

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<sup>1</sup> and Part B drugs account for just 3% of total program costs.<sup>2</sup>

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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<sup>1</sup> 2015 Medicare Trustees Report.

<sup>2</sup> 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