



Service to those affected by chronic kidney disease

July 16, 2007

To: House Ways and Means Subcommittee on Health

Re: Comments regarding Hearing on Ensuring Kidney Patients Receive Safe and Appropriate Anemia Management Care - Tuesday, June 26, 2007

The Renal Support Network (RSN) is a nonprofit, patient-focused, patient-run organization that strives to help patients develop their personal coping skills, special talents, and employability by educating and empowering them, as well as their family members, to take control of the course and management of the disease.

The Renal Support Network believes that patients should be educated on both routes of medication administration and the final decision should be made between the doctor and the patient.

I am writing to you as a patient who has lived with kidney disease for over 39 years, I am also President and Founder of Renal Support Network. I would like to provide an alternative perspective to the testimony that was given during your Subcommittee's recent hearing on the use of erythropoiesis stimulating agents (ESAs or EPO) in patients on dialysis. During this meeting, the route of administration of these agents was discussed, and it was stated that there is broad patient support for subcutaneous administration of these medications. In addition, it was stated that a bundling approach to reimbursement is globally acceptable to patients with kidney disease. The Renal Support Network is concerned that the subcommittee would be left with the impression that the "one size fits all" approach to medical care that was stated during some of these testimonies is actually acceptable to all patients.

In contrast to the statement that was made to your Subcommittee, it is clear that all patients **are not in favor** of subcutaneous administration, and that many feel it would be detrimental to quality of life. The Renal Support Network is currently conducting an online patient survey and initial results show that 86% patients prefer erythropoiesis stimulating agents to be given during their hemodialysis treatment. 6% preferred subcutaneous administration and 8% patients had no opinion. Many members of the Renal Support Network also confirmed the potential adverse implications of forcing all patients to receive subcutaneous ESAs.

A sampling of quotes from some of our members follows:

"When it comes to an additional needle stuck into my body, the first word that comes to mind is "OUCH!!!" Who in their right mind would believe that we would willingly wish to have our bodies invaded by a foreign object such as a needle for the administration of EPO?" Paul Rauch

"When I switched to nocturnal home hemodialysis, it made taking the medication much easier when I was able to give it through the blood line at the end of my treatment. Because I took it at the end of every treatment, it was also easier to remember. On PD, I sometimes forgot to take it, or just didn't feel like poking myself that day. I sometimes had to work up my courage and it was easier to 'forget.'" Shari Gilford

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

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“To a kidney patient, “just another stick”, besides the several other sticks throughout the week is just not nice medicine.” Julie Glennon

“I resent the implication that no kidney patients mind additional needle sticks. As a dialysis patient, with all the tests and medications and invasive treatments commensurate with that, even one more needle stick a week is very much an affront to me. I prefer to receive my EPO through my lines with my treatment, to make it as reasonable and tolerable as possible. I appreciate the improved health and quality of life my EPO dosing gives me, but we can maintain my hemoglobin levels safely and just as effectively with this route of administration, instead of with another 52 needle sticks a year.” Kathe LeBeau

“When I began EPO injections, I was very glad about how they made me feel; however, I was very apprehensive about injecting myself with a needle. Out of fear, I asked my husband to take on the task. When I went in for my follow up appointment, I was covered in black bruises. My nurse then showed me how to give my own injections. Luckily, I was able to overcome my fear; however, many people with kidney disease have many, many other issues that they're dealing with. Learning how to inject themselves, or having a family member do it, is not always the best option. Administration of EPO should be tailored to the patient's emotional and medical needs.” Cher Thomas

The survey data and the quotes from our patients show that the route of administration of medications is a very emotional and serious issue for patients with kidney disease, and that many patients do not relish receiving a subcutaneous injection. Patient and doctor preference, comfort, and quality of life should be paramount in any decision on medication administration, RSN respectfully requests that these factors be considered in any policy regarding administration of EPO.

I would also like to comment on the proposed move toward a bundled reimbursement dialysis system. Most of us believe that some form of bundling is inevitable. We are concerned that sudden revisions in the reimbursement policy toward a bundled reimbursement approach may unintentionally lead to a decrease in our quality of care, quality of life or potentially impacting access to care.

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 as stated by Leslie Norwalk the CMS Administrator during her recent testimony.

We would like to convey a few points to consider that we feel would ensure the new policy remains focused on the patient:

1. Ensure that any new policy **does not result in the elimination 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, every extra needle 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.

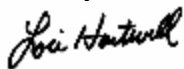
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3. Ensure that all individuals who have CKD **have access to quality care**, as jointly defined by medical professionals and patients.
4. Ensure that any newly implemented policies include provisions for **ongoing and timely modifications in the definitions 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 treatment modality options** (including home dialysis and kidney transplantation).
6. Include provisions that will continue to **allow patients real choices on where they dialyze** and have the ability to travel throughout the United States.
7. Include provisions and a financial model that will **allow both small and large dialysis service providers to remain viable**, thereby providing patients with true choices about 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 water treatment equipment, and integrate new 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 providers from “cherry picking” patients** to avoid treating those who require the most expensive care. Remember, MDs or other individuals with small units are more likely to be careful about the mix of payors than a larger enterprise would, so “company” would not be the correct word to use here.
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 has been traditionally been provided in the dialysis facility.

The Renal Support Network is grateful for the ESRD program and recognizes the need to conserve healthcare resources. However, 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. We respectfully request Congress to resist making premature decisions on clinical practices or reimbursement that may not include an accurate consideration of patient preferences or the impact of such changes on patient outcomes.

Thank you for your ongoing and longstanding interest in the ESRD program and for taking patients’ concerns into consideration. Please feel free to contact me if you have any questions or require further information.

Sincerely,



Lori Hartwell
RSN President & Founder