

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; Randall Rutta at 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