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February 18, 2014

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

RE: Transplant community opposition to CMS proposal to remove  
Immunosuppressive medications from Medicare Part D Protected Class category

Dear Administrator Tavenner:

The American Society of Transplantation has serious concerns regarding the proposed rule to remove immunosuppressant medications for transplant rejection prophylaxis as a protected class under Medicare Parts C and D. Our understanding is that the decision to target immunosuppressive drugs is per the recommendation of the CMS Protected Classes Review Panel. We strongly disagree with the Panel's determination that CMS will no longer require every drug product to be included on every formulary. We point out that the Panel recognizes, and we agree, that timely access to immunosuppressants is critical for patients with transplanted organs. Indeed, long-term success is only possible when the host immune response is continuously and effectively suppressed. Our point here is that inability to access the proper medications and combinations will lead to increased rates of chronic immune rejection characterized by organ injury, patient suffering and ultimately even death. We are certain that CMS will recognize that any decision with such a negative impact on an entire class of vulnerable patients is not correct.

The key point is that current immunosuppressive therapies in transplantation are based on the use of multiple drugs whose mechanisms are complementary. We create a level of effective immunosuppression by drug combinations, not by a single agent. Each agent has different toxicities and each drug effects the action and efficacy of the other agents in the combination. For example, within one class, a requirement to substitute cyclosporine for tacrolimus, can result in a 40% reduction in mycophenolate exposure and/or a five-fold increase in sirolimus exposure, requiring changes in multiple drugs and frequent additional monitoring. Thus, it is simply impossible to safely switch back and forth between individual drugs in the combinations without completely reevaluating the whole combination.

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The bottom line is that forcing physicians to constantly make such fundamental changes to life-saving immunosuppression would dramatically and negatively impact the entire transplant care model. As already noted, the impact would be entirely to the detriment of a vulnerable patient population. It will dramatically increase the need and costs for constant drug level monitoring. It will increase the number of necessary patient visits to evaluate the changing therapies that not only cost the program and payors but also the patient's employers in lost productivity and time. Consider simply the reality of a single transplant physician trying to constantly monitor what drugs are available to hundreds of individual patients typically being seen only a few times per year in the transplant center. Consider the impossibility of responsibly managing immunosuppressive therapy over the many years our patients live with their transplants, change jobs, move around and change the workflows of their care.

We strongly support the efforts of CMS to reduce health care spending and improve patient care. However, this particular proposal to prevent the accessibility of our patients and physicians to all the current immunosuppressive drugs in every formulary would not achieve either reduced health care spending or improved patient care. In the strongest possible terms, we state that this proposal will dramatically increase health care costs, profoundly damage the care and health of our transplant patients, and lead to significant patient and family suffering as the result of reducing organ survival.

Therefore, we strongly urge you to rescind the proposed rule and continue to maintain the current protections for access to all or substantially all immunosuppressive drugs for Medicare Part D beneficiaries.

Sincerely,

A handwritten signature in black ink that reads "Daniel R. Salomon M.D." The signature is written in a cursive, slightly slanted style.

Daniel R. Salomon, MD  
President, American Society of Transplantation