

**Statement of Kidney Care Partners**

Before the House Committee on Ways and Means  
Subcommittee on Health  
Hearing on Ensuring Kidney Patients Receive Safe and  
Appropriate Anemia Management Care

June 26, 2007

## **Introduction**

Chairman Stark, Representative Camp, and distinguished members of the Subcommittee, the undersigned members of Kidney Care Partners (KCP) thank you for the opportunity to provide written testimony regarding anemia management and the continuing effort to ensure safe and appropriate care for patients with End Stage Renal Disease (ESRD). KCP is a nationwide alliance of representatives from the entire kidney care community, including patients and their advocates, nephrologists, nurses, dialysis care providers, and manufacturers who have joined together to improve the quality of care and quality of life for individuals suffering from kidney disease and kidney failure.

KCP recognizes the serious and important questions that have been raised by recent analyses in the area of anemia management. KCP applauds the efforts of those who have demonstrated concern for the safety of different patient populations within the ESRD program and remains committed to the need for careful consideration of drug utilization patterns as new research is released. Advancements within the kidney care community during the last ten years have been well documented, and KCP desires to build on this history by volunteering the collective knowledge, experience, and perspective of its members as Congress reviews issues related to anemia management and endeavors to improve the ESRD program.

## **Commitment to Safe and Appropriate Anemia Management**

The kidney care community believes strongly that there should be one motivation for determining utilization of drugs used to treat anemia, and that motivation is patient well-being. The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) Guidelines and the Clinical Performance Measures (CPMs) developed by CMS and the ESRD Networks provide critical guidance for physicians to use as they work to keep patients feeling well, while also meeting important medical standards. KCP also believes there should be one goal for anemia management policy, and that goal is ensuring safe and high quality care. To those ends, KCP puts forth the following guideposts as essential to a proper consideration of anemia management and related policy.

First, drugs used to treat anemia have a history of enhancing patient care by improving clinical conditions and quality of life while reducing the risks from transfusions. In particular, KCP would like to point out with pride the continuous improvement in the mortality rate of ESRD patients for the past 10 years that has been repeatedly highlighted in the USRDS data. KCP believes any well-balanced consideration of anemia management and related policy should be attentive to this reality and this record.

Given the kidney failure patients on dialysis have experienced, treatment with erythropoietin stimulating agents (ESAs) ensures that dialysis patients have the hemoglobin levels necessary to sustain their energy levels and physical functioning, thereby improving patients' ability to engage in typical daily activities, including parents' capacity to raise their children and employees' potential to head to work.

Moving from the patient to the aggregate level, ESAs have been part and parcel of the kidney community's ability to advance the quality of care during the past ten years. As the Centers for Medicare and Medicaid Services (CMS) stated, "Since 1994, [CMS] has documented continued improvements, specifically in the adequacy of dialysis and anemia management. The providers of

dialysis services are to be commended for their ongoing efforts to improving patient care.”<sup>1</sup> CMS’ findings reflect the fact that most ESRD patients meet the CPM benchmarks developed by the Agency in consultation with independent experts. Ensuring that patients meet the core standard of the CPMs (*i.e.*, hemoglobin levels > 11g/dL) means that there are fewer hospitalizations and lower expenses for the Medicare program.

More directly, ESAs have reduced the rate of transfusion in the dialysis population, which has helped reduce the risk from transfusion, lower the impact on antibodies in transplant candidates, and mitigate the chance of infection and iron overload. These benefits, as well as ESAs’ ability to improve patient quality of life, should be considered in striking a safe and appropriate balance for individual ESA use.

Second, the entire kidney care community is committed to the highest standards and the most current science on anemia management. The community, however, is also acutely aware of the need for anemia management policy to be sensitive with respect to patients’ varied physiologic responses to ESAs and responsible with regard to the unanswered questions that overlay current anemia management research.

Because each patient receiving dialysis responds differently to the drugs used to treat anemia, it is not possible to determine a single dosing regime that works for all patients at all times. This means that physicians must establish unique dosing regimes for each patient for whom they provide care. Ultimately, a system impeding this flexibility is a system impeding its own goals of safe and appropriate care.

This point underscores the need for responsible action when reacting to current research on drug utilization in anemia management. There can be no doubt that current research raises many significant questions, but not all of the questions raised may be fully applicable to ESRD patients. The study results of CHOIR and CREATE, as reported in the *New England Journal of Medicine (NEJM)*, for example, focused on patients with kidney disease, but not those in full kidney failure (ESRD). As CMS has noted, “Anemia management for patients with ESRD cannot be assumed to be the same for patients, often younger, with chronic kidney disease who do not require dialysis...Patients receiving dialysis are exposed to clinical situations that patients with [Chronic Kidney Disease] CKD not requiring dialysis are not exposed to, including artificial kidney membrane exposure, large fluid shifts during dialysis...” and other situations.<sup>2</sup> In addition, the *NEJM* studies looked at patients intentionally maintained at hemoglobin levels outside the target range of 11-12 g/dL.

Although we believe it is important to review these studies in the context of current treatment protocols, policy-makers should not rush to judgment and implement broad policy changes based upon only a few studies where experts have yet to determine how they relate to patients with kidney failure and current practice protocols. Policy-makers must have access to the best cumulative data to answer properly the question of appropriate anemia management policy, and KCP is committed to maintaining a proactive dialogue as new research becomes available.

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<sup>1</sup> Centers for Medicare and Medicaid Services, *2005 ANNUAL REPORT ESRD CLINICAL PERFORMANCE MEASURES PROJECT 35&38* (2005).

<sup>2</sup> Statement of Leslie V. Norwalk, Acting Administrator, Centers for Medicare and Medicaid Services, Before the House Committee on Ways and Means, December 06, 2006.

As part of this cautious approach, KCP firmly and steadfastly rejects any effort to use current research on anemia management as a justification to withdraw funding from the ESRD program. The trail of concern leading to this hearing has been paved with the logic of structural reform, not the need for payment cuts. If one is convinced that the incentives are misaligned with respect to drug utilization, then it is the incentives that need to be fixed. Resources should not be taken away from the ESRD program.

### **Commitment to Overall Quality in Patient Care**

To the extent that questions about safe and effective care are driving the reform agenda, the discussion should not end with consideration of drug utilization alone. On the contrary, a genuine commitment to appropriate care should be carried through with respect to ensuring that the ESRD program as a whole continues to be structured so as to provide the highest quality care to patients with irreversible kidney failure.

At the broadest level, policies affecting patients with ESRD must be based upon the goal of ensuring continued improvements in the quality of care provided, and any changes to the system must reflect and advance this goal. More specifically, this means that policies impacting care for ESRD patients should ensure there are no incentives driving utilization. This requires equal vigilance against the possibility that patients will be under-provided essential drugs and services, or worse yet, selected against by a structural impetus to “cherry pick” relatively healthier patients with advantageous treatment scenarios.

Put another way, any reform effort should seek to enhance the existing high quality of the community and not hinder it. According to the most recent data collected by CMS, more than 90 percent of patients attain dialysis adequacy, approximately 83 percent have hemoglobin levels above 11, 82 percent have albumin levels (an indicator of nutrition) greater than 3.5 g/dL, and 54 percent of patients have an AV fistula as their access. These data demonstrate the quality has improved substantially over the years; yet, there is more that can be done. To that end, KCP strongly supports implementing a continuous quality improvement program, as outlined in legislation introduced by Representatives John Lewis and Dave Camp.

Quality in patient care is also a product of the stability and sustainability of the treatment system. At present, however, there is a piece missing from a stable programmatic foundation. While every other prospective payment system within Medicare is provided an annual update mechanism tied to inflation, so that the commitment to quality in those programs is paired with the resources necessary for its attainment, the ESRD program does not include such an assurance. Moreover, ESRD providers operate in a competitive marketplace with other health care providers that receive annual updates under their payment systems. Providers receiving annual updates enjoy a significant advantage in their ability to offer compensation designed to attract and retain nurses and other professional staff, for example. Over time, the lack of an annual update mechanism could impede ESRD providers’ ability to remain competitive with other health care sectors.

It is equally critical that any reform effort look beyond the clinical aspects of the ESRD program to consider the broader potential to make strides by renewing the community’s capability to focus on education, prevention, technology, and how services are delivered. Today’s reform agenda may rightly reflect today’s concerns, but insofar as the ESRD program has not been comprehensively reexamined since its creation in 1973, there is strong reason to believe we are not adequately considering tomorrow’s opportunities. KCP believes that reform should not be locked

into a responsive mode, but should be proactive in achieving innovations and interventions that can save lives and conserve resources.

Beginning with education, the ESRD program should provide mechanisms to inform patients about the ways to delay and prepare for the onset of irreversible kidney failure. Specific educational initiatives include protocols for patients with Stage IV chronic kidney disease; other prominent efforts involve the training of patient-care dialysis technicians. Prevention efforts are quite similar in concept, but operate earlier and more broadly. These seek to halt the development of risk factors and instances of early-onset, but also extend to initiatives that prevent older patients from developing such extensive co-morbidities as to irredeemably “crash into dialysis.”

Alongside education and prevention, the ESRD program should prioritize and incentivize new technological breakthroughs in pharmaceuticals, devices, and delivery mechanisms alike. The creation of the “fistula” - a surgically enlarged vein (usually located in the wrist or elbow) that provides access to the bloodstream for hemodialysis - offers a prime example of the cost savings and quality benefits that flow from innovation. The successful “Fistula First” initiative, sponsored by CMS, further exemplifies the latent potential of collaboration to improve technology - and with it the efficiency and quality of patient care.

Finally, policies to advance flexibility in service delivery are also critical given the weakened condition and regular treatments that characterize ESRD patients. All dialysis modalities should be adequately funded, and studies should proceed as to why some remain underutilized. For example, home dialysis and more frequent dialysis should be studied so as to improve both patient access and quality of clinical outcomes.

## **Conclusion**

KCP is committed to the goals of safe, appropriate, and high-quality care for ESRD patients. In turn, KCP operates under the conviction that any anemia management reform should be well balanced, well grounded, and well considered. This means taking into account the advances and achievements in anemia management brought about by ESAs, alongside any concern regarding their utilization, as one derives motivation and methods for reform. It also means that current research, given its preliminary state, should be viewed as an urgent call for further inquiry, but not as a springboard for precipitous action. It finally leads to the conclusion that reform, when achieved, should be responsive to its animating goals of safety and efficacy, and not to a desire for payment cuts.

KCP is also of the mind that a commitment to the goal of safe and effective care is not well served when it ends with anemia management alone; on the contrary, KCP believes this commitment should extend to all those elements of the ESRD program relating to the quality of patient care. This means, first and foremost, that any reform should strive to ensure continued improvements in the quality of care. More specifically, this means ensuring stable and sustainable system economics and an update mechanism while ensuring there are no non-clinical incentives for utilization. It also means endeavoring to proactively reform the ESRD program, to strengthen our commitment to education, prevention, technology, and flexibility in order to improve not only the care we deliver to those patients served by the ESRD program, but also the quality of life for those individuals who can avoid kidney failure.

In closing, KCP wishes to recognize and thank Representatives Camp and Lewis for their leadership in advancing the Kidney Care Quality and Education Act and to also recognize the commitments over the years by Chairman Stark and Representative McDermott to improve care for all kidney patients. We are committed to working with Congress to strengthen the Medicare ESRD program and welcome the opportunity to serve as a resource to the Committee in that regard.

**Abbott Laboratories**  
**Advanced Magnetics, Inc.**  
**American Kidney Fund**  
**American Nephrology Nurses' Association**  
**American Regent, Inc.**  
**American Renal Associates, Inc.**  
**American Society of Nephrology**  
**American Society of Pediatric Nephrology**  
**California Dialysis Council**  
**Centers for Dialysis Care**  
**DaVita, Inc.**  
**DaVita Patient Citizens**  
**Diversified Specialty Institutes**  
**Fresenius Medical Care North America**  
**Genzyme**  
**Kidney Care Council**  
**National Kidney Foundation**  
**National Renal Administrators Association**  
**National Renal Alliance, LLC**  
**Northwest Kidney Centers**  
**Renal Advantage, Inc.**  
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**U.S. Renal Care**  
**Watson Pharma, Inc.**