

June 18, 2012

Carolyn M. Clancy, MD
Scientific Resource Center, Oregon EPC
Mail code: BICC
3181 S.W. Sam Jackson Park Road
Portland, Oregon 97239-3098

RE: AHRQ Draft Report on “Laboratory Biomarkers for Assessing Iron Status and Managing Iron Deficiency in Late Stage Chronic Kidney Disease Patients with Anemia”

Dear Dr. Clancy:

On behalf of the American Society of Nephrology, thank you for the opportunity to provide comments regarding “Laboratory Biomarkers for Assessing Iron Status and Managing Iron Deficiency in Late Stage Chronic Kidney Disease Patients with Anemia.” ASN represents nearly 14,000 physicians, scientists and healthcare providers dedicated to providing the best care to kidney patients and developing future cures for kidney diseases. ASN and the professionals it represents are strongly committed to advancing research that improves the quality of care patients with kidney disease receive, including appropriate, evidence-based anemia management. The society submits the following comments regarding the draft report for consideration.

ASN appreciates AHRQ’s attention to patients with kidney disease, especially to the important issue of iron management in patients with chronic kidney disease (CKD), including patients who are receiving dialysis therapy. Iron management is a key element of anemia care for this patient population, and ASN is grateful for AHRQ’s recognition that more evidence is needed in this area.

Overall, the draft report is a useful, high-quality document. The key questions AHRQ sought to answer were balanced and appropriately selected, identifying the research gaps that exist in this area. ASN agrees with AHRQ’s conclusion in the draft report that hemoglobin content in reticulocytes (CHr) and percentage of hypochromic red blood cells (%HYPO) may have better predictability for a response to IV iron treatment than classical markers in patients with chronic kidney disease on hemodialysis. However, as the draft report notes, currently available laboratory biomarkers of iron status do not have good predictive ability when used singly to determine iron deficiency. Given that the strength of the evidence supporting this conclusion is weak, ASN recommends AHRQ and other entities dedicate greater resources to investigating the utility of these alternative biomarkers of iron status.

In addition, because the majority of the available data examine patients with chronic kidney disease receiving in-center thrice weekly dialysis, ASN recommends that subsequent studies include patients receiving home peritoneal dialysis and home hemodialysis. Moreover, ASN recommends that research include patients with less severe chronic kidney disease not requiring dialysis therapy. The pre-dialysis patient population is worthy of further investigation,

as their prevalence much larger and the needs of these patients are unique from those of patients on dialysis. Similarly, it is also critically important to consider the therapeutic needs of pediatric patients with CKD, which are distinct from the adult population. ASN appreciates AHRQ's recognition of this difference in its draft report and thanks the agency for including this important population in its study.

Moreover, like many other aspects of care for patients with CKD, there is a lack of data that includes a "gold standard" for the management of iron deficiency in CKD patients with anemia. Recognizing this unfortunate limitation, ASN believes that AHRQ's conclusions are reasonable based on the available data but also recommends more research be conducted in this important area.

Thank you for the opportunity to provide comments regarding the draft report on "Laboratory Biomarkers for Assessing Iron Status and Managing Iron Deficiency in Late Stage Chronic Kidney Disease Patients with Anemia." We appreciate your consideration of these suggestions and welcome the opportunity to discuss them further if it would be helpful. ASN stands ready to serve as a resource for AHRQ on this issue and other matters related to the care of patients with kidney disease. Please contact ASN Manager of Policy and Government Affairs Rachel Shaffer at (202) 640-4659 with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald J. Falk". The signature is fluid and cursive, with a large initial "R" and "F".

Ronald J. Falk, MD, FASN
President