period from 1999 through 2003 increased 8.4 percent when compared to survival among new patients in the 1994-1998 period. This finding should inform decision making about the tradeoffs between risk of cardiovascular events and the benefits of ESA therapy.

NKF made its concerns known to CMS before the August 30 deadline for comment on the Proposed Rule and would be pleased to provide additional information for congressional offices that wish to join in the campaign to protect Medicare beneficiaries who need access to ESA treatment to avoid transfusion and restore and maintain the highest quality of life possible. For additional information on this

critical issue, kindly contact Dolph Chianchiano, Health Policy Advisor for the National Kidney Foundation, at dolphc@kidney.org

Thank you for your attention to our concerns.

Sincerely,

Lynda A. Szczech

Lynda A Szczech, MD

President