

**Congress of the United States**  
**Washington, DC 20515**

February 14, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Tavenner:

As supporters of improved access to immunosuppressive drugs, we write to express our concerns about the Centers for Medicare & Medicaid Services (CMS) proposed rule, “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.”

This proposed rule would eliminate immunosuppressive drugs as one of the six protected drug classes in Medicare Part D plans. We believe this proposed rule is a major step back in our efforts to protect organ transplant recipients. In short, we believe this proposed rule will compromise patient care and could ultimately increase costs under Medicare Parts A and B.

Transplant physicians and surgeons often need to have all FDA approved immunosuppressive drugs available in order to tailor combinations of drugs to meet the unique needs of individual transplant recipients. Not all patients respond in the same way to a particular regimen, therefore limiting patient access fails to account for the unique nature of the drug and needs of patients.

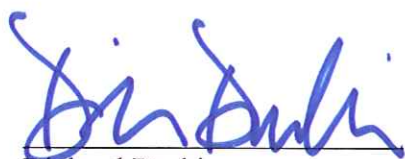
For these reasons, immunosuppressive drugs were established as one of six protected classes of drugs under the Medicare Part D program’s regulations. Since this regulatory designation, Congress has twice codified this protected status for immunosuppressive drugs. Nothing has scientifically changed to justify an elimination of these protections for immunosuppressive drugs under Medicare Part D.

While we understand that immunosuppressive drugs may continue to be covered under the CMS formulary guidelines, these guidelines do not permit stakeholder input and do not require public notification of changes to the guidelines. Without requiring the public notification of formulary changes, patients would only find out that their drugs are no longer covered once they attempt to refill their prescriptions.

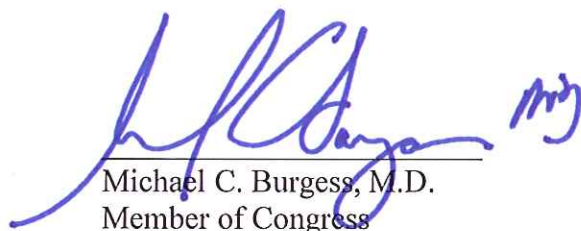
There are approximately 121,000 people waiting for an organ transplant and approximately 25,000 people received organ transplants last year.<sup>1</sup> Removing immunosuppressive drugs from the protected class status places Medicare beneficiaries at risk and creates the potential for the transplant waiting list to grow even longer. This proposal could ultimately cost lives and result in higher spending in other areas. Organ rejection could eventually lead to more expensive dialysis care and/or the need for another transplant.

We urge you to rescind the proposed rule regarding immunosuppressive drugs and continue to maintain the existing protections for this category of medications under the Medicare Part D program. If you have questions, please do not hesitate to contact Sarah Johnson with Rep. Burgess or Srinu Sonti with Senator Durbin. Thank you for your consideration of our comments.

Sincerely,



Richard Durbin  
United States Senator



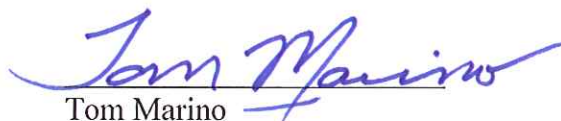
Michael C. Burgess, M.D.  
Member of Congress



Thad Cochran  
United States Senator



Ron Kind  
Member of Congress



Tom Marino  
Member of Congress

<sup>1</sup> United Network for Organ Sharing [www.unos.org](http://www.unos.org)