



December 10, 2018

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

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

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

We are writing on behalf of the Part B Access for Seniors and Physicians (ASP) Coalition, which is committed to advancing life-saving innovation in the U.S. We are greatly concerned about a proposal by the Centers for Medicare & Medicaid Services (CMS) to implement an unprecedented, mandatory experiment affecting Medicare beneficiaries who take Part B-covered drugs. We support efforts to strengthen the United States' health care system through patient-centered reforms that embrace competition, foster the provider-patient relationship, and value transformation.

The CMS "International Pricing Index" model is not aligned with the above principles. Instead of encouraging Medicare beneficiaries to work closely with their physicians to select treatments based on evidence and best practices, the model would import foreign-based price controls, regardless of value or innovation. Our greatest concern is that this model would impose decisions made in countries such as Greece or Japan on approximately half of all independent physicians and hospital providers, as well as their patients. Compounding these concerns, the model also interjects new middlemen between physicians and patients – vendors that would impose requirements dictating treatment for patients with cancer, autoimmune disorders and other complex, life-threatening conditions. The model would restrict access in the short-term, and reduce incentives for medical advancement in the long-term, ultimately posing serious risks to vulnerable Medicare beneficiaries.

The Medicare Part B International Pricing Index model would slash provider reimbursement for physician-administered medicines based on foreign "reference" prices. The danger of this approach is demonstrated by the experience of patients in countries CMS would use to set Medicare reimbursement. CMS plans to use reference pricing from countries with health care models where government bureaucrats, not physicians, make medical decisions. There is evidence that patients in these countries do not have access to state-of-the-art medical innovation and is not a model the U.S. should emulate on any level. For example, restrictions imposed by the United Kingdom's National Institute for Health and Care Excellence create substantial barriers between patients and life-saving

treatments – recent analysis shows that nearly 92 percent of oncology treatments were subjected to access restrictions from 2013-2017. Further, Americans get access to new cancer medicines an average of two years earlier than patients in Europe.

The model sets a risky precedent for other health care providers and services. Once Medicare uses foreign price controls to determine reimbursement for physician-administered drugs, CMS could apply the same principles to other services. The agency could tie foreign payment levels to reimbursement for medical devices, physician services, nursing care, diagnostic tests, or mental health and substance use disorder specialists. Use of foreign payment policies risks importing access delays to Medicare beneficiaries, limiting patient choice of provider, and potentially impeding development of more effective medicines for patients.

The proposed model would put vendors with no clinical or medical expertise between patients and doctors. Vendors would inevitably impose restrictions on beneficiary access to drugs through formularies, disrupting or delaying care in the pursuit of profit. Medicare Part B beneficiaries have a right to access the Part B-covered drug prescribed by their physician based on his or her medical knowledge and experience. Beneficiaries would effectively lose this right under the model, as vendors that beneficiaries did not choose will dictate the types of drugs they can use. This is particularly risky for vulnerable Medicare patients with cancer and autoimmune or ophthalmic conditions who require complex treatment regimens. Medicare Part B beneficiaries face debilitating consequences if they cannot access the Medicare Part B drugs prescribed by their physician, or if their physician cannot modify their treatment quickly as circumstances change. While this model will likely be positive for the bottom lines of vendors such as PBMs, it will be a net negative for patients and providers, and create new inefficiencies and burdens in the delivery system.

Health and Human Services Secretary Alex Azar set out key principles to improve value in Medicare. In a recent speech, he emphasized supporting patients as empowered consumers and providers as accountable navigators, paying for outcomes, and preventing disease before it occurs or progresses. None of these principles are evident in the International Pricing Index Model. The CMS notice focuses solely on short-term cost reductions, emphasizing only medication costs, with little, if any, meaningful analysis of overall health costs, the impact of medications on use of higher cost services, or quality measures.

Innovation will also suffer as the model would disrupt biopharmaceutical investment in research and development. Foreign price controls already hinder investment in biopharmaceutical research and development. A report for the U.S. Department of Commerce found that international reference pricing and other foreign price controls suppress worldwide private research and development investment by 11-16 percent annually, impacting the number of new and innovative medicines brought to market.

We support use of the Center for Medicare & Medicaid Innovation (CMMI) to test patient-centered, voluntary, small-scale reforms that can be fully evaluated. However, the IPI model is a wide-scale demonstration that would be mandatory, affecting 50 percent of physicians and hospitals serving Medicare Part B beneficiaries. The unprecedented scale and scope of the model would impact payment and access for beneficiaries in the rest of the Medicare Part B program. The mandatory nature of the

model would force beneficiaries into the experiment, eliminating their ability to choose a provider not subject to the model. There is little in the model that addresses key statutory principles for CMMI models that are intended to improve the coordination, quality, and efficiency of health care services. The new model would also overlap and interfere with existing CMMI demonstrations, making it difficult to evaluate the benefits of reforms that represent significant investments by CMS and providers.

Over 59 million seniors and persons with disabilities rely on Medicare Part B for essential treatments. Any potential changes to the program should be tested only in a limited and careful way, based on clinical evidence and guidelines focused on high quality care. These qualities are not part of the International Pricing Index model that CMS has proposed. On behalf of the 339 undersigned organizations, we urge you to work with us to halt implementation of the model and instead seek workable solutions that focus on patients and providers.

Sincerely,

1in9: The Long Island Breast Cancer Action Coalition

2020 Mom AZ

Action Wellness

Addario Lung Cancer Medical Institute

Advocates for Responsible Care (ARxC)

Aging2.0 Denver Chapter

AIDS Response Seacoast

Allergy & Asthma Network

Alliance for Patient Access (AfPA)

Alliance for the Adoption of Innovations in Medicine ("Aimed Alliance")

Alliance of Independent Pharmacists of Texas

ALS Association - Evergreen Chapter

ALS Association Greater Philadelphia Chapter

Alzheimer's and Dementia Alliance of Wisconsin

American Academy of Allergy, Asthma & Immunology (AAAAI)

American Autoimmune Related Diseases Association (AARDA)

American Behcet's Disease Association

American College of Mohs Surgery

American Kidney Fund

American Liver Foundation

American Medical Women's Association  
American Stroke Foundation  
American Urological Association  
AmerisourceBergen  
Ames Chamber of Commerce  
Anticoagulation Forum  
Applied Pharmacy Solutions  
APS Foundation of America, Inc. (APSFA)  
Arizona Aunt Rita's Foundation  
Arizona Bioindustry Association, Inc. (AZBio)  
Arizona Myeloma Network (AzMN)  
Association of Community Cancer Centers (ACCC)  
Association of Northern California Oncologists (ANCO)  
Association of Women in Rheumatology (AWIR)  
Asthma and Allergy Foundation of America  
Asthma and Allergy Foundation of America, New England Chapter  
BIO Alabama  
Bio Nebraska Life Sciences Association  
Biocom  
BioCT  
BioFlorida  
BioForward Wisconsin  
BioKansas  
BioME  
BioNexus KC  
BioNJ  
BioOhio  
Bioscience Association of North Dakota  
Bioscience Association of West Virginia  
BioUtah

Black Women's Health Imperative  
Bonnie J. Addario Lung Cancer Foundation  
Brain Injury Alliance of Arizona  
Brain Injury Alliance of Connecticut  
Brain Injury Association of Delaware  
California Association of Area Agencies on Aging  
California Chronic Care Coalition  
California Hepatitis C Task Force  
California Hispanic Chambers of Commerce  
California Life Sciences Association (CLSA)  
California Rheumatology Alliance (CRA)  
Cambridge Chamber of Commerce  
Cancer Support Community Central Ohio  
CancerCare  
Cardinal Health Specialty Solutions  
Caregiver Action Network  
Caregiver Voices United  
Caregivers of New Jersey  
Caring Ambassadors Program  
Carrie's TOUCH  
Center for Healthcare Innovation  
Central Florida Behavioral Health Network  
Centro de Mi Salud, LLC  
Chicago Hispanic Health Coalition  
Chronic Disease Coalition  
Chronic Disease Prevention Council  
COA Patient Advocacy Network (CPAN)  
Coalition of Hematology Oncology Practices (CHOP)  
Coalition of State Rheumatology Organizations (CSRO)  
Coalition of Texans with Disabilities (CTD)

Colorado BioScience Association  
Colorado Rheumatology Association  
Colorado State Grange  
Community Health Charities of Nebraska  
Community Oncology Alliance (COA)  
Community Oncology Pharmacy Association (COPA)  
Congress of California Seniors  
Connecticut Bioscience Growth Council  
Connecticut Rheumatology Association  
Conquer Myasthenia Gravis  
Cutaneous Lymphoma Foundation  
Danio Connect  
Danio Diary  
Delaware BioScience Association, Inc.  
Delaware Ecumenical Council on Children and Families  
Delaware HIV Consortium  
Dia de la Mujer Latina (DML)  
Digestive Disease National Coalition (DDNC)  
Digestive Health Physicians Association (DHPA)  
Easter Seals Massachusetts  
Easterseals Central Texas  
Easterseals Iowa  
Easterseals North Texas  
Easterseals Oak Hill  
ELLAS  
Empire State Hematology and Oncology Society  
Epilepsy Alliance Louisiana  
Epilepsy Association of Central Florida  
Epilepsy Association of the Big Bend  
Epilepsy California

Epilepsy Foundation Heart of Wisconsin  
Epilepsy Services of New Jersey  
FAIR Foundation  
Fenway Health  
Florida Allergy, Asthma & Immunology Society (FAAIS)  
Florida Osteopathic Medical Association  
Florida Society of Clinical Oncology (FLASCO)  
Florida Society of Rheumatology  
Florida State Hispanic Chamber of Commerce  
Free ME from Lung Cancer  
Georgia Bio  
Georgia Society of Clinical Oncology (GASCO)  
Georgia Society of Rheumatology  
Global Colon Cancer Association  
Global Healthy Living Foundation  
Global Liver Institute  
Greater Des Moines Partnership  
H.E.A.L.S of the South (Hepatitis Education, Awareness and Liver Support)  
Hawaii Society of Clinical Oncology  
Healthcare Institute of New Jersey (HINJ)  
HealthyWomen  
Hemophilia Alliance of Maine  
Hemophilia Council of California  
Hemophilia Federation of America  
Hemophilia Foundation of Michigan  
Hispanic Health Council  
ICAN - International Cancer Advocacy Network  
Idaho Chapter of the National Hemophilia Foundation  
Idaho Society of Clinical Oncology  
Idaho Tech Council

Illinois Biotechnology Innovation Organization (iBIO)  
Illinois Medical Oncology Society  
Indiana Health Industry Forum (IHIF)  
Indiana Oncology Society  
INDUNIV Research Center, Inc.  
International Association of Hepatitis Task Forces (IAHTF)  
International Foundation for Autoimmune & Autoinflammatory Arthritis (IFAA)  
International Institute For Human Empowerment  
International Pain Foundation  
International Pemphigus and Pemphigoid Foundation  
ION Solutions  
Iowa Biotechnology Association  
Iowa Oncology Society  
Kansas Society of Clinical Oncology  
KCCure  
Kentuckiana Stroke Association  
Kentucky Access to Care Coalition  
Kentucky Association of Medical Oncology (KAMO)  
Kentucky Hemophilia Foundation  
Kentucky Life Sciences Council  
Kidney Cancer Action Network  
Large Urology Group Practice Association (LUGPA)  
Latino Commission on AIDS  
Life Science Tennessee  
Life Science Washington  
Life Sciences Pennsylvania  
Living Hope for Mental Health  
Looms For Lupus  
Louisiana Oncology Society  
Lung Cancer Alliance



Lung Cancer Foundation of America  
Lupus Alliance of Upstate New York  
Lupus and Allied Diseases Association  
Lupus Foundation New England  
Lupus Foundation of America  
Lupus Foundation of Arkansas, Inc.  
Lupus of Nevada  
Maryland Society for the Rheumatic Diseases (MSRD)  
Maryland Technology Council  
Massachusetts Association for Mental Health (MAMH)  
Massachusetts Biomedical Initiatives  
Massachusetts Biotechnology Council (MassBio)  
Massachusetts, Maine & New Hampshire Rheumatology Association  
Matthew 25 AIDS Services  
McKesson Corporation  
Meals on Wheels of Wake County  
Medical Alley Association  
Medical Oncology Association of Southern California, Inc. (MOASC)  
Medical Society of Delaware  
Medical Society of the State of New York  
MedMates  
Mended Hearts  
Men's Health Network  
Mental Health America of Franklin County  
Mental Health America of Kentucky  
Mental Health America of Montana  
Metro Denver Oncology Nursing Society  
Metropolitan Atlanta Rheumatology Society (MARS)  
Michigan Biosciences Industry Association (MichBio)  
Michigan Lupus Foundation

Michigan Osteopathic Association  
Michigan Rheumatism Society  
Michigan Society of Hematology and Oncology (MSHO)  
Midwest Oncology Practice Society (MOPS)  
MidWest Rheumatology Association  
Minnesota Independent Physicians Association  
Minnesota Society of Clinical Oncology  
Mississippi Arthritis and Rheumatism Society (MSARS)  
Mississippi Oncology Society  
Missouri Biotechnology Association (MOBIO)  
Missouri Oncology Society  
MLD Foundation  
Montana BioScience Alliance  
Montana State Oncology Society  
Multiple Sclerosis Foundation  
Multiple Sclerosis Resources of Central New York, Inc.  
National Alliance of State Prostate Cancer Coalitions  
National Alliance on Mental Illness (NAMI) Alabama  
National Alliance on Mental Illness (NAMI) Cayuga County  
National Alliance on Mental Illness (NAMI) Dona Ana County  
National Alliance on Mental Illness (NAMI) Georgia  
National Alliance on Mental Illness (NAMI) Huntington  
National Alliance on Mental Illness (NAMI) Kansas  
National Alliance on Mental Illness (NAMI) Massachusetts  
National Alliance on Mental Illness (NAMI) Mercer NJ  
National Alliance on Mental Illness (NAMI) Nebraska  
National Alliance on Mental Illness (NAMI) North Carolina  
National Alliance on Mental Illness (NAMI) Rockland  
National Alliance on Mental Illness (NAMI) St. Louis  
National Alliance on Mental Illness (NAMI) Texas

National Alliance on Mental Illness (NAMI) Washington  
National Association of Hispanic Nurses Houston  
National Blood Clot Alliance  
National Consumers League  
National Grange  
National Hispanic Medical Association  
National Infusion Center Association (NICA)  
National Medical Association (NMA)  
National Minority Quality Forum  
National Oncology State Network (NOSN)  
National Organization of Rheumatology Managers (NORM)  
National Patient Advocate Foundation  
Nebraska Rheumatology Society  
Nevada Oncology Society  
New England Biotechnology Association Inc. (NEBA)  
New Jersey Association of Mental Health and Addiction Agencies, Inc. (NJAMHAA)  
New Jersey Mayors Committee on Life Sciences  
New Jersey Rheumatology Association (NJRA)  
New Mexico Biotechnology & Biomedical Association (NMBio)  
New Mexico Business Coalition (NMBC)  
New York State Rheumatology Society  
Newark Senior Center  
North Carolina Biosciences Organization (NCBIO)  
North Carolina Oncology Association  
North Carolina Rheumatology Association (NCRA)  
North Dakota Rural Health Association  
Northeast Kidney Foundation  
Northern Utah Cancer Foundation  
Ohio Association of Rheumatology  
Ohio Hematology Oncology Society

Oncology Managers of Florida  
Oregon Bioscience Association  
Oregon Rheumatology Alliance  
Oregon Urological Society  
Paths2PossAbilities  
Patients Rising  
Physicians Advocacy Institute  
Port Isabel-San Benito Navigation District  
Prevent Blindness  
Prevent Blindness Wisconsin  
Prevent Blindness, Ohio Affiliate  
Project Access NOW  
Project ReDirect D.C.  
Psychosocial Rehabilitation Association of New Mexico  
Quality Connection  
Rare New England  
Re: Cancer  
Relapsing Polychondritis Awareness and Support Foundation  
RetireSafe  
Rheumatology Alliance of Louisiana (RAL)  
Rheumatology Association of Iowa (RAI)  
Rheumatology Nurses Society  
Rheumatology Society of Delaware  
Rheumatology Society of North Texas  
Rio Grande Valley Partnership  
Rocky Mountain Oncology Society  
Rush To Live  
S.A.M.S. Stop All Multiple Sclerosis  
SCBIO  
Scleroderma Foundation Michigan Chapter

Scleroderma Foundation Tri-State Inc Chapter  
Senior Connections, The Capital Area Agency on Aging  
Seniors Matter  
Sick Cells - A Sickle Cell Disease Organization  
Sickle Cell Disease Association of Florida  
Sisters R Us Circle of Survivors  
Sisters Working It Out  
Sjogren's Syndrome Foundation  
Snake River Hemophilia & Bleeding Disorders Association  
Society of Utah Medical Oncologists  
South Carolina Oncology Society  
South Carolina Rheumatism Society  
South Dakota Biotech  
Southwest Center for Independent Living  
Spina Bifida Association  
State of Texas Association of Rheumatologists (STAR)  
StopAfib.org/ American Foundation for Women's Health  
Suicide Awareness Voices of Education (SAVE)  
Survivors Cancer Action Network  
Survivors Cancer Action Network (CAN) – Alabama  
Syndicus Inc.  
Tennessee Oncology Practice Society (TOPS)  
Tennessee Rheumatology Society  
Texas Healthcare and Bioscience Institute (THBI)  
Texas Kidney Foundation  
Texas Society of Clinical Oncology  
The Arizona Clinical Oncology Society  
The Family Resource Network - NJ  
The US Oncology Network  
Transplant Recipients International Organization of the Pacific Northwest

U.S. Rural Health Network  
Vasculitis Foundation  
Vets Place Northwest  
Virginia Association of Hematologists & Oncologists  
Virginia Biotechnology Association  
Virginia Breast Cancer Foundation  
Virginia Society of Rheumatologists  
VisMed3D  
Washington (State) Rheumatology Alliance  
Washington State Medical Oncology Society  
Washington State Oral Health Coalition  
West Virginia Oncology Society  
West Virginia Prostate Cancer Coalition  
Wisconsin Association of Hematology & Oncology  
Wisconsin Association of Osteopathic Physicians & Surgeons  
Wisconsin Rheumatology Association  
WomenHeart of Jamestown  
Wyoming Epilepsy Association  
ZERO - The End of Prostate Cancer

cc: Honorable Alex Azar, Secretary, Department of Health and Human Services  
Honorable Seema Verma, Administrator, Centers for Medicare and Medicaid Services  
Honorable Orrin Hatch, Chairman, Senate Finance Committee  
Honorable Ron Wyden, Ranking Member, Senate Finance Committee  
Honorable Kevin Brady, Chairman, Committee on Ways and Means  
Honorable Richard Neal, Ranking Member, Committee on Ways and Means  
Honorable Greg Walden, Chairman, Committee on Energy and Commerce  
Honorable Frank Pallone, Jr., Ranking Member, Committee on Energy and Commerce