

September 12, 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, the undersigned organizations, are deeply concerned with the recent memo from the Centers for Medicare and Medicaid Services (CMS) that changes long-standing policy and allows Medicare Advantage (MA) plans to implement step therapy to manage Part B drugs in circumstances where applicable. Original Medicare policies do not require step therapy. The new policy takes effect beginning January 1, 2019. CMS' sudden and disruptive decision to allow the inappropriate use of step therapy policies is inconsistent with the requirement that MA plans provide coverage consistent with Original Medicare and threatens to restrict access and decrease therapy choices for patients. This could put patients' health at risk and potentially creates long-term health care issues in the process. Absent significant patient protections, we urge CMS to withdraw this memo and reinstate the 2012 memo for the sake of the millions of beneficiaries who rely on Medicare to access needed care.

Our concerns grow from the direct negative experiences that many of our organizations' members have had with step therapy. As a result of insurers' step therapy (also known as "fail first") policies in the commercial market, patients have experienced delayed and restricted access to needed treatments which can impact quality of care, while physicians have experienced significantly increased administrative burdens. At a time when policymakers are seeking reforms that empower and engage patients, and reduce needless provider burden, the CMS guidance is a step in the wrong direction for Medicare and seniors.

Fail first policies limit the options available for patients and their physicians to treat conditions, forcing individuals to try the treatment that is preferred by the insurance company (often an older, cheaper medicine) rather than the medicine prescribed by the physician. Medical literature and news media are rife with data on the negative effects of these policies on patients and caregivers. That's because each patient has different needs, and often the treatment that best meets an individual's clinical circumstances and preferences conflicts with an insurer's one-size-fits-all step therapy requirement.

For example, a patient with rheumatoid arthritis (RA) may require a disease-modifying biologic medication to control his or her symptoms and prevent further joint damage. However, step therapy rules could force a patient to first try an older, cheaper RA medication that could lead to pain, limited mobility, and long-term joint damage. Patients with many other complex diseases that involve treatment with physician-administered medicines – such as cancer, macular degeneration, Crohn's

disease or colitis, multiple sclerosis, and neurological disorders – face similar barriers under fail first policies.

Despite the well-recognized patient access risks of step therapy, CMS' August 7, 2018 memo lacks basic patient safeguards that should be included in any utilization management policy. This includes, for example, a lack of adequate standards and transparency to ensure that any step therapy policies are clinically appropriate and evidence based. It also lacks a timely and accessible process for patients to seek exceptions to a step therapy requirement, and protections against potential increases in cost sharing for some patients who may be forced to try a Part D drug instead of a Part B drug that was their physician's first choice. Additionally, CMS' aggressive implementation timeline and lack of clarity around treatment "grandfathering" casts uncertainty on many beneficiaries' ability to continue treatment with their ongoing therapies.

Policies that sacrifice the health of patients in the hope of cutting program costs undermine the promise Medicare represents for so many individuals. We ask members of Congress to encourage the Trump administration to consider alternative solutions, like clinically appropriate utilization management, that instead utilize evidence-based guidelines designed with the input of medical practitioners, patients and advocates. By strengthening the critical doctor-patient relationship rather than insurance companies' bottom lines, Congress can improve the widely popular Medicare program through sensible, effective and tailored reforms.

We look forward to seeing your progress on behalf of patients in the coming weeks.

Sincerely,

1in9: The Long Island Breast Cancer Action Coalition

Advocates for Responsible Care (ARxC)

Aging2.0 Denver Chapter

Alabama Academy of Ophthalmology

Alabama Society for the Rheumatic Diseases

Alaska Rheumatology Alliance

Alliance for Aging Research

Alliance for Patient Access (AfPA)

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

Alzheimer's & Dementia Resource Center

Alzheimer's and Dementia Alliance of Wisconsin

American Academy of Allergy, Asthma & Immunology (AAAAI)

American Academy of Dermatology Association

American Academy of Ophthalmology

American Association of Clinical Urologists

American Autoimmune Related Diseases Association (AARDA)
American Behcet's Disease Association (ABDA)
American College of Rheumatology
American Kidney Fund
American Medical Women's Association
American Osteopathic Association
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology (ASCO)
American Urological Association
Anticoagulation Forum
Arizona Bioindustry Association, Inc. (AZBio)
Arizona Myeloma Network
Arthritis Foundation
Association of Black Cardiologists
Association of Community Cancer Centers (ACCC)
Association of Idaho Rheumatologists (AIR)
Association of Northern California Oncologists (ANCO)
Association of Women in Rheumatology (AWIR)
Asthma & Allergy Foundation of America, New England Chapter
Asthma and Allergy Foundation of America
Bio Nebraska Life Sciences Association
BioBuzz Workforce Foundation, Inc.
Biocom
BioFlorida
BioForward Wisconsin
BioKansas
BioNJ
BioOhio
Bioscience Association of North Dakota
Biotechnology Innovation Organization (FKA Biotechnology Industry Organization)

BioUtah
California Academy of Eye Physicians and Surgeons
California Chronic Care Coalition
California Hepatitis C Task Force
California Life Sciences Association (CLSA)
California Rheumatology Alliance (CRA)
Cancer Support Community
Cancer Support Community Arizona
Cancer Support Community Central Ohio
Cancer Support Community North Texas
Cancer Warrior Alliance
CancerCare
Caregiver Action Network
Caregiver Voices United
CARES Foundation, Inc.
Caring Ambassadors Program
Celiac Disease Foundation
Center for Independence of the Disabled, NY
Central Florida Behavioral Health Network
Chronic Disease Coalition
CNY HIV Care Network
Coalition of Hematology Oncology Practices (CHOP)
Coalition of State Rheumatology Organizations (CSRO)
Colorado BioScience Association
Colorado Gerontological Society
Colorado State Grange
Colorectal Cancer Alliance
Community Oncology Alliance (COA)
Connecticut Rheumatology Association
Cooley's Anemia Foundation

Cutaneous Lymphoma Foundation
Danio Connect
Danio Diary
Delaware Academy of Medicine / Delaware Public Health Association
Delaware BioScience Association, Inc.
Delaware Ecumenical Council on Children and Families
Delaware HIV Consortium
Digestive Disease National Coalition (DDNC)
Digestive Health Physicians Association (DHPA)
Easter Seals Massachusetts
Easter Seals North Georgia, Inc.
Eastern Pennsylvania Chapter of the National Hemophilia Foundation
Epilepsy Association of Central Florida
Epilepsy Association of the Big Bend
Florida Allergy, Asthma & Immunology Society (FAAIS)
Florida Osteopathic Medical Association
Florida Society of Rheumatology
GBS|CIDP Foundation International
Georgia Bio
Georgia Society of Rheumatology
Global Colon Cancer Association
Global Healthy Living Foundation
Global Liver Institute
Healthcare Institute of New Jersey (HINJ)
HealthyWomen
Hemophilia Alliance
Hemophilia Federation of America
IFAA - International Foundation for Autoimmune & Autoinflammatory Arthritis
Illinois Biotechnology Innovation Organization (iBIO)
Immune Deficiency Foundation (IDF)

Indiana Health Industry Forum (IHIF)
INDUNIV Research Center, Inc.
International Association of Hepatitis Task Forces (IAHTF)
International Cancer Advocacy Network (ICAN)
ION Solutions
Iowa Biotechnology Association
Jeffrey Modell Foundation
Kansas Rheumatology Alliance
KCCure
Kentucky Life Sciences Council
Large Urology Group Practice Association (LUGPA)
Life Sciences Pennsylvania
Lipodystrophy United
Living Hope for Mental Health
Los Angeles Wellness Station
Lung Cancer Alliance
LUNGevity Foundation
Lupus Alliance of Upstate New York
Lupus and Allied Diseases Association
Lupus Foundation New England
Lupus Foundation of America
Lupus Foundation of America, Indiana Chapter
Lupus Foundation of Arkansas, Inc.
Lupus Foundation of Colorado
Lupus LA
Lupus Society of Illinois
Martin Center Sickle Cell Initiative
Maryland Society for the Rheumatic Diseases (MSRD)
Maryland Tech Council
Massachusetts Association for Mental Health (MAMH)

MassBio
Medical Alley Association
Medical Oncology Association of Southern California, Inc. (MOASC)
Medical Society of the State of New York
Mended Hearts
Men's Health Network
Mental Health America of Franklin County
Metro Denver Oncology Nursing Society
Metropolitan Atlanta Rheumatology Society (MARS)
Michigan Biosciences Industry Association (MichBio)
Midwest Oncology Practice Society (MOPS)
MidWest Rheumatology Association
Mississippi Arthritis and Rheumatism Society (MSARS)
Mississippi Psychiatric Association
Missouri Biotechnology Association (MOBIO)
MLD Foundation
Montana BioScience Alliance
Multiple Sclerosis Foundation
Multiple Sclerosis Resources of Central New York, Inc.
Nashville CARES
National Alliance of State Prostate Cancer Coalitions
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) New Mexico
National Alliance on Mental Illness (NAMI) North Carolina
National Alliance on Mental Illness (NAMI) St. Louis
National Alliance on Mental Illness (NAMI) Virginia
National Association for Rural Mental Health
National Association of County Behavioral Health & Developmental Disability Directors (NACBHDD)

National Association of Social Workers, Texas Chapter
National Blood Clot Alliance (NBCA)
National Grange
National Hemophilia Foundation
National Hispanic Medical Association
National Infusion Center Association (NICA)
National Medical Association (NMA)
National Minority Quality Forum
National Multiple Sclerosis Society
National Oncology State Network (NOSN)
National Organization of Rheumatology Managers (NORM)
National Osteoporosis Foundation
National Psoriasis Foundation (NPF)
Nebraska Rheumatology Society
Nevada Biotechnology & Health Science Consortium (NevBio)
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 York State Rheumatology Society
New Yorkers for Accessible Health Coverage
North Carolina Rheumatology Association (NCRA)
Ohio Association of Rheumatology
Oklahoma Academy of Ophthalmology
Oncology Managers of Florida
Oregon Bioscience Association
Oregon Rheumatology Alliance
Patient Services Incorporated
Patients Rising
Pennsylvania State Grange

Physicians Advocacy Institute
Port Isabel-San Benito Navigation District
Prevent Blindness
Prevent Blindness Wisconsin
Prevent Blindness, Ohio Affiliate
Prevent Cancer Foundation
Psychosocial Rehabilitation Association of New Mexico
Re: Cancer
RetireSafe
Rheumatism Society of the District of Columbia
Rheumatology Alliance of Louisiana (RAL)
Rheumatology Association of Iowa (RAI)
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Association of Nevada
Rheumatology Nurses Society
Rush To Live
Seniors Matter
Sickle Cells - A Sickle Cell Disease Organization
Sickle Cell Community Consortium
Sickle Cell Disease Association of America, Inc.
Sickle Cell Disease Association of Florida
Sickle Cell Disease Association of Illinois
Sickle Cell Disease Foundation California
South Carolina Rheumatism Society
South Dakota Biotech
Southern California Biomedical Council (SoCalBio)
State of Texas Association of Rheumatologists (STAR)
State of West Virginia Rheumatology Society
StopAfib.org/ American Foundation for Women's Health
Tennessee Rheumatology Society

Texas Bleeding Disorders Advocacy Coalition
Texas Healthcare and Bioscience Institute (THBI)
The Headache and Migraine Policy Forum
The US Oncology Network
The Veterans Health Council
U.S. Pain Foundation
Uriel Owens Sickle Cell Disease Association of the Midwest
Valley AIDS Council
Vietnam Veterans of America
Virginia Society of Rheumatologists
Washington State Medical Oncology Society
Western Pennsylvania Chapter of the National Hemophilia Foundation
Wisconsin Rheumatology Association
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