December 20, 2010

To: Maria Ellis, Executive Secretary
Medicare Evidence Development and Coverage Advisory Committee
Coverage and Analysis Group, CMS

From: Robert Blaser, Director of Public Policy

RE: Dr. Velez'/RPA's Written Statement for January 19, 2011 CMS MEDCAC Meeting

Dear Ms. Ellis:

Please see below Dr. Velez'/RPA's written statement for the upcoming MEDCAC meeting. If you have any questions or comments regarding this correspondence, please do not hesitate to contact me at 301-468-3515, or by email at rblaser@renalmd.org.

RPA Written Statement

I am Ruben Velez, a practicing nephrologist from Dallas and I am here representing the Renal Physicians Association. RPA is the professional organization representing over 3,000 practicing nephrologists in the US, who take care of CKD and transplant patients.

As MEDCAC considers issues surrounding the impact of ESA use on renal transplant survival, RPA urges the panel to recognize the significant advances in renal transplant patients' care over the past two decades.

In particular, transplantation offers patients with kidney failure the best quality of life when compared with lifelong dialysis treatment. Blood transfusions given to patients awaiting transplantation may reduce the likelihood that these patients will receive transplanted kidneys. This is because blood transfusions often produce sensitization to HLA antigens. This sensitization reduces the possible donor matches for transplantation. Thus, patients with high PRA have longer waiting times pre-transplant (negatively affecting organ transplant survival), and lower graft survival post-transplant. It is therefore critically important to prevent avoidable blood transfusions whenever possible. RPA is concerned that an overly restrictive ESA policy revision that does not account for the need to minimize the use of transfusions will have an unintended and unnecessarily detrimental impact on transplant recipient waiting lists and organ survival. Fortunately, since ESAs became widely available in 1989, blood transfusions in outpatient

hemodialysis patients have significantly decreased. We urge the panel to recommend policies that preserve this advancement in kidney care.

RPA shares the safety concerns associated with ESA prescriptions that result in high Hgb levels or very high ESA doses, but we are simultaneously concerned about patients at the lower end of the typical treatment range. Importantly, the current nephrology standard of practice guiding the administration of ESAs does not target Hgb to 13. The current practice in the use of ESAs is to achieve a Hgb range of 10-12 while keeping Hgb above 10 to avoid transfusions and improve patient quality of life. We believe that this practice results in safe and appropriate use of ESAs, Therefore, RPA recommends that the panel not allow policy revisions intended to address the legitimate safety concerns at the upper end of the Hgb treatment range to create equally serious patient care issues at the lower end of the range.

We also urge MEDCAC to preserve the ability of physicians and patients to collaboratively make individualized treatment decisions that incorporate not only the physician's clinical expertise but also the patient's preferences and resulting quality of life. An effective process for determining appropriate administration of ESAs to kidney patients will include a discussion of the risks and benefits of ESA therapy. As the panel is aware, the Food and Drug Administration's Cardiovascular and Renal Drug Advisory Committee (CRDAC) recently reviewed evidence on the risks and benefits of ESAs, and that panel found no reason to recommend any change to the current labeled Hgb range of 10-12 in dialysis patients.

On behalf of the Renal Physicians Association, I thank you for this opportunity to speak today.