March 4, 2016

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell and Acting Administrator Slavitt:

We are writing to express our strong concern with the Centers for Medicare & Medicaid Services' (CMS) notice on the Medicare Part B Drug Payment Model released in early February. We believe that this type of initiative, implemented without sufficient stakeholder input, will adversely affect the care and treatment of Medicare patients with complex conditions, such as cancer, macular degeneration, hypertension, rheumatoid arthritis, and primary immunodeficiency diseases. We therefore respectfully request that you not proceed with the Medicare Part B payment initiative.

Medicare beneficiaries – representing some of the nation's oldest and sickest patients – must often try multiple prescription drugs and/or biologics before finding the appropriate treatment for their complex conditions. These patients need immediate access to the right medication, which is already complicated by the fact that treatment decisions may change on a frequent basis. These vulnerable Medicare patients and the providers who care for them already face significant complexities in their care and treatment options, and they should not face mandatory participation in an initiative that may force them to switch from their most appropriate treatment.

A Center for Medicare & Medicaid Innovation (CMMI) initiative that focuses on costs rather than patients and health care quality, implemented based on zip codes or similar units rather than the unique challenges of patients, as envisioned in the CMS-posted contractor instructions, is misguided and ill-considered. Medicare beneficiaries with life-threatening and/or disabling conditions would be forced to navigate a CMS initiative that could potentially lead to an abrupt halt in their treatment. This is not the right way to manage the Medicare program for its beneficiaries.

As CMS contemplates payment and delivery system reforms, there is a critical need for transparent, comprehensive communications with stakeholders throughout the process. We were deeply disappointed that CMS only provided a limited opportunity for stakeholder input before recently implementing a mandatory model for Medicare beneficiaries undergoing hip and knee replacement surgeries. In doing so, the agency largely failed to consider stakeholder concerns that the initiative could negatively affect the care provided to vulnerable patients. We strongly oppose any effort to rush through a similar initiative that may adversely impact patients' access to life-saving and life-changing Medicare Part B covered drugs.

We believe these types of initiatives should be initially implemented in a targeted, patient-centered and transparent way that accounts for the unique needs of Medicare beneficiaries. In fact, CMMI is statutorily required to ensure that its initiatives target "deficits in care," and can only expand the scope and duration of a model after careful assessment of the model's impact on quality of care, patient access, and spending. We are very concerned, therefore, that CMS plans to implement an initiative that would immediately impact a range of Part B providers and would be applied to "most Part B drugs." Furthermore, given the success of the current Part B reimbursement methodology in ensuring patient access to the most appropriate treatments, it is unclear what "deficits in care" CMS is attempting to address in this initiative.

CMS expressed concern in its contractor notice that the 6% ASP add-on payment may "encourage the use of more expensive products because the add-on to the drug's cost is a percentage of the sales price." This assumption fails to take into account the fact that providers' prescribing decisions depend on a variety of factors, including clinical characteristics and the complex needs of the Medicare population. Most importantly, there is no evidence indicating that the payment changes contemplated by the model will improve quality of care, and may adversely impact those patients that lose access to their most appropriate treatments. In fact, data suggests that the current Part B drug payment system has been both cost effective and successful in ensuring patient access to their most appropriate treatment, as Part B expenditures remain relatively stable[1] and Part B drugs account for just 3% of total program costs.[2]

Finally, CMS must recognize that the Budget Control Act cut Medicare reimbursement for physician-administered drugs, further impacting some providers' ability to purchase drugs at the current payment rate. It is imperative CMS understands and evaluates this current reimbursement rate and its outcome while engaging multiple stakeholders before implementing any demonstration that would further reduce reimbursement rates. In closing, we urge you to ensure that our nation's oldest and sickest patients continue to be able to access their most appropriate drugs and services. We therefore ask that you permanently withdraw the Part B Drug Payment Model from consideration.

Sincerely,

ADAP Advocacy Association (aaa+)
Aimed Alliance
Alabama Cancer Congress
Alliance for Patient Access (AFPA)
Alliance for Regenerative Medicine
American Academy of Allergy Asthma and Immunology (AAAAI)
American Academy of Ophthalmology
American Autoimmune Related Diseases Association (AARDA)
American Bechet's Disease Association
American College of Rheumatology

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[1] 2015 Medicare Trustees Report.

[2] Medicare Payment Advisory Commission, "Medicare Drug Spending;" presentation at September 2015 public meeting; available at: http://www.medpac.gov/documents/september-2015-meeting-presentation-medicare-drug-spending.pdf?sfvrsn=0.

American Gastroenterological Association
American Kidney Fund
American Society of Clinical Oncology
AmerisourceBergen
Arthritis Foundation
Association of Community Cancer Centers (ACCC)
Association of Northern California Oncologists
Biotechnology Innovation Organization (FKA Biotechnology Industry Organization)
Cancer Support Community
CancerCare
Cardinal Health
Caregiver Action Network
COA Patient Advocacy Network (CPAN)
Coalition of Hematology Oncology Practices (CHOP)
Coalition of State Rheumatology Organizations (CSRO)
Colon Cancer Alliance
Community Access National Network (CANN)
Community Oncology Alliance
Connecticut Oncology Association
Cutaneous Lymphoma Foundation
Fabry Support and Information Group
Fight Colorectal Cancer
Florida Society of Clinical Oncology
Georgia Society of Clinical Oncology
Global Colon Cancer Association
Global Genes
Global Healthy Living Foundation
Hawaii Society of Clinical Oncology
Healthcare Distribution Management Association
Healthcare Leadership Council
HealthHIV
Idaho Society of Clinical Oncology
Illinois Medical Oncology Society
Immune Deficiency Foundation (IDF)
Indiana Oncology Society
International Cancer Advocacy Network (ICAN)
ION Solutions
Iowa Oncology Society
Kansas Society of Clinical Oncology
Large Urology Group Practice Association (LUGPA)
Louisiana Oncology Society
Lung Cancer Alliance
McKesson
Medical Oncology Association of Southern California
Men's Health Network
Michigan Society of Hematology and Oncology
Midwest Oncology Practice Society
Minnesota Society of Clinical Oncology
Mississippi Oncology Society

Missouri Oncology Society
Montana State Oncology Society
National Alliance on Mental Illness
National Association for Rural Mental Health
National Association of County Behavioral Health & Developmental Disability Directors (NACBHDD)
National Grange
National Hispanic Medical Association
National Infusion Centers Association (NICA)
National Minority Quality Forum
National MPS Society
National Patient Advocate Foundation
National Psoriasis Foundation (NPF)
Nevada Oncology Society
North Carolina Oncology Association
Northern New England Clinical Oncology Society
Ohio Hematology Oncology Society
Oklahoma Society of Clinical Oncology
Oncology Nursing Society
Oncology Society of New Jersey
PCaBlue
Pharmaceutical Research and Manufacturers of America (PhRMA)
Premier Oncology Hematology Management Society (POHMS)
Prevent Cancer Foundation
Pulmonary Hypertension Association
RetireSafe
Rocky Mountain Oncology Society
Salud USA
Society for Women's Health Research
Society of Gynecologic Oncology
Society of Utah Medical Oncologists
South Carolina Oncology Society
Tennessee Oncology Practice Society
Texas Society of Clinical Oncology
The Arizona Clinical Oncology Society
The US Oncology Network
Vasculitis Foundation
Veterans Health Council
Vietnam Veterans of America
Virginia Association of Hematologists & Oncologists
West Virginia Oncology Society
Wisconsin Association of Hematology & Oncology
ZERO - The End of Prostate Cancer

cc: Patrick Conway, MD, MSc
Acting Principal Deputy Administrator, Deputy Administrator for Innovation & Quality, CMS Chief Medical Officer
Centers for Medicare & Medicaid Services

Tim Gronniger, MPP, MHSA
Director of Delivery System Reform
Centers for Medicare & Medicaid Services

The Honorable Orrin Hatch
Chairman
Committee on Finance
U.S. Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
U.S. House of Representatives

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
U.S. House of Representatives