

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 stable¹ and Part B drugs account for just 3% of total program costs.²

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

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>.

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