

The Honorable Orrin Hatch  
Chairman  
Senate Committee on Finance  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Ron Wyden  
Ranking Member  
Senate Committee on Finance  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Fred Upton  
Chairman  
House Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone, Jr.  
Ranking Member  
House Committee on Energy and Commerce  
2322A Rayburn House Office Building  
Washington, DC 20515

The Honorable Kevin Brady  
Chairman  
House Committee on Ways and Means  
1102 Longworth House Office Building  
Washington, DC 20515

The Honorable Sander M. Levin  
Ranking Member  
House Committee on Ways and Means  
1139E Longworth House Office Building  
Washington, DC 20515

Dear Chairman Hatch, Ranking Member Wyden, Chairman Upton, Ranking Member Pallone, Chairman Brady, and Ranking Member Levin:

Our organizations, which represent millions of patients across the country, write to express our opposition to the Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) March 8, 2016 proposed rule that would implement substantial changes to the Medicare Part B Payment program. In its current form, we believe that implementation of this Proposed Rule is misguided and would negatively impact the quality and accessibility of care that patients with complex conditions currently receive. We also remain deeply concerned with the lack of stakeholder engagement by CMMI throughout the development of this proposal. We believe that it is in the best interest of patients and providers that CMS withdraw this rule and, moving forward, implement a process that allows for those who will be most significantly impacted by a payment or delivery system change – patients and providers – to engage with CMMI and offer input throughout the development of any future proposed reforms.

Our organizations represent some of the sickest patients with the most complex conditions, such as arthritis, cancer, asthma and allergies, and primary immunodeficiency diseases. Many of these patients have complex conditions and a diagnosis of several chronic diseases. It can often take people with chronic diseases years to find the most appropriate medical services and drug that works best for them. It is critically important that these patients have access to the drugs that they need, and are not subjected to random programs that could threaten that access. Patients and providers already face considerable hurdles securing timely care; they should not also be faced with a mandate to participate in an initiative that could force a physician to alter his or her clinical decision making authority based solely on an economic model and not what is in the best interest of the patient.

We agree that the current system is unsustainable, but we fear that the proposal as written would result in major unintended consequences that would hinder patient access to care. For example, if physicians stop offering infusions in their offices as a result of this policy, it could force patients into the hospital setting for their infusions, which would ultimately be more costly to the patient and to Medicare. Some of the value based models may also pose access challenges to patients. For example, we fear that the “least costly alternative” model could result in a patient who is stable on a more expensive drug potentially losing access to that drug. The “indications based pricing” model also raises concerns, since the criteria that would determine clinical effectiveness have not been defined nor has the process by which it will be defined. Further, the pre-appeals and notification requirements are not adequate and do not provide patient safeguards. From this proposal, it is unclear how patients would even be notified about the demonstration project, let alone submit a pre-appeal from the demonstration project.

Additionally, any time CMS considers payment and delivery system reforms, it is imperative that the agency communicate with stakeholders through a transparent process that allows for engagement in the development of such a reform. Our organizations appreciated the process by which CMMI solicited stakeholder input during the development of the Oncology Care Model it released in 2015. It is disappointing that CMS provided only a very narrow opportunity for stakeholder input prior to announcing such drastic changes to the payment of drugs under Medicare Part B. In our view, this action failed to consider the consequences raised by the patient and physician communities about the negative impact this proposal will have on patients’ access to and physicians’ ability to prescribe drugs covered under Medicare Part B.

CMS has indicated they have no intention of denying patients access to the drugs they need, but the concerns outlined above make it clear that patient access is a real threat under the current proposal. As such, we respectfully request that you ask CMS to permanently withdraw the Proposed Rule from consideration. We stand able and willing to work with Congress and CMS to ensure that our nation’s sickest patients are able to access the treatments that work best for them.

Should you require additional information, please contact Sandie Preiss, the National VP of Advocacy and Access at the Arthritis Foundation [spreiss@arthritis.org](mailto:spreiss@arthritis.org) 202 887 2910.

Sincerely,

Alliance for the Adoption of Innovations in Medicine (Aimed Alliance)  
American Academy of Ophthalmology  
American Autoimmune Related Diseases Association  
American College of Rheumatology  
American Sexual Health Association  
Arthritis Foundation  
Asthma and Allergy Association of America  
CancerCare  
Coalition of State Rheumatology Association  
COPD Foundation  
Epilepsy Foundation

Fabry Support & Information Group  
Global Colon Cancer Association  
Immune Deficiency Foundation  
Lupus and Allied Diseases Association, Inc  
Lupus Foundation of America  
National Alliance on Mental Illness  
National Cervical Cancer Coalition  
National Fabry Disease Foundation  
National Fibromyalgia & Chronic Pain Association  
RetireSafe  
San Francisco AIDS Foundation  
The AIDS Institute  
The American Academy of HIV Medicine  
The Veterans Health Council  
US Pain Foundation  
Vietnam Veterans of America

cc: Majority Leader Mitch McConnell  
Minority Leader Harry Reid  
Members, Senate Committee on Finance  
Speaker of the House Paul Ryan  
Minority Leader Nancy Pelosi  
Members, House Committee on Energy and Commerce  
Members, House Committee on Ways and Means