

House Committee on Ways and Means

Statement of Kidney Care Partners

The undersigned members of Kidney Care Partners (KCP) appreciate the opportunity to provide written testimony to the Committee regarding the intersection of anemia management and Medicare policy. We commend the Committee for its efforts to learn more about anemia management for individuals with kidney disease and kidney failure. Through the Medicare program, the federal government has assumed responsibility for the health and safety of dialysis patients. Therefore, it is appropriate that the Committee examine the optimum care patients should receive, including issues related to drug utilization.

KCP is a coalition of patient advocates, dialysis providers, physicians, nurses, and manufacturers. Our mission, individually and collectively, is to ensure: (1) chronic kidney disease patients receive safe and optimal care; (2) chronic kidney disease patients are able to live quality lives; (3) dialysis care is readily accessible to all those in need; and (4) research and development leads to enhanced therapies and innovative products.

Our members are dedicated to providing the highest standard of care and ensuring patient safety. The Centers for Medicare and Medicaid Services (CMS), the Government Accountability Office (GAO), the Medicare Payment Advisory Commission, and other organization have recognized the improvement of quality by the kidney care community during the last ten years. We continue to support innovative policy initiatives that reward improvements in care and the attainment of quality benchmarks. As part of our efforts, KCP launched the Kidney Care Quality Alliance, which has developed a starter set of quality-related measures that could be used to evaluate and reward high quality care in the kidney care community.

In light of the recent studies published in the *New England Journal of Medicine*, KCP agrees that it is essential for the kidney care community to continue examining all available data to ensure that public policies reflect appropriate anemia management for patients with kidney disease and kidney failure. We are committed to working with clinical researchers to determine the appropriate hemoglobin levels for these patients. We also reaffirm our ongoing commitment to work with the Congress and CMS to ensure that Medicare policy reflects the best science and ensures the welfare of patients, the public interest, and Medicare's stewardship of patients with kidney disease.

Anemia is a complication of kidney disease, which is known as Chronic Kidney Disease (CKD) and kidney failure, also known as End Stage Renal Disease (ESRD or Stage V kidney disease). Patients with kidney failure suffer from anemia because their kidneys do not produce a hormone (erythropoietin) that regulates red blood cell production. Anemia has a profound physiological effect^[1] on every organ system (including the brain) and directly affects patients' quality of life.^[2] Anemic kidney disease patients have more difficulty performing activities of daily living and maintaining employment. They experience lower vitality and may suffer from depression.^[3] Doctors determine a patients' degree of anemia with simple blood tests, measuring the hemoglobin or

hematocrit levels. A healthy man has a hemoglobin level of 15 (roughly a hematocrit level of 45 percent), with slightly lower values in healthy women. Before effective treatment was available, a dialysis patient would typically have severe anemia with a hemoglobin level lower than 11 (hematocrit level of lower than 33 percent).

There is a large and extensive peer-reviewed volume of literature discussing what the optimal target hemoglobin/hematocrit level for patients with kidney failure should be. For example during the past ten years, several observational studies have suggested that higher hemoglobin levels reduce the risk of hospitalization and death, while increasing cognitive function.[\[4\]](#) As one of these studies suggests, these outcomes could result in lower costs to the Medicare program. Specifically, it found that Medicare patients with hematocrit values of 36 to less than 39 cost the program significantly less than those patients with hematocrit values of less than 30.[\[5\]](#) Other prospective clinical trials have not observed benefits with higher hematocrit levels.[\[6\]](#) The FDA label recommends maintaining patients at a hemoglobin level of 10-12.

Two recent studies published in the *New England Journal of Medicine*, which have engendered substantial controversy and discussion, demonstrate the continuing debate within the scientific community. The CHOIR study[\[7\]](#) indicated an association in kidney disease patients not yet on dialysis (patients diagnosed with Stages III and IV kidney disease) between higher hemoglobin levels and an increased risk for cardiovascular morbidity and death. The CREATE study[\[8\]](#) (which was also published in the same November issue of the *New England Journal of Medicine*), in a similar group of patients not yet on dialysis, found no significant difference in the combined incidence of severe adverse events between the higher and lower hemoglobin groups, although hypertensive episodes and headaches were more frequent in the former group.

Clinical studies have found that determining optimal hemoglobin levels is also complicated by patient variability in their response to the drug. Researchers believe patient comorbidities, intercurrent events like hospitalization, and practice patterns contribute to this variability, which is not unique to the kidney care community. One recent study concluded that the variability in the response of hemoglobin levels to epoetin treatment over time in individual patients may account for moving 28 percent of all dialysis patients above and below the target hemoglobin levels during a one-year timeframe.[\[9\]](#) Other studies support this finding as well.[\[10\]](#) Because of this variability in patient physiology, optimal anemia management requires a highly individualized approach to treatment.[\[11\]](#)

Congress and CMS should take all available studies, as well as the Food and Drug Administration (FDA) label, into account when setting Medicare policy. For example, the recent CMS EPO Monitoring Policy, issued before the publication of the CHOIR and CREATE studies recognizes the need for reimbursement policy to take into account patient variability. When reviewing this policy, it is important to understand that it is not a treatment guideline. Rather, it is a reimbursement auditing tool. Under the policy, if a patient's hemoglobin reaches 13 and the dose is not reduced, then CMS will reduce the payment 25 percent. It does not call for, nor recommend, that patients' hemoglobin levels should be maintained above 12.

In addition to the EPO Monitoring Policy, Congress may also consider anemia management studies when discussing reforms to the ESRD payment system. If Congress is considering payment revisions that incorporate any or all separately billable drugs or biologics into the composite rate, it is vital that an appropriate case-mix adjuster be developed that accounts for the variability in patient response to medications and the lack of predictability. Currently, there are no universally accepted case-mix adjusters for patients on dialysis that address patient variability in drug utilization. In its attempts to develop an ESRD bundle, CMS has recognized the difficulties of accounting for this variability as well: “Implementation of a revised outpatient ESRD payment system without consideration of this patient specific variability may compromise patient access to quality of care.”[\[12\]](#) In addition, it is critically important that if a bundle is adopted, Congress also provide an annual update mechanism that would allow CMS to provide updates to the base rate. Currently, the Medicare ESRD program is the only Medicare program without such an update mechanism. These challenges must be met before such revisions are made.

Congress should examine all of the literature before advising any policy changes. The recent trials should be reviewed along with those that are already a part of the literature, as well as the FDA package insert. Policy should not be based upon the result of a single clinical trial. KCP members are committed to continuing their work with experts in the kidney care community to determine appropriate hemoglobin levels for patients with kidney failure, as well as with the Congress and CMS to ensure that Medicare policy reflects the consensus of the scientific community.

KCP appreciates the opportunity to provide these comments to the Committee. Patient safety and quality care are at the heart of this discussion. It is imperative that the community and government promote the safest practices with the highest quality of care. We look forward to expanding upon our comments based upon today’s discussion as well.

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses’ Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Renal Administrators Association

**Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Satellite Healthcare
U.S. Renal Care
Watson Pharma, Inc.**

[1] Morrell Michael Avram, *et al.*, "Hemoglobin Predicts Long-Term Survival in Dialysis Patients: A 15-Year Single-Center Longitudinal Study and a Correlation Trend between Prealbumin and Hemoglobin" 87 *Kidney Internat'l* (Supp.) S6-S11, S9 (2003).

[2] Allen R. Nissenson & Lawrence T. Goodnough, "Anemia: Not Just an Innocent Bystander?" 163 *Arch. Intern. Med.* 1400 (June 23, 2003).

[3] Hans Furuland *et al.*, "A Randomized Controlled Trial of Haemoglobin Normalization with Epoetin Alfa in Pre-Dialysis Patients" 18 *Nephrol. Dial. Transplant* 353-61 (2003);

[4] S. Li & A.J. Collins, "Association of Hematocrit Value with Cardiovascular Morbidity and Mortality in Incident Hemodialysis Patients" 65 *Kidney Int.* 626-33 (2004); A.J. Collins, *et al.* "Death, Hospitalization, and Economic Associations among Incident Hemodialysis Patients with Hematocrit Levels of 36 to 39%" 12 *J. Am. Soc. Nephrol.* 2465-73 (2001); A.J. Collins, *et al.*, "Hematocrit Levels and Associated Medicare Expenditures" 36 [] 282-93 (2000); F. Locatelli, *et al.*, "Anemia in Haemodialysis Patients of Five European countries: Association with Morbidity and Mortality in the Dialysis Outcomes and Practice Patterns Study (DOPPS) 19 *Nephrol. Dial. Transplant* 121-32 (2004); N. Ofsthun *et al.*, "The Effects of Higher Hemoglobin Levels on Mortality and Hospitalization in Hemodialysis Patients" 63 *Kidney Int.* 1908-14 (2003); E.G. Lowrie *et al.*, "Medical Outcomes Study Short Form-36: A Consistent and Powerful Predictor of Morbidity and Mortality in Dialysis Patients" 41 *Am. J. Kidney Dis.* 610-9 (2003).

[5] Allan J. Collins *et al.* "Death, Hospitalization, and Economic Associations among Incident Hemodialysis Patients with Hematocrit Values of 36 to 39%" 12 *J. Am. Soc. Nephrol.* 2465-73 (2001).

[6] A. Besarab *et al.*, "The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin" 339 *N Engl J Med.* 584-90 (1998).

[7] Ajay K. Singh, *et al.*, "Correction of Anemia with Epoetin Alfa in Chronic Kidney Disease" 355 *N Engl J Med* 2085-98 (2006).

[8] Tilman B. Drueke, *et al.*, "Normalization of Hemoglobin Level in Patients with Chronic Kidney Disease and Anemia" 355 *N Engl J Med* 2071-84 (2006).

[9]E Lacson *et al.*, “Effect of Variability in Anemia Management on Hemoglobin Outcomes in ESRD” 41 *Am J. Kidney Dis.* 111-24 (2003).

[10]Norma J. Ofsthun, *et al.*, “The Impact of the Change in CMS Billing Rules for Erythropoietin on Hemoglobin Outcomes in Dialysis Patients” *To Be Presented at RRI International Dialysis Conference* (January 2007).

[11]Norma Ofthun *et al.*, “The Effects of Higher Hemoglobin Levels on Mortality and Hospitalization in Hemodialysis Patients” 63 *Kidney Internat’l* 1908-14, 1913 (2003).

[12]Department of Health and Human Services, “Report to Congress: Toward a Bundled Outpatient Medicare ESRD Prospective Payment System” 22 (2003).