



Statement by the National Kidney Foundation

Submitted to the Committee on Energy and Commerce  
Subcommittee on Health  
U.S. House of Representatives

Hearing to Examine Proposed Changes to Medicare Part D  
February 26, 2014

The National Kidney Foundation (NKF) thanks the Subcommittee for holding a hearing on the Administration's proposed changes to the Medicare Part D program, including the protected class status, and we appreciate the opportunity to share our concerns with you. NKF is America's largest and oldest health organization dedicated to the awareness, prevention and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI).

Under the Centers for Medicare & Medicaid Services (CMS) proposed rule issued on January 6, 2014, immunosuppressive drugs for transplant recipients would no longer be included as a protected class under Medicare Part D. This decision risks transplant physicians' ability to prescribe the drug regimen most appropriate for their individual patients. Immunosuppressants are prescribed in combinations tailored to meet the unique needs of the individual transplant recipient in order to achieve sufficient immunosuppression while minimizing the toxicity associated with individual agents. Kidney recipients must take immunosuppressive drug indefinitely to prevent organ failure. Consultation with our transplant physician members and our organ recipient members further underscores the need for all immunosuppressive drugs to be available on health plans formularies. Identifying the most appropriate immunosuppressive combination often requires fine tuning. Clinical guidelines support transplant physicians in identifying the combination with the strongest evidence base, but requires the expertise of the physician who knows the medical history of the patient to tailor the best regimen. Typically patients receive a tailored combination of drugs immediately after transplant (the induction phase) and then have another combination tailored for them for the long-term (the maintenance phase). Recipients require close monitoring after a new combination is prescribed to ensure it will sufficiently suppress the immune system and protect the organ, while minimizing the adverse side-effects. This delicate balance was recognized in the original decision to include these medications under protected status.

The CMS proposed rule referenced a report from a panel the agency had engaged to evaluate the new criteria against the current protected classes. The panel referenced only 2009 clinical guidelines for the Long-Term Treatment of the Liver Transplant Patient in its decision to remove protections for immunosuppressant. The panel appears to have incorrectly concluded that a more specific formulary that ensures only each *subclass* of immunosuppressive drugs is available would suffice for the treatment of all transplant recipients. However, the drugs under each subclass are not interchangeable. Any drug in a subclass may have a different mechanism of action providing a very different level of benefit, or, in a worst case scenario, may be more neurotoxic to a specific patient than another drug. NKF firmly believes patient access to *all* immunosuppressive drugs within each subclass must be maintained to provide optimal patient care.

Since the release of the proposed rule, NKF has heard from many of our patients about how difficult it was for their physician to identify the most appropriate and beneficial immunosuppressive therapy. Often, the first prescribed drug combination needs to be adjusted or replaced. Patients who have contacted us are terrified they will lose access to the specific drugs that best meet their needs. We have also heard from these patients that today they are stable and doing well on their immunosuppressive regimen. While CMS has recognized that subjecting transplant recipients to a lengthy appeals process would put patients' lives and organs at risk, the agency has not provided guidance as to how it will make sure patients are able to quickly access the combination of medications prescribed to them by their physician if immunosuppressants are no longer a protected class. Instead, this proposed rule risks the stability thousands of current patients have achieved with their current immunosuppressive regimen and limits physicians' ability to tailor regimens for new recipients. The proposed rule also sends the signal to other private insurance plans that it is ok to limit patient access to immunosuppressive drugs on their formularies, putting even more transplant recipients at risk.

This is not the way to achieve Medicare savings and in fact it could result in higher costs through an increase in hospitalizations or even failed organ transplants. With more than 120,000 Americans on organ transplant waiting lists and fewer than 27,000 transplants performed last year, policymakers must do everything possible to maintain the viability of the transplanted organ. We urge Congress to prevent the Administration from changing protected class status for immunosuppressive drugs and maintain patients' access to all immunosuppressants under Medicare Part D.

Thank you for your consideration and the opportunity to share our concerns.