February 20, 2013

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Rebasing of the End State Renal Disease Prospective Payment System

Dear Ms. Tavenner:

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 as the Agency prepares to rebase the Medicare End Stage Renal Disease (ESRD) Program Prospective Payment System ("the bundle").

We would like to offer our organizations as resources to CMS as the rebasing process moves forward. We think CMS should engage with the dialysis patient advocates to ensure a comprehensive and thoughtful rebasing process. As representative voices for the country's almost 500,000 ESRD and 31 million chronic kidney disease patients, we can provide valuable insights into the needs and wants of those living with kidney disease. With the goal of ensuring continued patient access to high quality care, including patient groups in the process will guarantee that the patient voice is heard and considered as plans for rebasing move forward. When CMS begins the rebasing process, we have several principles and priorities we would like the Agency to consider.

1. We are extremely concerned by the Food and Drug Administration's (FDA) ESA label change.

Since the FDA changed the label for erythropoietin stimulation agents (ESAs), there have been some disconcerting shifts in patient outcomes. We are pleased that the rate of cardiovascular incidents has declined with the drop in ESA utilization, but that is not the complete story. Recent data from the Dialysis Outcomes and Practice Patterns Study (DOPPS) Practice Monitor indicates that these changes in drug utilization have created a more mixed set of patient outcomes. The percentage of ESA-treated patients who have hemoglobin levels less than 10 g/dL has more than doubled from 9 percent in August

2010 to 20 percent in August 2012.[1] This increase in lower hemoglobin levels can have a dramatic impact on patients' day-to-day health and quality of life. Additionally, the United States Renal Data System (USRDS) continues to report an increasing rate of dialysis patient blood transfusions, which expose patients to infectious disease risks, fluid and potassium overload, and sensitization that could make kidney transplantation difficult—or even impossible.[2] While we plan to share these same concerns with the FDA, **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.**

2. We agree with the Medicare Payment Advisory Commission that one year of data is premature for rebasing.

At the same time, we recognize that CMS must proceed with rebasing as mandated by law. Therefore, we urge the Agency to use the most current and accurate data available. For rebasing to reflect current usage and pricing trends, it is vital for any updates to use timely data. Out-of-date information could dramatically compromise patient care, especially if the result is a reimbursement rate that does not cover the cost of providing care for dialysis patients. We understand that this is not an easy process, but also know that CMS is making it a priority to utilize more timely data. W**e urge CMS to provide transparency on how rebasing will be calculated, while also ensuring that it uses the most recent and accurate data.**

3. We want to protect the integrity of the ESRD system.

Our top priority is to ensure that all dialysis patients receive access to high quality care, and we know that CMS shares this commitment. Therefore, we urge CMS to use the rebasing process to address other outstanding issues with the ESRD bundled payment rate. Such issues include the case mix adjuster and standardization factor. We understand that the efforts to start the rebasing process were driven, at least in part, by the Government Accountability Office (GAO) December 7, 2012, report that suggests the bundled payment rate is too high as a result of the decrease in drug utilization between 2007 and 2011. The report finds that drug utilization in the final quarter of 2011 was about 31% lower than the average in 2007, driven mainly by changes in use of ESAs.[3] We encourage CMS to examine these changes but we hope this will not be the Agency's only focus in the rebasing process. The GAO report explicitly states that it only examined utilization patterns of injectable drugs because that was the narrow focus of its mandate. However, GAO also writes, "we would expect CMS to consider utilization and other factors in rebasing."[4] **We know that CMS can address outstanding items like the case mix adjuster or standardization factor to make sure that the new rate more accurately reflects the costs of services that patients receive, and therefore, would help to ensure the quality of care required for people with ESRD .**

[1] DOPPS Practice Monitor, December 2012.
[2] "United States Renal Data System 2012 Annual Report," United States Renal Data System, page 320.
[3] "Trends in ESRD Drug Utilization," Government Accountability Office, GAO-13-190R, December 7, 2012, Page 6
[4] "Trends in ESRD Drug Utilization," Government Accountability Office, GAO-13-190R, December 7, 2012, page 10.

As organizations that represent people with kidney disease, 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,

American Kidney Fund

Dialysis Patient Citizens

National Kidney Foundation

Renal Support Network

cc: Jonathan Blum, Deputy Administrator and Director, Center for Medicare
Laurence D. Wilson, Director, Chronic Care Policy Group, Center for Medicare