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Service to those affected by chronic kidney disease

June 22, 2007

To: House Ways and Means Subcommittee on Health  
Re: Hearing on Ensuring Kidney Patients Receive Safe and Appropriate Anemia Management Care - Tuesday, June 26, 2007

The Renal Support Network strives to help patients with chronic kidney disease (CKD) improve their employability and develop their personal coping skills and special talents by educating and empowering them, as well as their family members, to take control of the course and management of the disease. We who have CKD are very grateful for the ESRD program and how it has helped both prolong our lives and improve the quality of our lives. I am writing to provide the patient's perspective on two aspects of care for patients with CKD that are currently being considered by your Committee—namely, appropriate anemia management and the bundling of dialysis services.

Patients with kidney disease often have anemia because their kidneys do not produce enough of the hormone erythropoietin. This hormone stimulates red blood cell production. Anemia is common in patients with CKD and is almost universal in patients with stage 5 CKD who are on dialysis.

The introduction of Erythropoiesis Stimulating Agents (ESA) to treat anemia in patients with renal disease has dramatically improved patient quality of life. In addition, patients no longer have to be transfused on a regular basis. Before ESAs were available, we commonly received red blood cell transfusions, which carried the risks of infection, iron overload, and potentially reducing the chances of receiving a kidney transplant.

Please keep in mind the following when making decisions:

- All drugs carry risks. **Patient safety, coupled with respect for patient quality of life concerns, should always be paramount in drug prescribing and dosing.** A dialogue between the patient and physician is critical to determine what is best for each individual patient.
- Patients with CKD, especially those on dialysis, are exposed to conditions **that make their anemia significantly different than patients with cancer** (e.g., ongoing need for ESA therapy versus temporary need for those with cancer, ongoing blood loss from the dialysis procedure, etc.).
- ESAs remain the **best treatment for anemia in patients with CKD.**
- Given the major loss of blood inherent with dialysis, **ESA treatment sustains the hemoglobin level and allows patients to have higher levels of energy.**

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**An illness is too demanding when you don't have hope!**

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- Based on the newest safety data, RSN agrees with the latest recommendation from the National Kidney Foundation’s Kidney Dialysis Outcomes Quality Initiatives (KDQOI™) panel of experts that calls for **targeting patients’ hemoglobin levels (the blood test used to measure anemia) between 11 and 12 g/dL**. In making this recommendation, the KDQOI™ states that actual Hb levels may fluctuate to above or below this target range because of natural variations in Hb.
- In its most recent report, CMS found that 83 percent of all patients with ESRD had a mean hemoglobin  $\geq 11$  g/dL and that **the mean hemoglobin for patients was within the 11-12 g/dL range**.
- Patients want to make sure that **the progress in anemia outcomes that has been made over the past two decades is not reversed**.
- Patients want to make sure **that the therapies they receive are being administered safely**, but also **do not want to sacrifice the quality of life benefits associated with an appropriate hemoglobin, or run the risk of an increase in blood transfusions if Hb levels are kept inappropriately low**.

I, among fellow patients in our organization, have witnessed firsthand the evolution of anemia management in patients with kidney disease. With the introduction of ESAs, thousands of patients have been spared the risks associated with multiple blood transfusions. The quality of our life and level of functioning has improved markedly. This has been shown in many clinical studies and evidenced by the patients themselves. I would specifically like you to give high priority to considering the issue of quality of life as it pertains to the guidelines that will be used to manage anemia in patients with CKD.

Although some say that quality of life should not be considered when administering care, RSN supports the position stated in the 2007 Medicare handbook that the Medicare program is helping patients to **“stay healthy and active.”** The importance of quality of life is also eloquently stated in the mission statement of the National Center for Chronic Disease Prevention and Health Promotion which states that they strive to **“promote health and quality of life by preventing and controlling disease, injury, and disability.”**

Anemia is one of the most devastating and potentially debilitating conditions that affect those with CKD, and it can dramatically affect our quality of life. Many people who have CKD can relate experiences of how anemia has affected them personally (please visit our website to hear their personal stories). Symptoms include chest pain, feeling cold, feeling tired, low energy levels doing routine activities of daily living, poor appetite, shortness of breath, depression, a poor sense of well-being, and an inability to work, manage a home, or volunteer—in short, loss of a meaningful quality of life.

As patients, we visit doctors out of what we sense about some symptom that is affecting our quality of life (i.e. “how we feel”). We simply have no other way to communicate. While preservation of life is

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certainly a primary focus of medical care, **an equally important goal is to help us preserve or regain our quality of life. An illness is too demanding when you don't have hope!**

There is much to be learned about anemia management in the CKD patient population, and more analyses and studies need to be conducted. We hope that quality of life will not be ignored in the current dialogue and decision-making—to do so is tantamount to ignoring the patient.

A second issue that is currently under discussion by your Committee is potentially changing the dialysis payment process in favor of a bundling approach. We are concerned that sudden revisions in the reimbursement policy may unintentionally lead to a decrease in our quality of care or quality of life. We would like to bring up a few points to consider to ensure that the new policy remains focused on the patient:

1. Ensure that the new policy **does not result in the disappearance of patient care services** that dialysis facilities currently provide.
2. **Laboratory testing must be done in the dialysis setting to ensure patients receive optimal care.** This is crucial for dialysis patients to remain viable candidates on the transplant list. In addition, for every extra stick a kidney patient receives to draw blood is counterproductive to CMS's Fistula First and National Vascular Access Initiative. We need to preserve our veins.
3. Ensure that all people who have ESRD **have access to quality care**, as jointly defined by medical professionals and patients.
4. Ensure that any newly implemented policies include provisions for **ongoing and timely modifications in the definitions of quality of care and quality of life based on current data and the newest therapies.**
5. Ensure that all patients **continue to receive education on the differences between modality options** (including home dialysis and kidney transplantation).
6. Include provisions that will continue to **allow patients real choices on where they dialyze** and including the ability to travel throughout the United States.
7. Include provisions and a financial model that will **allow both small and large providers to remain viable**, thereby providing patients with true choices on where to dialyze.
8. Provide reimbursement structures that will continue to allow and motivate dialysis facilities to **employ the best professional staff, upgrade dialysis machines, and integrate new equipment based on technological innovations.**
9. Provide a reimbursement structure that will continue to **motivate researchers to develop innovative therapies that will improve our quality of care and overall well-being.**
10. Develop safeguards to **prevent companies from "cherry picking" patients** to avoid treating those who require the most expensive care.

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11. Ensure that safeguards are in place to allow medical professionals to provide care **based on individual patient needs**, while **protecting patients from needlessly being sent to the hospital** or for additional physician office visits for care that can be provided in the dialysis facility.

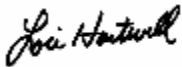
We salute CMS and Congress for their past and ongoing efforts to improve the quality of care and quality of life for patients with CKD. Prominent examples of how CMS continues to protect the interests of patients include Fistula First, National Vascular Access Improvement Initiative the Dialysis Facility Compare website, Know Your Numbers, and the Clinical Performance Measures. These efforts are currently benefiting hundreds of thousands of individuals, and may positively affect millions in the future. We urge CMS and Congress to continue and expand these efforts.

We respectfully request Congress to resist making a premature reimbursement decision that may not include complete or accurate information on the impact of such a change on patient outcomes. Demonstration projects are currently underway or being planned that will test whether proposed changes in reimbursement will preserve the quality of care for patients with kidney disease. **As stated in the Medicare handbook**, these demonstration projects are designed to **reduce health risks, improve quality of life, and provide savings**. It is critical to have an understanding of all the complexities that may impact how care is provided under a bundled model before such a model is implemented. In addition, when any new system is implemented, it is vital that there are regular reviews that allow for evaluation and prompt correction of the new payment system if problems arise.

The reality is that the ESRD program has a flawed reimbursement system and the incentives are wrong. Renal Support Network recognizes the need for the system to be changed. We urge Congress to take the necessary steps to ensure that any change does not unintentionally lead to an increase in mortality, decrease in our quality of life, or decrease in access to care.

Thank you for taking the patients' concerns into consideration. Please feel free to call if you have any additional questions.

Sincerely,



Lori Hartwell  
RSN President & Founder