August 29, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8016
Baltimore, MD 21244-1850

Re: [CMS-1676-P] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018

Dear Administrator Verma,

On behalf of the 54 million adults and nearly 300,000 children in the United States with doctor-diagnosed arthritis, the Arthritis Foundation appreciates the opportunity to comment on the proposed Medicare Physician Fee Schedule for calendar year (CY) 2018. Arthritis is a complex, chronic disease that can be difficult to treat, and people who suffer from the disease require regular, ongoing care. For many in the arthritis community, access to health care can mean the difference between a life of chronic pain and disability and a life of wellness and full mobility.

The Arthritis Foundation supports efforts by the Centers for Medicare and Medicaid Services (CMS) to improve the quality of care provided to Medicare beneficiaries. We believe any payment or delivery system reform approaches should be three-fold: patients should have timely and appropriate access to a broad range of high-quality health care services; strong provider-patient relationships should be protected, free from undo interference; and there should be an expectation that patient needs and values are prioritized as treatment decisions are reached. Below please find our comments on the proposed rule.

Payment for Biosimilar Biological Products
In the proposed rule, CMS is soliciting public comments on the appropriateness of the current policy that groups all biosimilars under a single Healthcare Common Procedure Coding System (HCPCS) payment code if they have the same reference product. We applaud CMS for recognizing that the biosimilar product marketplace is rapidly evolving, and for seeking comment on this policy.

The Arthritis Foundation is committed to ensuring that people with arthritis have access to as many treatment options as possible. Biosimilars offer the potential for more affordable treatment options for people with rheumatoid arthritis (RA) and other forms of inflammatory arthritis. Since Part B offers reimbursement for provider-administered

therapies and two of the biosimilars on the market are infused drugs indicated for RA, we have a particular interest in this section of the proposed rule.

The Arthritis Foundation urges CMS to revise its current policy in the final rule. Treating biosimilars as multiple source products stands counter to the intent of the Biologic Price Competition and Innovation Act and serves as a disincentive for manufacturers to invest the time and money necessary to obtain approval for new indications. Biosimilar medications are not generics, and should be treated separately in how they are coded and reimbursed.

Importantly, the current policy is detrimental to, and reduces the focus on, patient access, especially for those patients who have yet to find a therapy that works for them. A critical component to increasing access and affordability is ensuring patients benefit from a robust marketplace with sufficient competition. Since response rates to therapy vary widely, it is important that patients have access to as many innovative therapies as possible. As the biosimilar marketplace evolves, we are also concerned about the potential for patient access issues in the commercial market, whereby patients may be required to use the biosimilar even if they are stable on the reference product, as well as challenges rheumatologists may face prescribing a biosimilar because of formulary restrictions. The former is critical for continuity of care, since patients who are stable on a drug should be able to remain on that drug; the latter leaves patients without access to a full range of treatment options. We believe CMS has a responsibility to develop sound reimbursement policy to ensure patient access and to serve as a model for the commercial market.

In addition, patient and provider education about biosimilars is critical. Over the last several months, the Arthritis Foundation has undertaken a project to understand the most pressing healthcare challenges facing people with arthritis. The project included an assessment of the current state of awareness surrounding biosimilars among adults with RA. Among the findings, we learned that a majority of surveyed adults with RA would want to know if they were being given a biosimilar replacement instead of the biologic. Respondents also indicated that they rely heavily on their health care provider when it comes to appropriate treatments for their disease. We strongly encourage CMS to reinforce and protect this patient-provider relationship.

We urge CMS to reverse the current policy on biosimilar reimbursement and assign each biosimilar its own reimbursement code, and to allocate resources to patient and provider education.

Request for Information (RFI)
The Arthritis Foundation appreciates the opportunity to provide comments on the RFI included with the proposed rule regarding ways to reduce regulatory burdens for clinicians and patients and their families. We are particularly concerned about the challenges people with arthritis face in accessing and affording health care. Today, the onus is on the patient to ensure they receive the benefits and coverage they

need, regardless of how sick they are or how much time it takes. The key to ensuring patients choose plans that are best suited for their health needs is to create a more seamless and transparent health care system. Clear, user-friendly standards are needed that would allow consumers to estimate their total out-of-pocket costs, including deductibles, co-payments, co-insurance, and premiums for all medical encounters, medications, and medical equipment.

In addition, the proliferation of specialty tiers and the increasing co-insurance requirements are alarming. For instance, Avalere data shows the number of bronze and silver Exchange plans requiring over 30% cost-sharing increased 14% from 2014 to 2015, including 5 percentage points for RA drugs, giving many patients little if any choice but to face steep co-insurance rates.[1] We urge CMS to implement policies that will improve, rather than exacerbate, this very real problem.

Furthermore, health plans should not impose utilization management practices that are burdensome and restrict patient access to needed therapies. Step therapy and prior authorization standards should be uniform and streamlined, which would reduce the administrative burden for patients and providers. The Arthritis Foundation participated in an AMA-convened workshop to develop prior authorization principles that have now been endorsed by over 100 organizations. We encourage CMS to utilize these principles as it develops future health care policies.

Thank you for the opportunity to comment on the proposed calendar year 2018 Medicare Physician Fee Schedule. We look forward to working with CMS to ensure patients with arthritis have access to the innovative treatments they need. Please contact Vincent Pacileo, Director of Federal & Regulatory Affairs, at 202-887-2910 or vpacileo@arthritis.org with questions or for more information.

Sincerely,

Anna Hyde

Anna Hyde
Vice President, Advocacy and Access
Arthritis Foundation

[1] Avalere Planscape ® (2015).