September 11, 2017

The Honorable Seema Verna
Administrator
Center for Medicaid and Medicare Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1676-P (submitted electronically)

RE: Proposed rule addresses changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies.

Dear Administrator Verna,

On behalf of the Lupus and Allied Diseases Association, Inc., and the millions of Americans struggling to live with and treat autoimmune conditions and other diseases of unmet need who are eagerly awaiting access to affordable, appropriate and safe therapies, I am writing to express our concerns regarding the Center for Medicare and Medicaid Services (CMS) policy related to Payment for Biosimilar Biological Products that assigns shared codes to multiple distinct biological products. We strongly urge CMS to reconsider this policy and instead adopt a policy that allocates each biosimilar and biologic therapy its own distinctive payment code.

We thank you for the opportunity to provide our unique patient viewpoint regarding the payment policy of biological products. Lupus is an extremely complex, chronic inflammatory autoimmune disease affecting virtually any organ system of the body. Due to the heterogeneous nature of auto-immune diseases like lupus, no two cases are alike and treatment is highly individualized; *no one size fits all* products exist for our patients, their response to therapies is unique, contrary and at times adverse.

Because we represent patients who are distinctive and struggle daily with chronic, debilitating diseases, we have closely followed the biosimilar pathway to ensure that patient safety and accessibility are given the utmost priority by all agencies as you finalize biological product policies. We believe it is essential that all biological products, including biosimilars, be clearly discernible from one another to ensure patient safety especially among products that have not been deemed interchangeable and to improve pharmacovigilance. Applying a meaningful payment code will avoid confusion with the original reference product and ensure accurate physician-patient communication, as well as reliability in the prescribing, dispensing and compliance processes of specific therapies.

Biosimilar drugs hold tremendous promise and therapeutic advantages for lupus and autoimmune patients just as biologic medicines have for millions of individuals living with life-threatening and life-diminishing diseases. As biosimilars become more readily available in the United States we want to

ensure they are safe, efficacious, accessible, and affordable. We must remain vigilant in protecting patient safety while promoting unfettered access to vital and effective treatments. We believe that given that there will be multiple biosimilars available for a single reference product that are not approved for all of the indications of the reference product that assigning a single billing code will cause confusion and result in incorrect prescribing and potentially cause unintentional negative consequences to the patient.

Utilizing discernible payment codes rather than shared codes for each biological product, provides much-needed transparency by enabling better safety monitoring via tracking the therapy and tracing the product, promoting timeliness in addressing potential adverse events, and providing physicians with more information to recognize which products are likely to be safer or more effective in a specific patient.

Furthermore, discernible codes will facilitate pharmacovigilance which is essential when biological medicines are prescribed, as they may cause idiosyncratic reactions or immunogenic responses in lupus and autoimmune patients who can also be hypersensitive to changes in production methods or impurities. It is also important to recognize that adverse effects are difficult to predict and may only occur after many years of treatment. Distinguishable coding is particularly important with the advent of biosimilars in order that non-interchangeable biosimilars are not inadvertently and/or inappropriately substituted causing unexpected effects or adverse events as shared coding implies distinct biological products are identical which puts patients at risk for suboptimal treatment and adverse events.

We believe that applying individual codes to each and every biological product rather than utilizing shared codes will help to create transparency, be easily recognized, reduce errors, and facilitate prompt and accurate association between adverse events and specific products. This clarity will aid in accurate product identification during prescribing, dispensing, and pharmacovigilance which will in turn, promote product utilization.

In order for biosimilar development to advance, manufacturers must believe that their products are capable of evolving in the marketplace. Applying shared codes to these products will impede development and obstruct competition, in turn resulting in diminished patient choice and increased treatment costs.

In conclusion, we thank you again for the opportunity to share our unique perspective as you evaluate the final payment rule that calls for shared billing codes for biosimilars and their reference products and applaud CMS for recognizing the importance of the patient voice during the process.

Sincerely-

Kathleen A. Arntsen
President & CEO