February 2, 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 input and guidance with regards to current Medicare policy and erythropoiesis-stimulating drugs (ESAs). 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 is evidence that there have been substantive changes in ESA prescribing patterns. While it is true that reduced use of ESAs has generated a lower rate of ESA-related cardiovascular incidents, there is also growing evidence of adverse patient outcomes, primarily lower hemoglobin levels and increased reliance on blood transfusions. As CMS moves forward with the bundle rebasing process and updates the ESRD Program QIP, we urge CMS to carefully consider patient quality of care with regards 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 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 maintain more constant blood hemoglobin levels. Under the current incentive structure, dialysis centers are not held accountable for 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]

Additionally, according to the United States Renal Data System (USRDS), 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] With 400,000 people on dialysis and another 700,000 with stage 4 & 5 chronic kidney disease

[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.

(CKD), the impact of greater reliance on blood transfusions as an anemia management tool will increase demand for an already limited blood supply in the United States. There are also serious risks associated with red blood cell transfusions. It is not possible to test for every pathogen in every blood transfusion, so the risk for infection is real. Transfusions can also lead to congestive heart failure in the presence of severe chronic anemia, particularly in the elderly population. Transfusions carry many risks that are specific to kidney disease patients as well, such as potentially fatal potassium overload. Moreover, red blood cell transfusions can induce antibodies that interfere with transplantation, and transfusions should therefore be avoided in patients awaiting a kidney transplant. In short, blood transfusions are meant to be a treatment of last resort – not first.

During the forthcoming bundled payment rebasing process, we hope that CMS will consider both the positive and negative 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. Instead of solely focusing on ESAs, we urge CMS look at the system as a whole. 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. Overprescribing ESAs before the bundled payment system posed significant harm to patients, but it is essential not to discount the adverse effects of under-prescribing these necessary anemia management medications.

As patient advocacy groups we are proud to share CMS's commitment to ensuring high quality care for all dialysis patients. We thank you for the opportunity to share our feedback and welcome the chance to work with you on this important issue in the future.

Sincerely,

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