December 31, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicare Services
Department of Health and Human Services
P.O. Box 80135
Baltimore, MD 21244-1850

Submitted electronically via regulations.gov

RE: Medicare Program: International Pricing Index Model, CMS-5528-ANPRM

Dear Administrator Verma:

On behalf of the 54 million adults and 300,000 children in the United States with doctor-diagnosed arthritis, the Arthritis Foundation appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) advanced notice of proposed rulemaking (ANPRM) regarding the international pricing index (IPI) model for Medicare Part B drugs. We share the administration's goal to prioritize actions related to drug pricing and affordability – two issues that deeply impact people with arthritis.

Arthritis is a complex, chronic condition, and 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. People with arthritis can face extraordinary challenges, including years of diagnostic testing to find the right treatment; lifelong mobility issues; and co-morbidities ranging from diabetes and heart disease to depression. Accessing prescription drugs and treatments should not be one of those challenges.

General Comments

The Arthritis Foundation believes the IPI model's projected benefits are outweighed by potential negative impacts on patient access. We are not confident that patients will have access to needed treatment for rheumatic diseases under the model, as described in the ANPRM. Similarly, we are disappointed the ANRPM does not include any discussion of how CMS plans to conduct patient outreach and education, or otherwise communicate the model to patients who would be affected. Language used to communicate any model and its implications should be patient-tested and organizations like the Arthritis Foundation are well-positioned to partner with CMS. Additionally, as we have noted to CMS in prior comments, any proposed models must support broad, meaningful patient engagement throughout the development process to ensure models do not restrict access to

providers or treatments for people with chronic diseases like arthritis. The ANPRM is a first step in this direction.

Specific Recommendations

The Arthritis Foundation is committed to working with CMS on proposals that seek to lower drug costs and list prices overall, but we have several concerns related to the model and its impact on patient access to care. Below please find our recommendations.

1. **CMS should ensure that any cost savings realized through the IPI model are utilized to reduce patient out-of-pocket costs.**

In the ANPRM, CMS requested comment on whether cost savings from the IPI model should be passed on to patients. The Arthritis Foundation strongly believes any cost savings should be used to reduce total patient out-of-pocket costs. Finding a treatment that works for a patient with arthritis can be extremely difficult, and costly. Treatment of rheumatoid arthritis (RA) can involve trying many different therapies over time. For instance, one review of biologic therapies for RA found forty to fifty percent of RA patients treated for at least six months with one of the first-generation biologics failed to meet the American College of Rheumatology 50 percent improvement criteria (ACR50).[1] Another study estimated that rheumatologists switch their patients to another biologic over ninety percent of the time following an inadequate response.[2]

In addition, the ANPRM notes that CMS "expect[s] beneficiary cost-sharing for included drugs under the potential IPI Model would either be the same or lower than the non-model cost-sharing." This suggests that it is possible patients will face higher cost-sharing under the model, which runs counter to the goal of lowering drug costs for patients. If CMS moves forward with formal rulemaking, we strongly urge the agency to make explicit that patients will not have higher cost-sharing for medications reimbursed under the model as compared to the current payment system.

2. **The Arthritis Foundation strongly urges CMS to develop appropriate safeguards to ensure patient access to care is not jeopardized. The model must also be voluntary for patients and providers.**

In the Arthritis Foundation's comments on the Centers for Medicare and Medicaid Innovation's (CMMI) request for information on "new directions,"[3] we recommended that CMS make more explicit

[1] Singh JA, Christensen R, Wells GA, Suarez-Almazor ME, Buchbinder R, Lopez-Olivo MA, Tanjong Ghogomu E, Tugwell P: Biologics for rheumatoid arthritis: an overview of Cochrane reviews. Cochrane Database Syst Rev. 2009, 4: CD007848. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/19821440.
[2] Kamal KM, Madhavan SS, Hornsby JA, Miller LA, Kavookjian J, Scott V: Use of tumor necrosis factor inhibitors in rheumatoid arthritis: a national survey of practicing United States rheumatologists. Joint Bone Spine. 2006, 73: 718-724. 10.1016/j.jbspin.2006.05.002. http://europepmc.org/abstract/MED/16997599.
[3] https://www.arthritis.org/Documents/Sections/Advocate/Regulatory-Letters/AF-Comments-CMMI-RFI-New-Direction.pdf

a guidepost on patient-centeredness by directly engaging with patients and stakeholders as new models are developed and implemented. Going forward, we encourage robust engagement from CMS with patient organizations as the agency contemplates proposing a model through formal rulemaking.

The Arthritis Foundation also believes it is critical patients are fully aware when they are subject to, or are a participant in, a model demonstration with the option of opting-out of participation. Last year, an article in *Health Affairs* described one family's experience with the comprehensive joint replacement (CJR) bundled payment program and the lack of information provided regarding participation in the model. Unsurprisingly, testing of these types of payment arrangements can have substantial effects on provider behavior and the patient experience; the IPI model is significantly more complex and ambitious. We caution the agency against considering policies that create perverse incentives that diminish, rather than improve, the quality of patient care.

We are also concerned about models that are mandatory. In prior models that moved forward, CMS proposed limits on the size and scope of demonstrations, acknowledging that any payment or programmatic changes should be limited to the smallest population possible that permits collection of valid, scientific results. This type of small-scale testing is a key component of CMMI's mission and permits easier assessment of policy changes and patient outcomes. Large-scale and mandatory testing are much more likely to prove overly disruptive to patient access to care. More specifically, the benefits of small-scale testing include easily identifying access issues as they arise; clearer measurement of patient outcomes (e.g., adherence, disease outcomes, out-of-pocket costs, etc.); and more accurately assessing the extent of cost savings for the Medicare program and patients, if at all.

We strongly encourage CMS to reduce the size and scope of the IPI proposal as well as the requirement that providers randomized into the model must participate. A voluntary model could be accompanied by an incentive structure to drive provider participation, and we urge CMS to engage the provider community on how such a scheme might be operationalized while ensuring patient access and cost-sharing remains unchanged from the current system.

3. **If a vendor system were finalized, CMS must take on a significant oversight role regarding agreements negotiated between vendors and providers to assure patient access.**

In the context of this proposal, the Arthritis Foundation supports prohibiting vendors from engaging in utilization management. We would urge CMS to go a step further by prohibiting vendors from introducing formularies or any other tools that add to patient or provider administrative burdens. As we understand it, the role of vendors should be limited to purchasing drugs from manufacturers and subsequently transmitting them to participating providers in a reasonable amount of time so as to avoid disruptions in care. Vendors should not play a role in treatment decisions that are best left to

shared decision-making between patients and their providers. In addition, vendors should not use the model as an opportunity to achieve cost savings as a consequence of decreased utilization; as noted above, any projected or realized cost savings should accrue to patients for the purposes of reducing their out-of-pocket spending.

Ultimately, administrative barriers and high costs can lead to drug non-adherence, which results in worsening of disease and higher system-wide health care costs over time. Studies show a correlation between a patient's out-of-pocket costs and medication adherence: the higher the patient cost, the bigger the drop-off in adherence. Patients with chronic conditions like arthritis depend on treatments that are tailored to their specific needs and preserving the doctor-patient relationship is critical.

Patient advocacy organizations and other stakeholders are crucial partners in the design, implementation, and evaluation of new models. The Arthritis Foundation appreciates the opportunity to comment on the ANPRM and looks forward to continued discussions with CMS on solutions that balance issues of drug pricing and affordability with access to life-changing treatments. Please contact Vincent Pacileo, Director of Federal Affairs, at vpacileo@arthritis.org, with questions or for more information.

Sincerely,

Anna Hyde
Vice President, Advocacy and Access
Arthritis Foundation