

November 15, 2017

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue SW,  
Washington, DC 20201

Dear Administrator Verma,

In response to the Center for Medicare and Medicaid Innovation's (CMMI) recent request for information (RFI), the 113 undersigned organizations want to express our concern that absent clear guardrails, CMMI's authority could again be used to make wholesale changes to vital Medicare programs without proper oversight. We appreciate the initial guiding principles set forth in the RFI, and urge you to finalize clear safeguards within CMMI through notice and comment rulemaking before moving forward with any new payment models in order to protect patient access to vital therapies and ensure that care is not compromised as new models are tested.

In the past, CMMI exceeded statutory authority by issuing broad, compulsory models, like the Part B Drug Payment Model and Episode Payment Model (EPM) models. Unfortunately, these past CMMI proposals threatened to interfere in provider-patient relationships in ways that could negatively impact medical outcomes. Last year's Medicare Part B Payment Model clearly demonstrated how CMMI's unchecked authority could have harmful effects for beneficiaries across the country. By cutting reimbursements to medications under Part B, the model would restrict the ability of healthcare providers to tailor treatment regimens for patients and make adjustments as a patient's condition evolved. Patients with disabilities or chronic conditions often depend on treatments tailored to their specific needs. Failing to protect patient choice and access to their preferred providers and treatments is unacceptable. We therefore applaud the administration for withdrawing the model and for outlining guiding principles for future CMMI demonstrations.

We appreciate the recognition that CMMI's models were intended to be small, voluntary, and target specific populations or health needs. Moving forward, we urge you to finalize safeguards that ensure that all models are small-scale, voluntary tests. Models should be tested in a limited population to minimize unintended consequences before proper testing is completed. In the proposed rule: Cancellation of the Episode Payment Model, CMS proposed to limit the size of CJR to the number of hospitals necessary to obtain scientifically valid results. We encourage CMMI to finalize a safeguard limiting all future model tests to the size needed to obtain valid results. Additionally, we encourage CMMI to limit the duration of all models to no more than 5 years. Finally, CMMI should avoid making wholesale changes to existing law, and must have a process for engaging Congress in any broader programmatic changes. Small scale, voluntary testing, with a process for engaging lawmakers prior to making permanent programmatic changes will ensure CMMI serves its core purpose as a testing ground for new payment and delivery reforms.

It is also critical to prevent the same population of patients from being subject to multiple models simultaneously. For example, the proposed Part B Drug Payment Model would have imposed new payment changes on providers that were already participating in alternative payment models, such as the Oncology Care Model. Layering these models on top of one another would have been burdensome

for providers and could have severely limited provider options and patient access through multiple, competing directives. At best, layering multiple payment models would skew results and render findings from each test meaningless. We therefore encourage CMMI to finalize a requirement that prevents overlapping models.

As you note, measures must also be implemented to improve the transparency of model design and evaluation. CMMI should take care to solicit more input from providers, patient groups, and other interested parties who could be impacted by the model before proposing models, and must be more transparent in its deliberation of these ideas. CMMI should ensure there is an opportunity for a broad solicitation of comments on proposed models.

CMMI must also carefully evaluate how proposed changes will impact access to care and should not incorporate elements of an existing pilot or demonstration into new payment models before proper testing is completed. Proposed models should include a strategy to monitor, assess, and quickly address changes in patient outcomes and access to care. The results of CMMI model tests with respect to quality, access, and costs should be made available on a regular and timely basis to promote a better understanding of how CMMI models are performing and the impact they are having on patient care.

The Medicare Part B program is essential to providing beneficiaries with affordable treatment for disabilities and chronic conditions such as cancer, rheumatoid arthritis, macular degeneration, hypertension, Crohn's disease, ulcerative colitis, mental illness and primary immunodeficiency diseases. Patients struggling with these illnesses often depend on a complex combination of treatments that address their individual needs. Part B's current reimbursement structure ensures providers are properly compensated for offering a variety of treatment options, which allows the flexibility needed to effectively treat these complex conditions. As a result, Part B drugs continue to represent just 3 percent of overall Medicare spending.<sup>1</sup>

We understand that innovation in healthcare is crucial to the continued success of Medicare programs, but patient outcomes should not be sacrificed in the process. CMMI's current ability to mandate radical changes to a broad population of patients threatens to disrupt successful treatment plans and create additional roadblocks to care. We urge you to finalize CMMI safeguards through notice and comment rulemaking to ensure transparency and accountability in future models and continued access to care for patients who depend on Part B medicines.

Sincerely,

Advocates for Responsible Care (ARxC)  
Alabama State Rheumatology Society  
Alliance of Specialty Medicine  
Alzheimer's & Dementia Resource Center  
American Academy of Allergy, Asthma & Immunology (AAAAI)  
American Academy of Ophthalmology  
American Autoimmune Related Diseases Association (AARDA)  
American Behcet's Disease Association (ABDA)  
American College of Rheumatology  
American Gastroenterological Association

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<sup>1</sup> MedPAC. Health Care Spending and the Medicare Program: A Databook. June 2017.

American Kidney Fund  
American Society of Cataract and Refractive Surgery  
American Society of Clinical Oncology (ASCO)  
American Urological Association  
Arkansas Rheumatology Association  
Arthritis Foundation  
Association of Idaho Rheumatologists (AIR)  
Asthma & Allergy Foundation of America, New England Chapter  
Breathe New Hampshire  
California Life Sciences Association (CLSA)  
California Rheumatology Alliance (CRA)  
Caregiver Action Network  
Catholic Charities New Hampshire  
Central Florida Behavioral Health Network  
Coalition of State Rheumatology Organizations (CSRO)  
Coalition of Texans with Disabilities (CTD)  
Community Health Charities of Nebraska  
Community Oncology Alliance (COA)  
Delaware Building Trades  
Delaware State AFL-CIO  
Dia de la Mujer Latina  
Digestive Disease National Coalition (DDNC)  
Digestive Health Physicians Association (DHPA)  
Epilepsy Association of Central Florida, Inc.  
Epilepsy Association of the Big Bend  
Epilepsy Foundation of East Tennessee  
Epilepsy Foundation of Louisiana  
Florida Society of Rheumatology  
Florida State Hispanic Chamber of Commerce  
Global Healthy Living Foundation  
H.E.A.L.S of the South (Hepatitis Education, Awareness and Liver Support)  
HealthyWomen  
ICAN, International Cancer Advocacy Network  
IFAA - International Foundation for Autoimmune & Autoinflammatory Arthritis  
Immune Deficiency Foundation (IDF)  
International Institute For Human Empowerment  
ION Solutions  
Iowa Biotechnology Association  
Kentuckiana Rheumatology Alliance  
Kentuckiana Stroke Association  
Kentucky Life Sciences Council  
Large Urology Group Practice Association (LUGPA)  
Louisiana Lupus Foundation  
Lung Cancer Alliance  
LUNGevery  
Lupus and Allied Diseases Association  
Lupus Foundation of America  
Lupus Foundation of Southern California

Massachusetts Biotechnology Council  
Massachusetts, Maine & New Hampshire Rheumatology Association (MMNRA)  
Matthew25 AIDS Services  
Medical Association of Georgia  
Men's Health Network  
Mental Health America of Franklin County  
Mental Health America of Kentucky  
Michigan Osteopathic Association  
Michigan Rheumatism Society  
MidWest Rheumatology Association  
Montana BioScience Alliance  
Multiple Sclerosis Foundation  
National Alliance on Mental Illness (NAMI)  
National Alliance on Mental Illness (NAMI) Alabama  
National Alliance on Mental Illness (NAMI) Florida  
National Alliance on Mental Illness (NAMI) Huntington  
National Alliance on Mental Illness (NAMI) of Central Suffolk  
National Alliance on Mental Illness (NAMI) Texas  
National Hispanic Medical Association  
National Infusion Center Association (NICA)  
National Medical Association (NMA)  
National Minority Quality Forum  
New Jersey Rheumatology Association (NJRA)  
New York State Rheumatology Society  
NORM - National Organization of Rheumatology Managers  
North Carolina Biosciences Organization (NCBIO)  
North Carolina Rheumatology Association (NCRA)  
OAHE Inc.  
Ohio State Grange  
Oncology Nursing Society  
Oregon Rheumatology Alliance  
Physicians Advocacy Institute  
Prevent Blindness  
RetireSafe  
Rheumatology Association of Minnesota and the Dakotas  
Rheumatology Association of Nevada  
Rheumatology Society of North Texas  
SAGE Utah  
Scleroderma Foundation Tri-State Inc Chapter  
Sick Cells  
Sickle Cell Community Consortium  
Sickle Cell Disease Association of America  
Sickle Cell Disease Association of Florida  
South Carolina Rheumatism Society  
State of West Virginia Rheumatology Society  
Survivors Cancer Action Network  
Tennessee Rheumatology Society  
Texas Healthcare and Bioscience Institute (THBI)

The US Oncology Network  
U.S. Pain Foundation  
U.S. Rural Health Network  
Utah Coalition of La Raza  
Utah Pride Center  
Wisconsin Rheumatology Association  
Wyoming Medical Society