

November 17, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Request for Information, CMS Innovation Center New Direction

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 is pleased to offer comments on the request for information (RFI) concerning a new direction for the Center for Medicare and Medicaid Innovation (the "Innovation Center"). The Arthritis Foundation is pleased that the Innovation Center is interested in fostering patient-centeredness as new models are developed, as well as renewing the focus on stakeholder outreach and engagement.

Arthritis is a complex, chronic condition. 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. As a patient advocacy organization, we value our role in helping policymakers understand the nuanced nature of treating arthritis and the needs of people who suffer from this disease. Below please find our comments on the RFI.

Guiding Principles and Areas of Focus

The Arthritis Foundation applauds the Innovation Center for putting forward six guiding principles to assist in the evaluation of new models and complement what has been learned from existing initiatives. We are pleased the Innovation Center included a principle focused on patient-centered care; acknowledging the need for a guidepost on patient-centeredness is a welcome first step. However, we urge the Innovation Center to make this guiding principle more explicit by acknowledging the importance of directly engaging patients and stakeholders as new models are developed, implemented, and evaluated. This principle should be further supported by the development, in partnership with patients and stakeholders, of criteria for patient-centeredness, as aligned with the Innovation Center's statutory guidance.

These criteria could then be used by patient and stakeholder partners to review and evaluate new models and initiatives, similar to patient-centeredness merit review criteria used in the Patient-Centered Outcomes Research Institute (PCORI) merit review process. Our goal is that the Innovation Center will make patient-centeredness criteria the cornerstone of all its work within and among Innovation Center teams for the purposes of building an infrastructure that supports broad, meaningful patient engagement. Other guiding principles would benefit from such an approach, especially in the context of gathering appropriate data and harnessing techniques for shared decision-making.

Patient Protections and Notifications

The Arthritis Foundation would also be supportive of the development of appropriate safeguards to ensure patient access to care is not jeopardized as new models are developed. As an example, in the proposed rule that cancelled the episode payment model, CMS proposed to place limits on the size of the Comprehensive Care for Joint Replacement model, acknowledging that it should be tested in only the number of hospitals necessary to attain valid, scientific results. This type of small-scale testing, as described in the guiding principles, marks a welcome return to the original intent of the Innovation Center.

Similarly, as seen in the episode payment models and the Part B drug payment model, it is critical that the Innovation Center avoid mandatory changes to how care is delivered, which affect large patient populations and could prove disruptive to the care of stable patients. Patients with chronic conditions like arthritis often depend on treatments that are tailored to their specific needs; preserving the doctor-patient relationship is critical as new models are developed. Another important safeguard is to ensure 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. We also urge the Innovation Center to consider the role of Congress in making mandatory changes to health policy.

In addition, in instances where small-scale testing of payment interventions appears successful, we agree that the model may be scaled up if it meets requirements for expansion under the Affordable Care Act (ACA). Importantly, under section 1115A of the ACA, which established the Innovation Center, the evaluation and testing of models must include an analysis of “the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary...”. We note that such criteria have not yet been developed and encourage the Innovation Center, in concert with patient stakeholders, to identify appropriate patient-centered quality or

performance measures. As the largest non-profit organization representing people with arthritis, we are a primary conduit for reaching this population, and welcome the opportunity to provide the patient perspective as a new direction is charted for the Innovation Center.

Patient Engagement in Model Development

The Arthritis Foundation is pleased the Innovation Center is seeking out ways to empower patients and best serve them through more routine feedback in the development and testing of small-scale models. Over the last year, the Arthritis Foundation has built a patient engagement strategy focused on infusing the lived experience of arthritis patients into all aspects of the health care system. We support a process in which patients are part of early model development, ensuring their perspectives and values are incorporated before models are finalized and formally proposed.

To maintain ongoing patient and stakeholder engagement, we encourage the Innovation Center to create an advisory panel on patient engagement similar to the Patient-Centered Outcomes Research Institute (PCORI). The PCORI Advisory Panel on Patient Engagement allows for diverse perspectives from patients, caregivers, advocates, researchers, and other experts to prioritize research questions and model meaningful patient engagement efforts. The panel also holds public meetings and employs working groups to prioritize topics for study and the development of criteria and guidelines. This type of panel could help develop guidance on specific approaches for patient engagement in Innovation Center processes, for example during the design of evaluation survey questions. One key theme the Arthritis Foundation urges the Innovation Center to adopt is that of “upstream involvement” of patient partners, embracing the concept that it is never too early to involve patients. We urge the Innovation Center to implement a similar model of patient engagement to that of PCORI, using a variety of models and modes of patient engagement as warranted.

An example of why patient engagement is so important is the Comprehensive Care for Joint Replacement (CJR) model. A recent article in *Health Affairs* described one family’s experience with the CJR bundled payment program and the lack of information provided regarding participation in the model.¹ As the article suggests, the trend toward these types of payment arrangements can have significant effects on provider behavior and the patient experience, creating perverse incentives that diminish, rather than improve, the quality of patient care. Two examples are in the

¹ Hoff, T. (2017). The Battle of The Bundle: Lessons From My Mother’s Partial Hip Replacement. *Health Affairs*, 36(8), 1511-1514. <https://doi.org/10.1377/hlthaff.2017.0356>.

disclosure process and the timing of the bundle. If patients are notified when they first schedule their surgery, rather than when they are admitted into the hospital for surgery, they have time to learn how the program might affect their care and can plan accordingly.

Patient engagement would also ensure that the method and language used in the disclosure mirrors what resonates most with patients. On timing of the bundle, we believe the model could have greatest impact if it began before surgery, rather than upon admission to the hospital for surgery. Research shows that patients receiving physical therapy prior to joint replacement surgery have easier recoveries and better outcomes post-surgery. This could ultimately result in lower overall episodic costs, if patients require less intervention post-surgery. The Innovation Center has an opportunity to incorporate the most up-to-date research in its models and test how these findings can improve patient care and lower costs, which is the ultimate goal of the Innovation Center. We urge the Innovation Center to apply a consistent approach for patients, caregivers, and other stakeholders in the design, testing, and implementation of any new models.

With that in mind, there are also provisions in the CJR model that we believe can improve patient care and outcomes, and we encourage the Innovation Center to consider scaling those up. For example, one component of the CJR model is a waiver that eliminates the telehealth geographic and originating site requirements. The ability of patients to access telehealth services and home visits could greatly improve treatment adherence and other positive health behaviors that may result from easier access to their providers.

Future Model Development

Many patient organizations have the infrastructure to collect rapid patient feedback to help inform the Innovation Center's work and ensure we are collectively meeting the needs and values that matter most to patients. For instance, last year the Arthritis Foundation launched an initiative to proactively address the challenges people with arthritis face in accessing and affording their health care treatments. The initiative also involved dozens of meetings with various stakeholders across the health care system, including the pharmaceutical industry, insurers, pharmacy benefit managers, and healthcare providers, to understand their perspectives on these issues.

Our experiences with this process have taught us the value of patients' active involvement in their own care, in the health care system in which they participate, and in research that pertains to them. There are many sectors of the healthcare system that a patient must navigate, yet all too often these sectors are not aligned.

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. We believe the Innovation Center could help to shift this paradigm and begin to make health care truly patient-centered.

Patient advocacy groups and other stakeholders are crucial partners in the design, implementation, and evaluation of new models. There are several ways in which the Arthritis Foundation can serve as a resource to the Innovation Center, including the dissemination of information about proposed models to our patients; collecting data from patients on the best ways for them to receive information about the work conducted by the Innovation Center (e.g., webinars, podcasts, and social media); and helping to identify patients to participate across aspects of the Innovation Center's processes for model development, testing, evaluating, and scaling.

Below please find several areas where we encourage future model development.

Addressing Chronic Pain

Recent Arthritis Foundation surveys have indicated that chronic pain continues to be the largest arthritis-related challenge people with the disease face. Chronic pain continues to gain attention across the federal government as the number of people who suffer from chronic and acute pain associated with chronic conditions increases.

For people with osteoarthritis (OA), there is currently no disease modifying therapy to treat the disease. Current therapies, including pain management, improved nutrition, and exercise can have a significant impact in relieving symptoms of OA. As an example, studies have shown that a combination of weight loss and exercise can significantly improve physical function among patients with osteoarthritis of the knee.² Such therapies can not only reduce pain, but also lead to improved knee stability, reduction in the use of opioid medications, and a delay or even avoidance of surgery.

Further, patients with arthritis may benefit from integrated, non-opioid interventions and care such as physical therapy, meditation, alternative medicine such as acupuncture, and access to evidence-based self-management tools and programs. Since its inception, the Centers for Disease Control and Prevention Arthritis Program has developed and implemented several evidence-based exercise and self-management programs that have proven to be effective in reducing arthritis

² Messier SP. (2004). Exercise and dietary weight loss in overweight and obese older adults with knee osteoarthritis: the Arthritis, Diet, and Activity Promotion Trial. *Arthritis Rheum.* 2004 May;50(5):1501-10. <https://www.ncbi.nlm.nih.gov/pubmed/15146420>.

symptoms. These include *Walk with Ease* and *EnhanceFitness*, which help tailor exercise programs to a person's disease state. Online tools such as the Arthritis Foundation's *Your Exercise Solution* have broadened the potential reach and impact by allowing patients to design their own exercise programs to suit their needs. We encourage the Innovation Center to incorporate these programs into any models that seek to coordinate care and address pain.

Physician Specialty Models

The Arthritis Foundation is working with the American College of Rheumatology on the development of a rheumatoid arthritis-specific Alternative Payment Model (APM) for rheumatologists as an additional option for payment outside of the Merit-Based Incentive Payment System (MIPS). This effort would reflect the wide-ranging role rheumatologists play over time in the treatment of rheumatoid arthritis (RA). The American College of Rheumatology's APM would also divide payment into diagnoses as well as ongoing care according to severity of disease. Rheumatoid arthritis is complex and difficult to treat, and an RA-specific APM is vital to ensuring the health care needs of people with arthritis are met as CMS continues to shift care delivery from paying for volume to paying for value.

Coordinated Care

One of the most important factors for patients with arthritis to remain healthy and prevent joint degeneration is adherence to prescribed treatments. While low adherence is not unique to the arthritis community, it remains a persistent problem that warrants further attention. Some examples of nonadherence include taking an incorrect medication dose, taking the medication at the wrong time, failing to fill a prescription, or missing scheduled visits with a health care provider. However, there are myriad reasons patients fail to adhere to their treatment regimen; from extensive focus groups, surveys, and interviews with patients, we know some of the reasons include high out-of-pocket costs, mail delivery failures, confusing or overwhelming information at the point of care, and feeling well enough to reduce their dose. Among patients with rheumatoid arthritis, studies have shown low adherence is associated with increased disease activity and progression.³ Increasing the focus on patient-provider relationships and shared decision-making may enhance patient adherence to treatments. The use of digital tools to map the arthritis patient's journey – in between visits to his or her provider – can also facilitate improved adherence and better outcomes. These contextual factors are important for policymakers to

³ Waimann, CA et al. (2013). Electronic monitoring of oral therapies in ethnically diverse and economically disadvantaged patients with rheumatoid arthritis: consequences of low adherence. *Arthritis Rheum.* 2013 Jun; 65(6): 1421–1429 . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3691007/>

understand as they design drug adherence policies, and further highlights the importance of patient engagement.

We also support integration of care for people with chronic disease who also suffer from behavioral health disorders. Multiple studies have shown that people with arthritis have higher levels of depression and anxiety. In fact, a Centers for Disease Control and Prevention (CDC) study found that 1 in 3 people with arthritis age 45 years or older suffer from depression and anxiety. However, only half of respondents with mental health issues had sought treatment. Untreated depression and anxiety can have a significant impact on the level of disability and functional limitations among people with arthritis. Due to the association between pain and depression, self-management programs that seek to help patients cope with pain are an important component to integrating behavioral and physical health care. Physical activity is also an important component to overall management of arthritis, and likewise can have an impact on mental health. As stated previously, the CDC Arthritis Program provides grants to fund evidence-based physical activity and self-management programs. We recommend scaling these programs to a broader geographic area and making them a covered benefit for Medicare beneficiaries.

Integrating Value Frameworks

The Arthritis Foundation also encourages the Innovation Center to incorporate value frameworks into existing models that can further facilitate moving the health care system from paying for volume to paying for value. Coupled with improved shared decision-making, value frameworks have the potential to truly place the patient at the center of health care. Patients may define value and quality differently than a physician, researcher, or policymaker, and ultimately health care should seek to meet the values of patients. Therefore, patients must be at the center of conversations about designing and implementing value models.

The Arthritis Foundation has been a stakeholder in multiple value framework projects, including the patient-perspective value framework released jointly by Avalere and FasterCures earlier this year.⁴ Work on a second iteration of this framework is ongoing. At the time, comments the Arthritis Foundation submitted on the draft framework noted there are currently many good Patient Reported Outcome (PRO) tools reflective of disease activity, treatment response, and other important outcomes, but no consensus or standard reporting form that rheumatologists or orthopedic surgeons use. We also applauded the model for utilizing measures aside from quality adjusted life-years (QALY) and emphasized that population-based assessments that fail to

⁴ See <http://avalere.com/expertise/life-sciences/insights/avalere-health-and-fastercures-release-version-1.0-of-the-patient-perspecti>

reflect the heterogeneity of disease subpopulations, patient treatment responses, and patient preferences increases the risk of mischaracterizing the value of the treatments. No single QALY threshold estimate can or should be generalizable to all populations, and QALY thresholds vary by decision-maker, population, and disease.

Value frameworks should also benefit health care at the population health level, creating improvements and efficiencies within health care systems; and at the individual patient level, emphasizing and enhancing shared-decision making. Current challenges include building consensus among varying value frameworks, implementing them across multiple populations, and determining how to incorporate them into existing value models like those implemented under the Medicare Access and CHIP Reauthorization Act (MACRA). If implemented properly, value frameworks can transform the patient experience, dramatically improving quality and ultimately reducing costs, and we encourage the Innovation Center to prioritize the incorporation of value frameworks into future models.

The Arthritis Foundation appreciates the opportunity to provide comments and welcomes the opportunity to partner with you in the future. Please consider the Arthritis Foundation as a resource as you continue your work, and contact Anna Hyde, Vice President of Advocacy and Access, at ahyde@arthritis.org, with any questions or for more information.

Sincerely,



Cindy McDaniel
Senior Vice President, Consumer Health
Arthritis Foundation