



March 2, 2020

The Honorable Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-9916-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: Comments to Proposed Rule—Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans (CMS-9916-P)

Dear Administrator Verma:

On behalf of tens of millions of Americans who struggle every day with serious illnesses, including autoimmune diseases, and the health care providers who treat them, we are writing to express deep concern regarding specific aspects of the recently proposed Notice of Benefit and Payment Parameters for 2021 (NBPP Proposed Rule). In particular, one of the proposed changes under the NBPP Proposed Rule would expressly allow insurance plans to exclude drug manufacturer copay assistance amounts from counting towards patients' annual limitation on cost sharing. In addition, the NBPP Proposed Rule would interpret the definition of "cost sharing" as not including "expenditures covered by drug manufacturer coupons."<sup>1</sup> We believe that these proposed changes, if finalized, would significantly harm patients, inappropriately hinder physicians' independent clinical treatment decisions, and unnecessarily impede our important collective efforts to address the negative impact of chronic diseases across the country.

At a time when policymakers should be focused on improving access to and affordability of prescription drugs for patients, these proposed changes would do the opposite. We strongly urge the Centers for Medicare and Medicaid Services (CMS) not to finalize these proposed changes. Instead, any cost-sharing assistance provided to a patient by a third party for purposes of increasing the accessibility and affordability of a prescribed medicine should be counted toward the patient's annual cost-sharing limitation.

The American Autoimmune Related Diseases Association (AARDA) convenes and collaborates with the National Coalition of Autoimmune Patient Groups, the Let My Doctors Decide national coalition, and other stakeholders to raise awareness and promote access to appropriate care and

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<sup>1</sup> NBPP Proposed Rule, 85 Fed. Reg. 7088, 7090 (Feb. 6, 2020).

treatment for autoimmune diseases and other serious and chronic conditions. As part of these efforts, we seek to ensure that policies are in place to facilitate affordability, access, and adherence to medicines and other items and services that support of the health and well-being of people living with autoimmune diseases and other chronic conditions. The undersigned organizations join AARDA in submitting these comments to the NBPP Proposed Rule.

Currently, many patients have improved access to medically necessary medications through various types of assistance that help cover the costs of the treatments prescribed to them by their physicians. Patients should not be punished for accessing such assistance. Indeed, it is vital that patients, especially those living with complex and chronic illnesses, are afforded the opportunity to access the medications deemed best for them by doctors who understand their unique case and condition. Copay assistance helps patients and their families cover their out-of-pocket costs for medicines, thereby facilitating the ability to maintain stability in their health conditions, avoid exacerbations or relapses, and achieve continuity of care. Those outcomes, in turn, reduce overall health care expenditures. Yet, under the NBPP Proposed Rule, drug manufacturer copay assistance amounts would be expressly excluded from CMS's interpretation of a patient's cost-sharing expenditures, and insurers would be permitted to avoid counting those amounts toward patients' annual limitation on cost sharing. We believe these proposed changes are arbitrary and unfair and would increase—rather than reduce—health care costs.

If insurers are permitted to exclude the amounts of this assistance from patients' annual limitation on cost sharing, patient access and affordability to prescribed therapies will be reduced, to the detriment of individuals, insurers, and the health care system overall. Moreover, policies that require insurers to include such assistance amounts in the annual limitation on cost sharing do not harm the insurer. Under such policies, health plans remain whole, as they still receive the full amount of required cost-sharing for the medicine – part from the patient and part from copay assistance or other support.

As we advocate for people with autoimmune diseases and other chronic conditions in America, we understand the complexity and the importance of this issue. Each patient requires highly individualized care. And effective treatments can take years of trial and error to safely implement. Physicians take great care in personalizing therapies and treatment plans for their patients. Under the NBPP Proposed Rule, however, we fear there would be significant interference with the doctor-patient relationship and with physicians' informed and independent clinical decisions. Preserving this critically important doctor-patient relationship is a core focus of the Let My Doctors Decide national campaign, which speaks out against access restrictions, particularly those stemming from non-medical reasons, that create barriers between what a physician prescribes and what a patient can receive and afford.

For these reasons, people living with autoimmune conditions and other serious chronic illnesses are gravely concerned by the proposed copay accumulation policy changes under the NBPP Proposed Rule. These individuals face significant prescription drug costs in order to follow the treatment regimen that they and their doctors have found works best for them. In the 2019 health care exchanges, the average health plan deductible is \$4,320 for an individual and \$8,071 for a family<sup>2</sup> – more than three times the IRS definition of a “high deductible” health plan of \$1,350

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<sup>2</sup> eHealth, Inc., "Health Insurance Index Report for the 2019 Open Enrollment Period," July 2019

(individual) and \$2,700 (family). In many cases, patients do not have an option for a generic medication; or, in light of an individual's specific condition, the different available treatments are not interchangeable.

Permitting insurers to exclude manufacturer copay assistance amounts from patients' annual cost-sharing limitation is, fundamentally, unfair to patients. Patients who are stable on a medication regimen depend on uninterrupted access to their prescribed therapies. We acknowledge that action must be taken to improve affordable access for patients, but these proposed changes are not the answer. Patients should not be penalized for using the resources available to them.

At a time when we should all be working to help patients with complex diseases to obtain and maintain access to the prescribed care and treatment that they need, we should avoid policies that impede—rather than improve—such access. Effective treatments greatly improve quality of life for millions of Americans, increase productivity, and assist in containing overall health care costs. Yet, many individuals living with serious and chronic conditions routinely face substantial financial challenges in managing their health. Our organizations - with patient, provider, advocate, and stakeholder members - are committed to policies that put patients' needs first.

We urge CMS and the Department of Health and Human Services to join us in prioritizing patients' needs when considering these policies and developing the final rule. In particular, drug manufacturer copay assistance amounts should be included in and counted towards patients' annual limitation on cost sharing.

Respectfully,

American Autoimmune Related Diseases Association (AARDA)  
Advocacy & Awareness for Immune Disorders Association (AAIDA)  
Aimed Alliance  
Allergy & Asthma Network  
Alliance for Aging Research  
Alliance for Patient Access  
American Association of Colleges of Pharmacy  
American Behcet's Disease Association (ABDA)  
American Liver Foundation  
Arthritis Foundation  
Asthma and Allergy Foundation of America  
Axis Advocacy  
Beyond Type 1  
Children with Diabetes  
Cystic Fibrosis Lifestyle Foundation  
Cystic Fibrosis Research, Inc. (CFRI)  
Cutaneous Lymphoma Foundation  
Derma Care Access Network  
Diabetes Patient Advocacy Coalition  
Global Healthy Living Foundation

Global Liver Institute  
HIV + Hepatitis Policy Institute  
Immune Deficiency Foundation  
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)  
International Pemphigus and Pemphigoid Foundation  
Lupus Foundation of America  
Lupus and Allied Diseases Association, Inc.  
Multiple Sclerosis Foundation  
NAACP New York State Conference  
National Alliance on Mental Illness  
National Diabetes Volunteer Leadership Council  
National Hispanic Medical Association  
National Infusion Center Association  
National Pancreas Foundation  
National Psoriasis Foundation  
National Organization of Rheumatology Managers  
Project Sleep  
RetireSafe  
Rheumatology Nurses Society  
Sjogren's Foundation  
The diaTribe Foundation  
The Myositis Association  
The National Kidney Foundation  
US Hereditary Angioedema Association

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