

## House Committee on Ways and Means

### **Statement of the Renal Physicians Association, Rockville, Maryland**

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease. RPA greatly appreciates the interest of Committee Chair William Thomas and Ranking Member Charles Rangel in the issues surrounding anemia management services provided to patients with kidney disease and kidney failure. We welcome the opportunity to offer our perspective on these complex issues. Our testimony will focus on the use of clinical practice guidelines and best evidence in healthcare delivery, the role of the nephrologist in the care of patients with kidney disease and the importance of maintaining physician prescribing autonomy, the issue of ESRD patient variability related to EPO dose, and common misperceptions regarding anemia management and reimbursement for these services.

#### **Clinical Practice Guidelines and Physician Prescribing Autonomy**

RPA believes that clinical practice guidelines in renal care, like those in other medical disciplines, should be evaluated on the basis of the strength of evidence, an assessment of harms and benefits, and should benefit from robust physician and other multidisciplinary input and review. Guidelines developed with these considerations in mind will enhance the delivery of high quality patient care and help ensure kidney patient safety. RPA also believes that the current body of literature in the area of anemia management fulfills these criteria, and forms a solid foundation for public policy making efforts such as the Centers for Medicare and Medicaid Services (CMS) recently finalized EPO Monitoring Policy (EMP). Further, it is our opinion that the CHOIR and CREATE studies recently published in the *New England Journal of Medicine*, once they have been subject to the full measure of robust scientific review, will likely represent an important addition to this already significant body of literature, and should be considered thoughtfully and thoroughly by care providers and policymakers.

However, RPA also feels compelled to note that clinical practice guidelines are in fact guidelines, not required protocols, and that the most important determining factor in the care of the patient should be the physician's clinical judgment considered in the context of the physician-patient relationship. RPA believes that it is of paramount importance to maintain the physician's autonomy and ability to exercise clinical judgment in prescribing for the individual patient. Decisions for the individual may and should be permitted to deviate from the norm on the basis of individualized clinical evaluation and specific patient needs. This is a fundamental and well-recognized clinical principle in medicine, and it is mandatory that it be maintained and protected. RPA believes the CMS' EPO Monitoring Policy accounts for such use of the physician's clinical judgment.

#### **Variability in ESRD Patient Hemoglobin Levels**

RPA believes that in the recent discourse on national coverage of EPO, the critical issue of variability of individual patient response to EPO dose has been understated. As noted in RPA's previous correspondence to CMS on EPO coverage policy development, attempts to assess or

quantify individual sensitivities (i.e. responsiveness) to EPO at a narrow level have not been successful. Thus, there is no single, predictable response to a given dose of EPO, a fact that accounts for the wide range in individual responses to treatment. As a result, in the aggregate it is physiologically not rational to tailor a normal distribution of patient responses to a payment limit: such a paradigm cannot be successful in delivering optimal treatment with sophisticated agents to complicated patients. Payment limits structured in this fashion place emphasis on the wrong arm of therapy: emphasis should be placed rather on reducing the number of patients with low hematocrits/hemoglobins (<30%/10 gm/dL). At the same time, Medicare coverage policy should strive to maintain levels in all patients >11 gm/dL, given the ample data disclosing the adverse short and long-term effects to patients with persistent anemia. Simply put, overemphasis on monitoring patients at the upper end of the range should not create problems for patients at the lower end, and RPA believes that the current CMS EPO Monitoring Policy strives to avoid such problems in the broad Medicare ESRD beneficiary population.

### **Misperceptions Regarding EPO Reimbursement**

Finally, RPA would also like to take this opportunity to dispel some common misperceptions regarding reimbursement for erythropoietin. There have been articles in both the mainstream and medical trade press implying that nephrologists have a financial incentive to prescribe higher doses of erythropoietin to ESRD patients. This is simply not true. Nephrologists prescribe EPO based on their clinical judgment of what will optimize the individual patient's hemoglobin level. Moreover, it is the dialysis facility that receives reimbursement for EPO prescribed to ESRD patients, not the nephrologist, and thus any inference that the nephrologist will personally benefit from prescribing higher doses of EPO, or any drug, to ESRD patients is erroneous.

### **Conclusion**

In conclusion, RPA supports the use of clinical practice guidelines in the development of protocols enhancing the delivery of high quality patient care but believes they must be considered in the context of the physician's clinical judgment. RPA believes that physician prescribing autonomy must be maintained, and that the variability in ESRD patient hemoglobin levels must be accounted for in the development of national coverage policy for EPO. Finally, the misperception that nephrologists have a financial incentive to prescribe high doses of EPO to ESRD patients is erroneous. Once again, RPA appreciates the opportunity to provide our perspective on these issues to the Committee, and we make ourselves available as a resource to the Committee in its future efforts to ensure the best possible health outcomes and quality of life for Medicare beneficiaries with ESRD.