March 26, 2013

Jonathan Blum
Deputy Administrator and Director for the Center of Medicare
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 314G
200 Independence Ave., SW
Washington, DC 20201

Dear Mr. Blum:

As the nation's leading kidney disease and dialysis patient advocacy organizations, we are contacting the Centers for Medicare and Medicaid Services (CMS) to provide feedback and guidance with regards to current Medicare policy and erythropoiesis-stimulating agents (ESAs) utilization. With the inclusion of ESAs into the End Stage Renal Disease (ESRD) Program Prospective Payment System ("the bundle"), label changes made by the Food and Drug Administration (FDA), and the subsequent removal of the sub 10 g/dL hemoglobin measure from the Quality Incentive Program (QIP), there have been significant changes in ESA utilization. These changes have generated growing evidence of negative patient outcomes, including lower hemoglobin levels and increased reliance on blood transfusions. **As CMS moves forward with the bundle rebasing process and updates to the QIP measures, we urge CMS to carefully consider patient quality of care with regard to ESA utilization and anemia management.**

According to the Government Accountability Office (GAO) report in December of 2012, decreased use of ESAs in 2011 significantly contributed to a 23 percent drop in ESRD drug utilization. The report urged CMS to adjust the bundle rate accordingly. However, the percentage of ESA-treated patients that have a hemoglobin level below 10 g/dL has more than doubled from 9 percent in August 2010 to 20 percent in August 2012.[1] This is problematic in that mortality rates increase substantially when blood hemoglobin levels are less than 11 g/dL.[2] We believe this concerning trend is evidence of the need to amend the QIP either by reinstating a lower-limit hemoglobin level or by adding some other anemia management measure, such as transfusion rates. While we understand the removal of the sub-10 g/dL measure following the ESA label change by the FDA, we are extremely concerned that patient quality of care is not being properly measured.

Adding a new anemia management measure to the QIP would also incentivize providers to work more closely with prescribers to help maintain more constant blood hemoglobin levels. Under the current incentive structure, dialysis centers are not held accountable for the fluctuation of hemoglobin levels as long as those levels stay below 12 g/dL. Fluctuation in hemoglobin levels has also been linked to increased morbidity among kidney patients.[3]

Further, data from the United States Renal Data System (USRDS) reinforces the growth of these concerning trends. Evidence shows that between September 2010 and September 2011, the percentage of patients who received at least one red blood cell transfusion increased from 2.4 to 3.0, a relative increase of 24 percent.[4] Red blood cell transfusions

[1] DOPPS Practice Monitor, December 2012
[2] DOPPS Practice Monitor, November 2005
[3] DOPPS Practice Monitor, February 2011
[4] "United States Renal Data System 2012 Annual Report," United States Renal Data System, page 320.

are particularly troubling for kidney disease patients. For individuals who are pursuing an organ transplant, transfusions can introduce antibodies that interfere with transplantation. Transfusions may also lead to potentially fatal potassium overloads in dialysis patients and can cause congestive heart failure in the presence of severe chronic anemia, particularly in the elderly. And, there is always the possibility of infection due to the imperfect pathogen screening process. With more than 415,000 people on dialysis, a number that is expected to double over the next decade, the impact of greater reliance on blood transfusions will also increase demand for an already limited blood supply in the United States. Therefore, in the dialysis community, blood transfusions should be the treatment of last resort.

While we recognize that the latest Dialysis Outcomes and Practice Patterns Study (DOPPS) report found that the number of cardiovascular events and strokes has decreased and hemoglobin levels appear to have stabilized for the time being, we remain concerned over the many potentially adverse impacts on patients.

During the forthcoming bundled payment rebasing process, we hope that CMS will consider the impacts of the recent changes in ESA utilization. We want to ensure that CMS rebasing does not drive practice patterns further in the direction of increased transfusions to the detriment of patient outcomes. CMS must also work quickly to return a blood hemoglobin lower limit or other appropriate anemia management measure to the QIP. While we understand the reasoning to incentivize reduced use of ESAs in the QIP, we call on CMS to instead incentivize *proper anemia management*. It is essential not to discount the adverse effects of under-prescribing these necessary anemia management medications.

As patient advocacy groups, we are grateful for CMS's commitment to ensuring high quality care for all dialysis patients. We appreciate your attention to this issue and your consideration of our input. We would like to offer ourselves as a resource as this process moves forward and we welcome the chance to work with you on this important matter in the future.

Sincerely,

American Association of Kidney Patients
American Kidney Fund
Dialysis Patient Citizens
Home Dialyzors United
Medical Education Institute
National Kidney Foundation
Renal Support Network