

## House Committee on Ways and Means

Statement of Dennis J. Cotter, President, Medical Technology and Practice Patterns Institute, Inc., Bethesda, Maryland

Testimony Before the House Committee on Ways and Means

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Chairman Thomas, Congressman Stark, distinguished Committee members, good morning. I am Dennis J. Cotter, President of the Medical Technology and Practice Patterns Institute. I appreciate the opportunity to talk about patient safety and quality issues. We have studied clinical outcomes of ESRD patients for more than 10 years.

For almost two decades, great controversy has surrounded the anemia management treatment goal, that is, the target hematocrit. During this time, CMS has increased hematocrit targets, from 33% to 37.5%, and most recently, to 39% and higher. Were these changes warranted? The answer to that question became clear when results of new clinical trials, joined with earlier trial results, demonstrated that patients, targeted to higher hematocrit levels, have increased mortality and many other adverse side effects. Through the current rules which endorse expanding EPO reimbursement to allow hematocrit to be targeted to any level, CMS tacitly has implemented a policy that can be harmful to its beneficiaries and will cost hundreds of millions of dollars in additional expenditures.

### **THE SCIENCE**

For some patients, it takes a small amount of EPO to elevate the hematocrit (EPO responders) and, for others, it takes a large amount (EPO non-responders). Clinical trials have shown that those targeted to high hematocrits and high EPO doses have higher mortality rates than those targeted to low hematocrits and low EPO doses. Because the population is made up of both EPO responders and EPO non-responders, the question remains whether patients who experienced higher mortality rates were predominately EPO responders or EPO non-responders. It is unlikely that industry-sponsored research will answer this important question. Answering this question is the subject of our on-going NIH funded research which addresses the concern that EPO therapy, itself, might contribute to harmful outcomes. Current CMS policy and industry-sponsored clinical practice guidelines support both high target hematocrit and high EPO doses, assuming that high hematocrits improve outcomes, an assumption that is contrary to clinical trial results. To date, no formal assessment of the appropriate dosing levels has been conducted, nor has a payment policy been implemented to encourage optimal dosing. Removing the profit incentive, by adding EPO to the composite rate should reduce over-utilization and would also encourage research to determine optimal dosing.

### **THE POLICY**

CMS policy appears to be heavily weighted both on opinion and on the notion that hematocrit variability is the over-riding problem. As a result, over the years this policy has encouraged EPO over-utilization, driving higher Medicare payments. Given the new

policy, which opens the upper limit of the target hematocrit, it is anticipated that providers will respond to the new financial incentive with even more aggressive use of EPO.

## **WHERE WE GO FROM HERE**

Our recommendations are the following:

Adhere to the FDA-approved label until further studies clarify the causal link among EPO, hematocrit, and patient outcome. Following FDA dose titration recommendations should be sufficient to maintain hematocrits within the 30-36% hematocrit range, deemed to be the safest range for all patients.

Treatment guidelines and reimbursement policies must put restrictions on the level of EPO dose, if necessary. Further studies are needed of patients who are hypo-responsive to high EPO doses.

Regarding EPO, and for all future drug evaluations, avoid over-reliance on observational studies, often industry-sponsored, as opposed to rigorously controlled randomized clinical trials. It is imperative that the EPO coverage decisions adhere to established hierarchy of evidence that focuses primarily on RCTs and systematic reviews.

Promote research which is independently funded, rather than industry-sponsored, for the development of treatment guidelines and payment policies.

Thank you for your consideration of our concerns.