March 7, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G2
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Administrator Tavenner:

On behalf of the Transplant Roundtable, a coalition of organ transplant patients, health professionals, and related organizations dedicated to preserving transplant patients' access to optimal care, the undersigned organizations appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (the "Proposed Rule").

As currently drafted, the Proposed Rule would enable Part D sponsors to impose formulary restrictions on immunosuppressive drugs, resulting in substantial risk of organ rejection, serious side effects, and adverse drug reactions for Medicare Part D beneficiaries who are transplant recipients. Our organizations urge CMS not to finalize the proposal to remove immunosuppressive drugs from the list of six protected classes.

As you are aware, the 2003 Medicare Modernization Act (MMA) created the Medicare Part D drug program. When CMS implemented the program, it recognized the need to cover "all or substantially all" medications within certain protected classes by issuing sub-regulatory guidance identifying six classes and categories of drugs (including immunosuppressants) that would not be subject to formulary restriction. Due to uneven implementation of this informal guidance, Congress enacted Section 176 of the Medicare Improvements for Patients and Providers Act (MIPPA), which established statutory protection for immunosuppressants and five other protected classes of drugs under Medicare Part D, by requiring Medicare Part D drug plans to include in their formularies access to all or substantially all drugs in the six identified classes. It is against this backdrop that the Affordable Care Act (ACA) provided CMS with the authority to develop criteria to "identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern." As such, Congress has twice codified protected class status for immunosuppressants and the other five pre-existing protected classes of drugs and expanded protected status to all drugs within these six classes.

Under the Proposed Rule, a class or category of medication must meet both of the following standards to retain or obtain protected status:

- For a “typical individual,” hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and

- More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.”

Experts from the Transplant Roundtable believe that immunosuppressive drugs unequivocally meet both of the standards set forth for protected class status in the Proposed Rule.

CMS correctly determined that Immunosuppressive drugs meet the first of the two standards proposed for inclusion in the protected class, and our organizations concur. Indeed, significant health consequences result if patients do not receive immunosuppression within seven days of a prescription. However, CMS’ determination errs in concluding that immunosuppressive drugs fail to meet the second of the two proposed standards. In fact, there is a critical need for physicians to have the flexibility to individualize immunosuppressant therapy, both to protect against rejection and to minimize potentially serious side effects. Because individual patient response to various immunosuppressants is idiosyncratic and cannot be predicted, it is impossible for CMS to impose formulary requirements without unreasonably restricting access to those drugs that may be critical for individual patients.

Moreover, on February 26, 2014, the United States House of Representatives Energy and Commerce Subcommittee on Health hosted a hearing to examine the Proposed Rule. CMS Principal Deputy Administrator Jonathan Blum was asked what, if any, new scientific evidence has been developed to justify eliminating protections for immunosuppressive drugs under Medicare Part D; Mr. Blum testified that no such changes have occurred. Our organizations concur that no new scientific evidence has been developed that would warrant the proposed change in immunosuppressive drugs’ protected status.

Members of the Transplant Roundtable understand and are fully supportive of the need to control healthcare spending, but are adamant that putting transplant patient safety at risk by limiting access to the full range of immunosuppressive drugs is not an acceptable approach. In 2013, approximately 121,000 patients were on the list waiting for an organ transplant, and only about 25,000 patients received a transplant.[i] The fortunate 25,000 who did receive a lifesaving transplant have to take the proper medications daily in order to keep the graft healthy. These medications are imperative for the survival of transplanted organs. Our organizations encourage CMS not to finalize its proposal to exclude immunosuppressive drugs from the six protected drug classes

under Medicare Part D plans, thereby ensuring that Medicare Part D patients who receive a transplant maintain access to the full range of immunosuppressive drugs and optimal care.

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

If you have any questions regarding this comment letter, please do not hesitate to contact any of our organizations. An organizational contact sheet is included in this correspondence.

Again, thanks.

Sincerely,

Alliance for Paired Donation
American Association for the Study of Liver Diseases
American Association of Kidney Patients
American Society of Nephrology
American Society of Pediatric Nephrology
American Society of Transplant Surgeons
American Society of Transplantation
Dialysis Patient Citizens
Eye Bank Association of America
NATCO, the Organization for Transplant Professionals
National Kidney Foundation
Renal Physicians Association
Texas Transplantation Society
Transplant Recipients International Organization
United Network for Organ Sharing

[i] United Network for Organ Sharing www.unos.org

Transplant Roundtable 2014

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