March 7, 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

Dear Administrator Tavenner:

As healthcare stakeholders, we thank you for the opportunity to share our perspective on the CMS proposed changes for Medicare Advantage and Prescription Drug Benefit Programs for contract year 2015. Collectively, we represent millions of patients and caregivers who deal with serious medical conditions on a daily basis and we are deeply concerned that the proposed federal regulations would impose greater restrictions on health care options available to Medicare beneficiaries and negatively impact their access to lifesaving and life-enhancing medications.

Furthermore, the recommended changes are equally perplexing and alarming to us because they would adversely affect programs that are currently delivering high-quality care at affordable costs to both beneficiaries and taxpayers and are extremely popular among recipients. The Medicare Part D program has succeeded far beyond expectations in enhancing the health and well-being of enrollees. It is both unreasonable and counterproductive to alter a thriving program such as Medicare Part D.

By reducing plan choices and limiting treatment options, the proposed rule would have unintended consequences to the countless individuals with chronic conditions who are presently covered by Medicare either because of disability or age; as well as future implications as millions of Americans eventually become dependent on the Medicare program due to our aging population.

We are particularly concerned about the proposed new criteria for identifying protected classes of drugs that when applied would no longer require all drugs from the immunosuppressant drug classes to be on all Part D formularies.

- Individuals with autoimmune diseases such as lupus, rheumatoid arthritis, crohn's disease, scleroderma, sjögren's syndrome, multiple sclerosis, psoriasis, vasculitis and other diseases of unmet need – require individually tailored treatments. Many of these individuals have multiple co-morbid conditions that require unencumbered access to the full array of treatments. Individuals with complex care needs require unique strategies to manage their care.

- Basing the criteria for identifying Part D Drug categories or classes solely on initiation of therapy and not on the interruption in existing drug therapy would delay patient access, deny medical care and cause harm. Patients and their providers need open access to all medications in order to maintain stability and consistent disease management. Disrupting continuity of care by limiting coverage could result in detrimental life threatening consequences to the individuals who are the most vulnerable, reduce adherence and could actually lead to more medical complications, worse health outcomes and higher health care costs.

- Limiting the number of drugs from the immunosuppressant drug classes for inclusion on all Part D formularies overlooks many clinical considerations and ignores important variations that exist among patients in terms of safety, efficacy, and tolerability. New scientific research shows there are gender, racial, and ethnic differences in responses to treatments, and limiting access would greatly widen already existing health disparities.

- Individual response to any given treatment is not equal. Immunosuppressant drugs are not always equivalent; what is tolerable for one individual may not be in the next. There is no single medication that individuals respond to – again treatment is highly individualized and no two people are alike. Transplant patients are particularly vulnerable and rely on their immunosuppressant medications to maintain the life of their organ. Their immune systems are sensitive and response to drug therapies differs from patient to patient. Once stabilized, any change in drug therapy could have adverse effects resulting in multiple complications – not the least of which may be rejection.

- Individuals with multiple chronic conditions are extremely complex and may require multiple medications for each of their chronic conditions. Health providers know best what therapies they intend to use to balance the various therapeutic and safety concerns in these complex patients. Many diseases are limited in treatment choices. The entire patient picture must be considered including: unique bio-chemical needs, individual compliance, side effect tolerability, and limited heterogeneity. There are over 100 Autoimmune and Related Diseases and more than half of them have never had a drug specifically developed for the condition, therefore few therapeutic choices exist for these individuals.

- There is ample evidence that new medications offer some therapeutic advantages over conventional medicines. For example, older immunosuppressant therapies attacked a patient's entire immune system; causing detrimental side effects, while newer therapies target a particular cell or biomarker making the treatment much more efficient and safer. Simply put, access to innovative therapies in the protected classes matters to patients and their treating physicians.

- The determination of the most appropriate medication for a particular individual with multi-system autoimmune disease; musculoskeletal condition; or the recipient of an organ donation/transplant must be made on the basis of patient acceptability, prior individual drug response and side-effect profile, and long-term treatment planning. Many of these individuals already face enough adversities in their daily lives and do not need another obstacle to further complicate their medical care.

For the above reasons the undersigned organizations strongly believe it is imperative that CMS maintain its current, long-standing "protected classes" policy and urge CMS to reconsider and rescind the proposed federal regulations that would undermine the success of the Medicare Part D program for recipients. Ironically, this policy was initiated because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans. We also ask that the agency work with various stakeholders through an open and transparent process to develop methods to improve Medicare Advantage and Medicare Part D that build on the strengths of these programs and continue to offer excellent and affordable health coverage and accessibility to treatments.

Sincerely,

Lupus Foundation of Mid and Northern New York, Inc.
American Autoimmune Related Diseases Association (AARDA)
New York State Rheumatology Society (NYSRS)
Lupus Research Institute (LRI)
Society for Women's Health Research (SWHR)
US Pain Foundation
Coalition of State Rheumatology Organizations (CSRO)
Arthritis Foundation
Sjögren's Syndrome Foundation
Global Healthy Living Foundation (GHLF)
National Psoriasis Foundation
Digestive Disease National Coalition
Crohn's & Colitis Foundation of America
Scleroderma Foundation, Inc.
Vasculitis Foundation
US Hereditary Angiodema Association
APS Foundation of America, Inc.
International Institute of Human Empowerment, Inc.
Movement is Life
Molly's Fund Fighting Lupus
Latino Commission on AIDS
Hispanic Health Network
New York State Rare Disease Alliance (NYSRDA)
Northeast Kidney Foundation
New York State Osteopathic Medical Society (NYSOMS)
S.L.E. Lupus Foundation
NAACP New York State Conference
1 in 9 The Long Island Breast Cancer Action Coalition
Lupus Alliance of Long Island / Queens
Michigan Lupus Foundation
Lupus Foundation of Southern California
Lupus Foundation of Northern California
National Alliance on Mental Illness NYS (NAMI NYS)
Lupus Alliance of Upstate New York
Lupus Foundation of Florida, Inc.
Scleroderma Foundation / Tri-State, Inc. Chapter
Lupus LA
Lupus Foundation of Genesee Valley NY, Inc.
New Jersey Association of Mental Health and Addiction Agencies, Inc.
Lupus Foundation of Colorado
Lupus Foundation of Pennsylvania
Lupus Foundation of New England
Scleroderma Foundation, Greater San Diego Chapter
Florida Society of Rheumatology