

Secretary Alex Azar
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

July 16, 2018

Dear Secretary Azar,

We, the undersigned, are deeply concerned that recent Medicare Part B proposals outlined in President Trump's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs and corresponding Request for Information (RFI) could have harmful consequences for patients with serious diseases. As advocates for both patients reliant on Part B medicines and the physicians and other healthcare professionals who care for them, we are alarmed that proposals to create a new Competitive Acquisition Program (CAP) in Medicare Part B and move Part B medicines under Part D coverage would place middlemen between patients and their doctors and as a result create substantial risk of impeding access to needed care, increasing costs for our nation's sick and vulnerable patients, and creating new delays and inefficiencies in care delivery.

Part B medicines are vital to treating seniors and individuals living with conditions that require intensive management, such as cancer, rheumatoid arthritis, macular degeneration, Crohn's disease, or primary immunodeficiency diseases. Most of the medicines used to treat these conditions are administered by a physician and have highly specialized storage, handling, and patient monitoring requirements. For example, ophthalmologists inject complex therapies for macular degeneration directly in the eyes of patients; oncologists administer infused chemotherapy to patients with cancer at infusion centers that offer important monitoring and support services; and rheumatologists, gastroenterologists and neurologists treat immune mediated conditions with infused biologics.

Due to the specialized nature of these conditions and the medicines used to treat them, many Part B patients rely on a specific treatment regimen, decided with their physician, that addresses the complexities of their disease. Often, patients must try multiple treatment options and work with their physician to identify the right medicine or combination of medicines that fit their individual needs. As a result, it is critically important that physicians have flexibility to tailor treatment to patients' needs and that patients have prompt access to appropriate treatment as determined by their physician.

We are very worried that proposals to create a CAP and move Part B medicines under Part D coverage would restrict patient access to these needed treatments by inserting third-party middlemen between physicians and their patients. Unlike Part B, which covers all medicines that are medically necessary, Part D plans are only required to cover two medicines per class and can decide which medicines are made available to patients. Part D plans may also impose restrictions on those medicines (e.g., prior authorization, step therapy) that delay access to care.

The recent proposal by the Medicare Payment Advisory Commission to create a new competitive bidding program for Part B drugs further illustrates our concerns. Proposals like MedPAC's pave the way

for access restrictions and treatment delays, because they are designed as if patients are homogenous and treatments are commodities. In the care of patients who need physician-administered medicines, nothing could be further from the truth. In addition, experience under the previous Part B CAP program demonstrated how such programs can impede physicians' ability to deliver and tailor treatment in a timely way. Under the original CAP, for example, physicians were required to place an order for a specific treatment with the CAP vendor in advance of the patient's visit. This limited their ability to adjust the treatment plan if laboratory work showed a different medicine, formulation, or dosage was needed at the time of the patient's visit.

Dosing based on weight is another example that arises with some chemotherapy treatments based on a patient's weight – if a patient's weight changes before their next treatment, the physician may be unable to treat the patient because they must now order these medicines in advance through a separate vendor. This could delay treatment and impact health outcomes if they need to return to the office for a second visit.

Patient access and cost sharing must be a primary concern. Proposals to move Part B medicines into the Part D program could increase out-of-pocket costs for patients or even result in a loss of coverage for certain Medicare beneficiaries. Over 80 percent of Part B beneficiaries have supplemental coverage that helps with their coinsurance. Allowing Part B medications to shift to Part D, where cost sharing for specialty medicines can reach 30, 40, or 50 percent, could significantly increase costs for those Part B beneficiaries. A recent report from Avalere Health found that average out-of-pocket costs were about 33 percent higher for Part D-covered new cancer therapies (\$3,200) than for those covered in Part B (\$2,400).¹ Furthermore, not all Medicare beneficiaries are currently enrolled in a Part D coverage plan, and shifting Part B medicines to Part D will result in loss of coverage for these patients.

A recent survey found that a majority of oncologists and rheumatologists are concerned about the impact proposals like these could have on treatment choices, access to care, and the administrative burden on physicians.² While we commend and support the administration's efforts to lower costs for Medicare, patient access to treatment must come first. To that end, we urge the administration to reject proposals that could have a damaging impact on access and affordability of Part B medications for our most vulnerable beneficiaries.

Sincerely,

1in9: The Long Island Breast Cancer Action Coalition

ADAP Advocacy Association (aaa+)

Advocates for Responsible Care (ARxC)

¹ Matt Brow and Richard Kane. "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D." May 21, 2018. http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top

² Community Oncology Alliance. "Medicare Part B Proposals Will Harm Patients, Increase Costs and Bureaucracy." May 16, 2018. <https://www.communityoncology.org/2018/05/16/may-16-coa-physician-survey-medicare-part-b-proposals-will-harm-patients-increase-costs-and-bureaucracy/>

Aging2.0 Denver Chapter
Alabama Lifespan Respite
Alabama Society for the Rheumatic Diseases
Alaska Rheumatology Alliance
Alliance Community Services
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 Association of Clinical Urologists
American Autoimmune Related Diseases Association (AARDA)
American Behcet's Disease Association (ABDA)
American College of Rheumatology
American Kidney Fund
American Society for Bone and Mineral Research
American Society for Parenteral and Enteral Nutrition (ASPEN)
American Society of Cataract and Refractive Surgery
American Society of Hematology
American Urological Association
Ames Chamber of Commerce
Arizona Bioindustry Association, Inc. (AZBio)
Arkansas Rheumatology Association
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
Atrius Health
Bio Nebraska Life Sciences Association

BioBuzz Workforce Foundation, Inc.
Biocom
BioCT
BioForward Wisconsin
BioKansas
BioNJ
BioOhio
Bioscience Association of North Dakota
Bioscience Association of West Virginia
BioUtah
California Chronic Care Coalition
California Life Sciences Association (CLSA)
California Rheumatology Alliance (CRA)
Cancer Warriors Alliance
CancerCare
Caregiver Action Network
Caregiver Voices United
CARES Foundation, Inc.
Center for Healthcare Innovation
Center for Independence of the Disabled, NY
Centro de Mi Salud, LLC
Charleston Parkinson's Support Group
Coalition of Hematology Oncology Practices (CHOP)
Coalition of State Rheumatology Organizations (CSRO)
Coalition of Texans with Disabilities (CTD)
Colorado BioScience Association
Colorado Gerontological Society
Colorado Rheumatology Association
Colorado State Grange

Community Access National Network (CANN)
Community Health Action Network
Community Health Charities of Nebraska
Community Oncology Alliance (COA)
Congress of California Seniors
Connecticut Bioscience Growth Council
Cutaneous Lymphoma Foundation
Danio Connect
Danio Diary
Deadliest Cancers Coalition
Debbie's Dream Foundation: Curing Stomach Cancer
Delaware Academy of Medicine / Delaware Public Health Association
Delaware BioScience Association
Delaware Ecumenical Council on Children and Families
Delaware HIV Consortium
Digestive Health Physicians Association (DHPA)
Easter Seals Massachusetts
Easter Seals North Georgia
Epilepsy Association of Central Florida, Inc.
Florida Allergy, Asthma & Immunology Society (FAAIS)
Florida Society of Rheumatology
Georgia Bio
Georgia Society of Clinical Oncology (GASCO)
Global Healthy Living Foundation
Healthcare Institute of New Jersey (HINJ)
HealthyWomen
ICAN, International Cancer Advocacy Network
IFAA - International Foundation for Autoimmune & Autoinflammatory Arthritis
Illinois Biotechnology Innovation Organization

Immune Deficiency Foundation (IDF)
Indiana Health Industry Forum (IHIF)
INDUNIV Research Center, Inc.
Inncuvate
International Institute For Human Empowerment
ION Solutions
Iowa Biotechnology Association
Joe Niekro Foundation
Kansas Rheumatology Alliance
Kentuckiana Rheumatology Alliance
Kentuckiana Stroke Association
Kentucky Life Sciences Council
KYSA
Large Urology Group Practice Association (LUGPA)
Life Science Tennessee
Life Sciences Pennsylvania
Liver Health Connection
Living Hope for Mental Health
Louisiana Oncology Society
Lupus Alliance of Upstate New York
Lupus and Allied Diseases Association, Inc.
Lupus Foundation New England
Lupus Foundation of America
Lupus Foundation of America, Indiana Chapter
Lupus Foundation of Arkansas, Inc.
Lupus Foundation of Colorado
Maryland Life Sciences
Massachusetts Association for Mental Health
Massachusetts Biotechnology Council

Massachusetts, Maine & New Hampshire Rheumatology Association (MMNRA)

Matthew25 AIDS Services

Medical Alley Association

Medical Oncology Association of Southern California, Inc. (MOASC)

Medical Society of Delaware

Mental Health America of California

Mental Health America of Franklin County

Metro Denver Oncology Nursing Society

Michigan Biosciences Industry Association (MichBio)

Michigan Lupus Foundation

Michigan Rheumatism Society

Midwest Oncology Practice Society (MOPS)

MidWest Rheumatology Association

Mississippi Arthritis and Rheumatism Society

Mississippi Psychiatric Association

Montana BioScience Alliance

Mountain Mission Inc.

Multiple Sclerosis Foundation

Multiple Sclerosis Resources of Central New York, Inc.

National Alliance on Mental Illness (NAMI) Georgia

National Alliance on Mental Illness (NAMI) Huntington

National Alliance on Mental Illness (NAMI) Massachusetts

National Alliance on Mental Illness (NAMI) New Mexico

National Alliance on Mental Illness (NAMI) St. Louis

National Alliance on Mental Illness (NAMI) Texas

National Alliance on Mental Illness (NAMI) Virginia

National Association of Social Workers, Texas Chapter

National Black Nurses Association (NBNA), Tampa BlackNurses

National Infusion Center Association (NICA)

National Medical Association (NMA)
National Organization of Rheumatology Managers (NORM)
Nebraska Rheumatology Society
New England Biotech 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 York State Rheumatology Society
New Yorkers for Accessible Health Coverage
NMBio
North Carolina Rheumatology Association (NCRA)
OAHE Inc.
Ohio Association of Rheumatology
Oncology Managers of Florida
Oregon Bioscience Association
Oregon Rheumatology Alliance
Patient Services Incorporated
Port Isabel-San Benito Navigation District
Prevent Blindness Wisconsin
Prevent Blindness, Ohio Affiliate
Psychosocial Rehabilitation Association of New Mexico
Re: Cancer
RetireSafe
Rheumatology Alliance of Louisiana (RAL)
Rheumatology Association of Iowa (RAI)
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Association of Nevada
Rheumatology Nurses Society
Rheumatology Society of Delaware

Rocky Mountain Health Network

Rush To Live

Rx in Reach GA Coalition

Rx Partnership

S.A.M.S. Stop All MS

Salud USA

Scleroderma Foundation Tri-State Inc Chapter

Seniors Matter

Sick Cells - A Sickle Cell Disease Organization

Sickle Cell Community Consortium

South Carolina Rheumatism Society

South Dakota Biotech

South Florida Cancer Association

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

Survivors Cancer Action Network

Survivors Cancer Action Network (CAN) - Alabama

Texas Healthcare and Bioscience Institute (THBI)

The Playing for Life Foundation

The Rheumatism Society of the District of Columbia

The US Oncology Network

The Veterans Health Council

U.S. Pain Foundation

U.S. Rural Health Network

Utah Advocates

Valle Del Sol

Valley AIDS Council

Vietnam Veterans of America

Virginia Biotechnology Association

Virginia Gastroenterological Society

Virginia Society of Rheumatologists

Washington Rheumatology Alliance

Westbrook Clinic

Wisconsin Rheumatology Association

Wound Care Clinic - ESU

Wyoming Epilepsy Association

ZERO - The End of Prostate Cancer