

February 18, 2014

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Orrin Hatch
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Baucus and Ranking Member Hatch:

As organizations who advocate for the needs of transplant recipients, we request you to contact the Administration and the Centers for Medicare & Medicaid Services (CMS) and urge them not to proceed with the proposal to remove immunosuppressive drugs for transplant recipients as a protected class under Medicare Part D. On January 6, 2014 CMS released a proposed regulation to change the criteria for the six protected classes of prescription drugs under Medicare Part D. Under the proposal, Part D plans may no longer be required to cover all approved immunosuppressive medications. The proposed rule referenced a report from an unidentified panel the agency had engaged to evaluate the new criteria against the current protected classes. That panel recommended eliminating protection for immunosuppressive drugs in addition to two other drug classes. Citing a review of clinical guidelines, the panel incorrectly concluded that a more specific formulary that ensures only each *subclass* of immunosuppressive drugs is available would suffice. However, the drugs under each subclass are not interchangeable. Each subclass includes different agents with different mechanisms of action. Patient *access* to all immunosuppressive drugs is necessary. Immunosuppressive drugs 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. Restrictive formularies limit physicians' ability to prescribe the right combination of medications to protect the recipient from organ rejection and other serious side-effects. This delicate balance was recognized in the original decision to include these medications under protected status.

Not all patients respond the same to just one or two combinations of medications. Often, the first prescribed drug combination needs to be adjusted or replaced altogether, further underscoring the need to have all drugs available under Part D plans. While CMS has recognized that subjecting transplant recipients to an 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 access the combination of medications prescribed to them by their physician if immunosuppressants are no longer a protected class.

While we understand the need to control healthcare spending, this is not the way to achieve savings. Last year there were 26,513 organ transplants in the U.S. and many were Medicare beneficiaries for whom Medicare Part B covers immunosuppressive drugs. While this proposal will impact a small number of organ recipients, it puts those who do get their immunosuppressive drugs under Part D, health and lives at risk. It is also likely to result in higher spending under Medicare Parts A and B,

particularly if more patients' organs fail, fueling the need for more health care services and/or the need for another Medicare covered transplant. While each of our organizations will submit written comments to CMS, we ask that you please contact the Administration and CMS as soon as possible and ask them to maintain immunosuppressants as a protected class.

Sincerely,

National Kidney Foundation
American Association of Kidney Patients
American Kidney Fund
Dialysis Patient Citizens
Hepatitis Foundation International
Leukemia & Lymphoma Society
Lupus Foundation of America
PKD Foundation
Renal Support Network