

July 20, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services Attention: CMS–2482-P

RE: Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS 2482-P)

Dear Administrator Verma:

The undersigned organizations, on behalf of tens of millions of Americans with serious illnesses, chronic conditions, and disabilities, are submitting this formal comment pertaining to your recent Notice of Proposed Rule Making. While we appreciate the Centers for Medicare and Medicaid Services (CMS) prioritizing efforts towards expanding access to care and lowering prescription drug costs, we are concerned that the proposed rule contains a provision that will increase barriers to access of care and put those individuals struggling with chronic and debilitating disease at risk for further health complications.

The provision in question would require drug manufacturers to include the value of cost-sharing assistance when calculating best price unless they are able to prove that individuals utilizing patient assistance programs, such as copay assistance, are receiving 100% of intended benefits. While we can all agree that patients, especially lower-income persons, deserve as much assistance to afford their medication as can be provided, this will be extremely difficult to prove for manufacturers due to lack of transparency and the actions of insurers and the middlemen.

We are deeply concerned that this impossible burden of proof will undermine manufacturers' ability to continue offering patient assistance programs to individuals in the larger commercial market. This is extremely troubling from our perspective, as many patients rely on these programs in order to afford vital drugs and treatments. The COVID-19 pandemic elevates the challenge facing at-risk patients, interrupting access to treatments, straining household finances, and adding stress that erodes health and well-being. Considering these uncertain and difficult times, we need policies that help patients afford the treatments they need to manage their conditions rather than adding additional roadblocks to accessing care. We believe that patients deserve better.

We urge CMS to omit this provision from the finalized rule and instead focus its efforts on policy proposals that will not limit access or increase costs for those most vulnerable populations among us.

Please do not hesitate to contact Carl Schmid at [cschmid@hivhep.org](mailto:cschmid@hivhep.org); Randall Rutta at [randallrutta@aarda.org](mailto:randallrutta@aarda.org); or any of the undersigned organizations with questions and for additional information on our views. Thank you for your consideration.

Sincerely, and on behalf of:

Academy of Physicians in Clinical Research  
ACCSES  
Advocacy & Awareness for Immune Disorders Association (AAIDA)  
Aimed Alliance  
Allergy & Asthma Network  
Alliance for Aging Research  
Alliance for Patient Access  
Allies for Independence  
ALLvanza  
Alpha-1 Foundation  
American Academy of Allergy, Asthma & Immunology  
American Autoimmune Related Diseases Association  
American Behcet's Disease Association (ABDA)  
American Cancer Society Cancer Action Network, Inc.  
American College of Gastroenterology  
American Kidney Fund  
American Liver Foundation  
Applied Pharmacy Solutions  
APS Foundation of America, Inc  
Arthritis Foundation  
Association of Women in Rheumatology  
Asthma and Allergy Foundation of America  
Beyond Celiac  
Beyond Type 1  
Boomer Esiason Foundation  
Brain Injury Association of America  
Bridge the Gap - SYNGAP Education and Research Foundation  
California Access Coalition  
California Chronic Care Coalition  
California Hepatitis C Task Force  
Caregiver Action Network  
Chronic Care Policy Alliance  
Chronic Disease Coalition  
Coalition of State Rheumatology Organizations  
Colorectal Cancer Alliance  
Conquer Myasthenia Gravis  
Consumers for Quality Care

CURED Nfp  
Cutaneous Lymphoma Foundation  
Cystic Fibrosis Research, Inc. (CFRI)  
Diabetes Patient Advocacy Coalition (DPAC)  
Digestive Disease National Coalition  
Easterseals  
Fabry Support & Information Group  
FORCE: Facing Our Risk of Cancer Empowered  
Friends of Cancer Research  
GLMA: Health Professionals Advancing LGBTQ Equality  
Global Healthy Living Foundation  
Global Liver Institute  
Healthy Women  
Hepatitis C Association  
Hepatitis C Mentor and Support Group - HCMSG  
Hispanic Health Network  
HIV + Hepatitis Policy Institute  
Human Rights Campaign  
International Association of Hepatitis Task Forces  
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)  
International Pemphigus Pemphigoid Foundation  
Latino Commission on AIDS  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
Lupus Research Alliance  
MANA, A National Latina Organization  
Men's Health Network  
Multiple Sclerosis Foundation Inc  
National Adrenal Diseases Foundation (NADF)  
National Alliance on Mental Illness  
National Association of Nutrition and Aging Services Programs (NANASP)  
National Coalition for LGBT Health  
National Community Oncology Dispensing Association, Inc.  
National Diabetes Volunteer Leadership Council  
National Disability Rights Network  
National Eczema Association  
National Grange  
National Hispanic Council on Aging  
National Kidney Foundation  
National Organization of Rheumatology Managers  
Neuropathy Action Foundation  
New York State Sickle Cell Advocacy Network INC. NYS -Chapter of the National SCDA  
Not Dead Yet

Ohio Association of Rheumatology  
Ohio Bleeding Disorder Council  
Partnership to Fight Chronic Disease  
Patient Advisor  
Patient Services, Inc.  
Patients Rising Now  
Platelet Disorder Support Association  
Project Sleep  
Pulmonary Fibrosis Foundation  
Pulmonary Hypertension Association  
Relapsing Polychondritis Foundation  
RetireSafe  
Schizophrenia and Related Disorders Alliance of America  
Scleroderma Foundation, Inc.  
Sickle Cell Thalassemia Patients Network  
Sjogren's Foundation  
The Foundation for Sarcoidosis Research  
The Mended Hearts  
The Myositis Association  
United for Charitable Assistance  
United Ostomy Associations of America  
US Hereditary Angioedema Association  
Vasculitis Foundation  
Whistleblowers of America