CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

March 6, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4159-P, Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Dear Administrator Tavenner:

The Cystic Fibrosis Foundation invests in cystic fibrosis (CF) research and therapy development, supports CF care centers in providing quality care and undertaking constant quality improvement, and represents individuals with CF in public policy matters that affect therapy development and access to quality care. We are writing to urge the Centers for Medicare & Medicaid Services (CMS) to reconsider its proposal to remove certain classes of drugs from the "protected classes of drugs" in the Medicare Part D program. The removal of immunosuppressants from "protected class" status would pose a great risk to individuals with CF who have undergone lung or other solid organ transplants.

The agency established a two-part test for determining whether a class of drugs is a class of "clinical concern." A class will only meet the requirement to be a class of clinical concern if 1) hospitalization, disability, or death is likely to result if administration of a drug in the class does not occur in less than seven days, and 2) access to drugs in the class cannot be addressed by more specific formulary requirements due to the diversity of the disease or condition manifestations and associated specificity or variability in drug therapies necessary to treat such manifestations. CMS concluded that immunosuppressants for transplant rejection meet the first prong of the test because immunosuppressant therapy "cannot be delayed for up to 7 days because of the risk of hospitalization, incapacity, disability, or death." However, the agency also determined that it was possible to establish specific formulary requirements that will protect access to immunosuppressants without continuing the protected classes policy with respect to that class of drugs.

We disagree with the conclusion of the agency that the second part of the two-part test could be met by specific formulary requirements for coverage of immunosuppressants. Instead, it is our experience that

it is necessary to ensure coverage of "all or substantially all" immunosuppressants – according to the terms of the current protected classes policy – so that individuals with CF who have undergone lung or other solid organ transplants have access without delay to the immunosuppressants or combinations of such drugs that they require. Formulary requirements other than an "all or substantially all" standard might include limits that would restrict ready access to immunosuppressants or require an exceptions policy that might not be responsive to the urgent needs of CF patients who have undergone transplantation. There is no standard immunosuppression regimen for solid organ transplant recipients. A subset of patients requires additional immunosuppressants to sustain life, and restricting access to specific classes of immunosuppressant agents will limit options for prolonged survival.

Although CMS has concluded that immunosuppressants meet the first prong of the protected classes policy and that is not the reason for the removal of the class's protected status, we recommend that going forward the agency consider a more rigorous test for assessing the impact of prescription drug access delays on hospitalization, disability, or death. In the case of immunosuppressants for transplant patients, any delay at all can cause harm to the patient. As the agency states in the proposed rule, "Due to the immune system's ability to mount progressively faster and stronger attacks against a beneficiary's new organ, and to maintain a memory relative to those attacks, initiation of therapy in a Part D setting generally cannot be delayed for up to 7 days because of the risk of hospitalization, incapacity, disability, or death, and thus meets the first criterion." We contend that in the case of immunosuppressants any delay in access can cause harm to the patient, and that the test regarding delay should be even more aggressive in shielding patients from such injury.

We understand that the reconsideration of the protected classes policy is related in part to cost concerns and the desire on the part of the agency to increase the ability of Part D plan issuers to negotiate lower drug prices. Lowering prices of drugs in the three classes of drugs that are proposed to be removed from protected status – immunosuppressants, antidepressants, and antipsychotics – may not translate to savings for the entire health care system. For example, limits on access to appropriate immunosuppressant therapies due to a short-sighted cost-containment effort could increase overall costs to the system for transplantation if outcomes are compromised. We strongly urge the agency to take a longer and more comprehensive view and to avoid a cost-related effort that could threaten access to life-sustaining care and that could have unanticipated long-term fiscal consequences.

We appreciate the opportunity to comment on the proposed Medicare Part D policy change. We urge a prompt decision by CMS to abandon its proposal to change the Part D protected classes policy.

Sincerely,

Robert J. Beall, Ph.D.
President and Chief Executive Officer