

April 24, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-1670-P
P.O. Box 8016
Baltimore, MD 21244-8016

**RE: Docket Number CMS-2016-0036
Docket Name Medicare Program; Part B Drug Payment Model (CMS-1670-P)**

Dear Mr. Slavitt:

As both leaders of national patient advocacy organizations and patients ourselves, we fervently oppose the CMS proposed Medicare Part B Drug Payment Model designed to alter the reimbursement for indispensable, lifesaving drugs that are administered to patients in physicians' offices. Collectively, we represent countless patients, loved ones, caregivers, and healthcare providers who deal with serious medical conditions on a daily basis and as such, we certainly understand the importance of addressing healthcare costs, especially given the expanding specialty and biological treatments market. Nevertheless, we support provisions that allow providers to treat their patients in a manner that they deem most appropriate in order to safeguard vulnerable Americans.

We are deeply concerned that the proposed federal regulations will create obstacles for healthcare providers in obtaining and administering biologic medications as well as imposing greater restrictions on healthcare options available to Medicare beneficiaries by forcing them to more expensive hospital settings for treatment. This will negatively impact patient accessibility to vital life-sustaining and life-enhancing medications and actually result in increasing Medicare costs. Therefore, we urge both CMS and CMMI to withdraw the proposed rule and consider engaging with appropriate patient and provider stakeholders before moving forward with any other modifications to Part B reimbursement.

The Lupus and Allied Diseases Association is a passion driven, patient advocacy organization dedicated to improving quality of life for those impacted by lupus and allied diseases and conditions of unmet need by promoting innovative advocacy, awareness and biomedical research program initiatives. We are committed to fostering collaboration among stakeholders in order to encourage patient-centered care and ensure public policy keeps pace with biomedical research innovation.

The International Foundation for Autoimmune Arthritis is a global nonprofit organization both created and run by business professionals and educators who are also patients, and is the only nonprofit that

focuses primarily on the core diseases that are both autoimmune and/or auto-inflammatory and have a strong arthritic component, promoting patient-centered research, education, and awareness to patients, supporters, industry professionals, and practitioners around the world.

Please recognize that this broadly proposed payment model will not adequately address all diseases and specialties as there is no current list of “least expensive drug(s)” in existence that offers options for providers in numerous areas where Part B specialty and biologic medications are prescribed. As a matter of fact, the treatment standard of care for many autoimmune disorders such as lupus, rheumatoid arthritis, inflammatory bowel disease, multiple sclerosis, psoriasis, ankylosing spondylitis, vasculitis and other diseases of unmet need like osteoporosis, happens to be a biologic and/or specialty medication.

For individuals struggling to manage complex, chronic and rare conditions, access to appropriate medication can dramatically improve disease outcome and quality of life. Effective treatment can reduce the severity and frequency of disease activity and decelerate its progression, circumvent debilitating symptoms, and avoid complications and long-term disability, thus enabling individuals to remain productive. Simply put, access to innovative therapies such as biologics, matters to patients and their treating providers.

There is ample evidence that newer medications such as biologic medications and specialty drugs offer therapeutic advantages over conventional medicines. For example, older less expensive immunosuppressive therapies such as high-dose steroids or chemotherapy agents attack and ablate a patient’s entire immune system; causing detrimental side effects and poorer health outcomes, while newer therapies target a particular cell or biomarker making it much more efficient and safer.

Limited therapies exist for individuals with autoimmune conditions and other diseases of unmet need since hardly any drugs have been developed specifically for these conditions. It can take years for patients with multifarious conditions to find treatments with few side effects to manage their diseases, and drugs that treat these conditions are often complex and non-interchangeable. There is also no single medication that patients respond to—treatment is highly individualized and no two people are alike, so what is tolerable for one individual may not be in the next.

In addition, individuals with complex autoimmune conditions require tailored treatments and biologic therapeutic regimens that include multiple medications which must be frequently adjusted or halted in response to the patient’s progression. Many of these individuals also have multiple co-morbid conditions that require unique strategies to manage their care. Once a patient finds a biologic therapy that works, which often may be their only option, he or she should not be forced to switch treatment center locations based on cost.

Currently, many Medicare beneficiaries are able to access physician-based infusion centers that are conveniently located, affordable, and sufficient for their specific needs. More importantly though, this care is under the direction of their treating provider who knows their unique medical history, concomitant medications, past complications and is in the best position to monitor for potential adverse reactions. Hospital-based infusions usually include higher copays, longer commutes, and the distinct disadvantage of patients having to receive complex therapies without the supervision of their trusted providers. In order for any proposed reimbursement model to be successful, treatment options must be both financially worthwhile for the provider to administer and accessible and affordable to the patient.

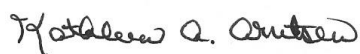
By reducing treatment site choices and limiting access to care, the proposed policy will result in inadvertent consequences for countless individuals struggling with complex, chronic conditions who are presently covered by Medicare either because of disability or age; as well as cause future implications for millions of Americans eventually becoming dependent on the Medicare program due to our aging population.

Establishing administrative barriers based on cost rather than clinical considerations, such as CMS' proposed policy, will limit treatment site options as well as the provider's ability to make treatment decisions in the best interest of the patient. Patients and their providers need access to innovative medications in order to maintain stability and consistent disease management. Disrupting continuity of care by limiting access to preferred treatment centers could result in detrimental life-threatening consequences to individuals who are the most vulnerable, reduce adherence, and could actually lead to more medical complications, worse health outcomes and higher health care costs. Many of these individuals already face enough adversities in their daily lives and do not need another hurdle to further complicate their medical care.

Now more than ever, as we usher in an era of personalized health care and initiatives like 21st Century Cures, Healthier Americans and Precision Medicine move forward, public policy must promote patient-centered care in order to keep pace with biomedical innovation. It is imperative that we protect all consumers and preserve the rights of the healthcare providers who are educated and ethically bound to make medical decisions in the best interest of the patient based on their unique characteristics.

The potential repercussions of this proposal will significantly impact providers' ability to effectively care for their patients and restrict affordable patient access to high quality healthcare. Therefore, we implore you to reconsider and rescind the proposed federal regulations and request that HHS, CMS, and CMMI work with various patient and provider stakeholders through an open, transparent and comprehensive process to identify and develop subsequent payment adjustments that would improve Medicare by enhancing quality of care, reducing costs, and continuing to offer access to treatments. **Please contact Kathleen Arntsen at lupuskaa@aol.com or 315-264-9101 if you have any questions and thank you for the opportunity to share our perspective on this important issue.**

Sincerely-



Kathleen A. Arntsen
President and CEO
Lupus and Allied Diseases Association



Tiffany Westrich-Robertson
Co-Founder & CEO
International Foundation for Autoimmune Arthritis