

March 17, 2016

The Honorable Mitch McConnell  
Majority Leader  
U.S. Senate  
Washington, D.C. 20510

The Honorable Paul Ryan  
Speaker of the House of Representatives  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Harry Reid  
Minority Leader  
U.S. Senate  
Washington, D.C. 20510

The Honorable Nancy Pelosi  
Minority Leader  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Leader McConnell, Leader Reid, Speaker Ryan and Leader Pelosi:

We, the 316 organizations listed below, are writing to express our strong concern with the Centers for Medicare & Medicaid Services' (CMS) March 8, 2016 proposed rule that would implement a new "Medicare Part B Payment Model." 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, Crohn's disease and ulcerative colitis, and primary immunodeficiency diseases. We previously sent a letter to Department of Health and Human Services (HHS) Secretary Sylvia Burwell asking her not to move forward with this type of initiative, and we now respectfully request that you ask CMS to withdraw the proposed rule.

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 primary care service areas, rather than the unique challenges of patients, 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 announcing sweeping proposed changes to Medicare Part B drug payments. In doing so, the agency largely failed to consider stakeholder concerns that the initiative could 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 deeply concerned, therefore, that CMS' proposed Part B Model would be applied on a nationwide basis – to all states except Maryland, due to its all-payer model – and would include the “majority” of 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 incredibly wide-ranging initiative.

In the proposed rule, CMS expresses concern that the 6% ASP add-on payment “may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.” 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, it is important to understand that with the Budget Control Act, CMS has already cut Medicare reimbursement for physician-administered drugs by 2%, further impacting some providers' ability to administer essential drugs at the current reimbursement rate. It is imperative CMS acknowledges and evaluates the impact of the current, real payment rate and engages multiple stakeholders, starting with patients and providers, before implementing a new, severe reimbursement cut that is effectively ASP + 0.86% (plus a small flat fee). 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 request that you ask CMS to permanently withdraw the Part B Drug Payment Model from consideration.

Sincerely,

1 in 9: The Long Island Breast Cancer Action Coalition

Action CF

ADAP Advocacy Association (aaa+)

Advocates for Responsible Care (ARxC)

Aimed Alliance

Alabama Academy of Ophthalmology

Alabama Cancer Congress

Alabama Gastroenterological Society

Alaska Society of Eye Physicians and Surgeons

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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>.

Alliance for Patient Access (AfPA)  
Alliance of Specialty Medicine  
Alzheimer's and Dementia Alliance of Wisconsin  
American Academy of Allergy Asthma and Immunology (AAAAI)  
American Academy of Ophthalmology  
American Association of Diabetes Educators  
American Bechet's Disease Association  
American College of Mohs Surgery  
American College of Rheumatology  
American Gastroenterological Association  
American Liver Foundation, Upper Midwest Division  
American Society of Clinical Oncology (ASCO)  
American Urological Association  
AmerisourceBergen  
Anticoagulation Forum  
Arizona BioIndustry Association (AZBio)  
Arizona United Rheumatology Alliance  
Arkansas State Rheumatology Association  
Arthritis Foundation  
Asian Americans for Community Involvement  
Association of Black Cardiologists  
Association of Community Cancer Centers (ACCC)  
Association of Idaho Rheumatologists  
Association of Indian Physicians of Ohio  
Association of Northern California Oncologists (ANCO)  
Association of Women in Rheumatology (AWIR)  
Asthma & Allergy Foundation of America, New England Chapter  
Axis Advocacy  
Biocom  
BioFlorida, Inc.  
BioForward  
BioHouston  
BioKansas  
BioNJ  
Bionorth TX  
Bioscience Association of West Virginia  
Biotechnology Innovation Organization (FKA Biotechnology Industry Organization)  
BioUtah  
Brain Injury Association of Georgia  
California Academy of Eye Physicians and Surgeons  
California Hepatitis C Task Force  
California Life Sciences Association (CLSA)

California Rheumatology Alliance (CRA)  
Cancer Support Community  
Cancer Support Community Central Ohio  
Cancer Support Community North Texas  
CancerCare  
Cardinal Health  
Caregiver Action Network  
Caring Ambassadors  
Cascade AIDS Project  
Center for Healthcare Innovation  
Central Texas Rheumatology Society  
Chicago Life Sciences Consortium (CLSC)  
COA Patient Advocacy Network (CPAN)  
Coalition of Hematology Oncology Practices (CHOP)  
Coalition of State Rheumatology Organizations (CSRO)  
Coalition of Texans with Disabilities (CTD)  
Colon Cancer Alliance  
Colorado BioScience Association  
Colorado Gerontological Society  
Colorado Rheumatology Association  
Colorado Society of Eye Physicians and Surgeons (CSEPS)  
Colorado State Grange  
Community Access National Network (CANN)  
Community Liver Alliance  
Community Oncology Alliance (COA)  
Connecticut Oncology Association (CtOA)  
Connecticut Rheumatology Association  
Cutaneous Lymphoma Foundation  
Delaware Academy of Ophthalmology  
Delaware BioScience Association  
Dia de la Mujer Latina  
Digestive Disease National Coalition (DDNC)  
Digestive Health Physicians Association (DHPA)  
Easter Seals Massachusetts  
Eastern Pennsylvania Chapter, National Hemophilia Foundation  
EDSers United Foundation  
Elder Care Advocacy of Florida  
Epilepsy Foundation of Greater Chicago  
Epilepsy Foundation of Western Wisconsin  
Fabry Support and Information Group  
Florida Allergy, Asthma & Immunology Society (FAAIS)  
Florida Gastroenterologic Society

Florida Psychiatric Society  
Florida Society of Clinical Oncology (FLASCO)  
Florida Society of Neurology  
Florida Society of Ophthalmology  
Florida Society of Rheumatology  
Florida State Hispanic Chamber of Commerce  
GBS|CIDP Foundation International  
Georgia Bio  
Georgia Chapter of the American College of Cardiology  
Georgia Mental Health Consumer Network  
Georgia Society of Clinical Oncology (GASCO)  
Georgia Society of Rheumatology  
Global Colon Cancer Association  
Global Healthy Living Foundation  
H.E.A.L.S of the South  
Hawaii Society of Clinical Oncology  
Health Coalition, Inc.  
Healthcare Distribution Management Association  
Healthcare Institute of New Jersey (HINJ)  
Healthcare Leadership Council  
HealthHIV  
Hematology-Oncology Managers of New York (HOMNY)  
Hepatitis Foundation International  
iBio - Illinois Biotechnology Industry Organization  
Idaho Society of Clinical Oncology  
Idaho Society of Ophthalmology  
Illinois Medical Oncology Society  
Illinois Society of Eye Physicians & Surgeons (ISEPS)  
Immune Deficiency Foundation (IDF)  
Indiana Academy of Ophthalmology (IAO)  
Indiana Health Industry Forum (IHIF)  
Indiana Oncology Society  
INDUNIV Research Consortium  
International Cancer Advocacy Network (ICAN)  
International Foundation for Autoimmune Arthritis (IFAA)  
International Institute For Human Empowerment, Inc.  
ION Solutions  
Iowa Academy of Ophthalmology (IAO)  
Iowa Biotechnology Association  
Iowa Oncology Society  
Iowa State Grange  
Kansas City Area Life Sciences Institute, Inc.

Kansas Rheumatology Alliance  
Kansas Society of Clinical Oncology  
Kansas Society of Eye Physicians & Surgeons (KSEPS)  
Kentuckiana Rheumatology Alliance  
Kentucky Association of Medical Oncology (KAMO)  
Kentucky Life Sciences Council  
Large Urology Group Practice Association (LUGPA)  
Life Science Washington  
Louisiana Oncology Society  
Lung Cancer Alliance  
LUNGevity  
Lupus Foundation of America (LFA), Indiana Chapter  
Lupus Foundation of Colorado  
Maryland DC Society of Clinical Oncology  
Maryland Society for the Rheumatic Diseases (MSRD)  
Massachusetts Association for Mental Health  
Massachusetts Society of Eye Physicians and Surgeons (MSEPS)  
Massachusetts, Maine and New Hampshire Rheumatology Association  
MassBio  
Mayors Committee on Life Sciences  
McKesson  
Medical Oncology Association of Southern California (MOASC)  
Medical Partnership 4 MS  
Medical Society of the State of New York  
Men's Health Network  
Mental Health Systems, Inc.  
Metropolitan Atlanta Rheumatology Society (MARS)  
MichBio - Michigan Biosciences Industry Association  
Michigan Lupus Foundation  
Michigan Osteopathic Association  
Michigan Rheumatism Society  
Michigan Society of Eye Physicians and Surgeons (MiSEPS)  
Michigan Society of Hematology and Oncology (MSHO)  
Midwest Oncology Practice Society (MOPS)  
Minnesota Academy of Ophthalmology  
Minnesota Society of Clinical Oncology  
Mississippi Academy of Eye Physicians and Surgeons  
Mississippi Arthritis and Rheumatology Society  
Mississippi Oncology Society  
Missouri Biotechnology Association (MOBIO)  
Missouri Oncology Society  
Missouri Society of Eye Physicians & Surgeons (MoSEPS)

Montana BioScience Alliance  
Montana State Oncology Society  
NASW-NC (National Association of Social Workers)  
National Alliance on Mental Illness (NAMI)  
National Alliance on Mental Illness Greater Des Moines (NAMI)  
National Alliance on Mental Illness Iowa (NAMI)  
National Alliance on Mental Illness Kentucky (NAMI)  
National Alliance on Mental Illness Texas (NAMI)  
National Association for Rural Mental Health  
National Association of County Behavioral Health & Developmental Disability Directors (NACBHDD)  
National Association of Hepatitis Task Forces  
National Blood Clot Alliance (NBCA)  
National Cancer Care Alliance  
National Hispanic Medical Association  
National Infusion Center Association (NICA)  
National Medical Association (NMA)  
National Minority Quality Forum  
National MPS Society  
National Patient Advocate Foundation  
Nebraska Academy of Eye Physicians and Surgeons  
Nebraska Medical Association (NMA)  
Nebraska Oncology Society  
Neurofibromatosis Mid-Atlantic  
Nevada Oncology Society  
New England Biotech Association (NEBA)  
New Jersey Academy of Ophthalmology  
New Jersey Association of Mental Health and Addiction Agencies, Inc. (NJAMHAA)  
New Jersey Rheumatology Association  
New Jersey Society for Oncology Managers (NJSOM)  
New York State Ophthalmological Society  
New York State Rheumatology Society  
NewYorkBIO  
NMBio  
NORM - National Organization of Rheumatology Managers  
North American Thrombosis Forum  
North Carolina Biosciences Organization (NCBIO)  
North Carolina Oncology Association  
North Carolina Psychiatric Association  
North Carolina Psychological Association  
North Carolina Rheumatology Association (NCRA)  
North Carolina Society of Eye Physicians and Surgeons (NCSEPS)

Northern New England Clinical Oncology Society  
Ohio Association of Rheumatology  
Ohio Foot and Ankle Medical Association  
Ohio Gastroenterology Society  
Ohio Hematology Oncology Society  
Ohio Ophthalmological Society (OOS)  
Oklahoma Academy of Ophthalmology  
Oklahoma Society of Clinical Oncology  
Oncology Managers of Florida  
Oncology Nursing Society  
Oregon Bioscience Association  
Oregon Rheumatology Alliance  
Oregon Society of Medical Oncology (OSMO)  
Oregon State Grange  
Oregon Urological Society  
Patients Rising  
PCa Blue Inc.  
Pennsylvania Academy of Ophthalmology  
Pennsylvania Bio  
Pennsylvania Rheumatology Society  
Pennsylvania State Grange  
Pharmaceutical Research and Manufacturers of America (PhRMA)  
Philadelphia Rheumatism Society  
Phoenix Rheumatology Association  
Physicians Advocacy Institute (PAI)  
Premier Oncology Hematology Management Society (POHMS)  
Prevent Blindness  
Prevent Blindness, Ohio Affiliate  
Prevent Cancer Foundation  
Prostate Conditions Education Council (PCEC)  
Puerto Rico Society of Ophthalmology  
Pulmonary Hypertension Association  
Quality Cancer Care Alliance (QCCA)  
RetireSafe  
Rheumatism Society of the District of Columbia  
Rheumatology Alliance of Louisiana  
Rheumatology Association of Iowa (RAI)  
Rocky Mountain Oncology Society  
Rush To Live  
Salud USA  
SCBIO  
Society for Women's Health Research



Society of Utah Medical Oncologists  
South Carolina Gastroenterology Association  
South Carolina Oncology Society  
South Carolina Rheumatism Society  
South Carolina Society of Ophthalmology  
South Dakota Biotech  
South Florida Cancer Association  
Southern California Rheumatology Society (SCRS)  
Spina Bifida Association of Kentucky  
State of Texas Association of Rheumatologists (STAR)  
State of Texas Kidney Foundation  
StopAfib.org  
Taking Control Of Your Diabetes (TCOYD)  
Tech Council of Maryland  
Tennessee Oncology Practice Society (TOPS)  
Tennessee Rheumatology Society  
Texas Association of Business  
Texas Association of Manufacturers  
Texas BioAlliance  
Texas Healthcare and Bioscience Institute (THBI)  
Texas Life Sciences Collaboration Center  
Texas Nurse Practitioners  
Texas Ophthalmological Association  
Texas Society of Clinical Oncology  
Texas State Grange  
The American College of Surgeons/Commission on Cancer  
The Arizona Clinical Oncology Society  
The Crohn's Colitis Effect  
The Medical Alley Association  
The Mended Hearts, Inc.  
The Retina Society  
The US Oncology Network  
The Vasculitis Foundation  
U.S. Hereditary Angioedema Association  
United States Cutaneous Lymphoma Consortium  
Utah Ophthalmology Society  
Veterans Health Council  
Vietnam Veterans of America  
Virginia Association of Hematologists & Oncologists  
Virginia Biotechnology Association  
Virginia Hematology Oncology Association (VAHO)  
Virginia Society of Eye Physicians and Surgeons

Washington Academy of Eye Physicians and Surgeons  
Washington Rheumatology Alliance  
Washington State Medical Oncology Society  
Washington State Prostate Cancer Coalition  
Washington State Urology Society  
Wellness and Education Community Action Health Network  
West Virginia Oncology Society  
West Virginia Rheumatology State Society  
Wisconsin Academy of Ophthalmology  
Wisconsin Association of Hematology & Oncology  
Wisconsin Association of Osteopathic Physicians & Surgeons  
Wisconsin Rheumatology Association  
Wyoming Epilepsy Association  
Wyoming Ophthalmological Society

**cc:** 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