



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