March 6, 2014

Marilyn B. Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4159-P: Medicare Program; 2015 Contract Year Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Programs; Proposed Rule

Dear Administrator Tavenner:

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. We are writing to offer comments on changes affecting immunosuppressive drugs in Medicare Parts C and D.

In the rule, CMS proposes to remove immunosuppressive medications for transplant rejection as a protected class under Medicare Parts C and D. **RPA strongly urges the Agency to rescind this proposal.** As senior CMS leadership knows, kidney transplants are safe, cost-effective procedures that can extend and significantly improve the lives of patients suffering from end-stage renal disease (ESRD), allowing them the freedom to forgo time-consuming and costly dialysis treatments three to four times per week. However, the timely availability of immunosuppressive drugs is critically important to the success of the transplanted organ. In fact, in the proposed rule, the CMS Protected Classes Review Panel (the body overseeing this aspect of the proposed rule) seems to concur with this view by acknowledging that:

> Due to the immune system’s ability to mount progressively faster and stronger attacks against a beneficiary’s new organ, and to maintain a memory relative to those attacks, initiation of therapy in a Part D setting generally cannot be delayed... because of the risk of hospitalization, incapacity, disability, or death...

RPA would posit that any policy revision that could serve as a barrier to transplant patients receiving immunosuppressive drugs should be rescinded.

Further, we would urge the agency to consider the potential long term health policy ramifications of the proposal as it specifically applies to ESRD. Immunosuppressive drugs not only facilitate
the long-term viability of transplanted kidneys, but they also help avoid costly dialysis treatments and reduce the likelihood that the expense originally incurred by Medicare in transplanting the kidney to a patient that would otherwise require dialysis is not squandered. RPA is sensitive to CMS’ fiduciary responsibilities, and we appreciate the Agency’s efforts to ensure that the Medicare program’s finite resources are managed appropriately. However, RPA also believes that the proposal to remove immunosuppressive drugs from a protected class will both unnecessarily threaten the health outcomes of kidney transplant patients and heighten the possibility that Medicare will incur the additional expense of a kidney patient returning to dialysis. This proposed policy is neither in the best interest of patient-centered quality kidney care nor the financial viability of the Medicare program.

RPA believes that any action that exacerbates the difficulty (financial or otherwise) of patients acquiring these medications increases the potential for transplant failure, with medication loss being a frequent cause of such failure. Given that CMS has invested considerably in the initial transplant, RPA urges CMS to rescind the proposal to remove immunosuppressive drugs as a protected class.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation’s kidney patients, and we stand ready as a resource to CMS in its future endeavors. Any questions or comments regarding this correspondence should be directed to RPA’s Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Thank you,

Robert J. Kossmann, MD
President