July 16, 2018

The Honorable Alex Azar
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via regulations.gov

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

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 offer comments on the Department of Health and Human Services (HHS) request for information (RFI) to lower drug prices and reduce out-of-pocket costs. We applaud the administration for prioritizing actions related to drug pricing and affordability – two issues that deeply impact people with arthritis. As you move forward, it is critical that proposals are developed and implemented carefully to ensure there are neither unintended consequences for patient access nor adverse impacts on research and development of the medicines that could transform the diagnosis and treatment of arthritis. Further, it is imperative that the patient perspective remains at the center of policy decisions.

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. Our comments reflect the fact that finding a treatment that works for a patient with arthritis can be extremely difficult. Treatment of rheumatoid arthritis (RA), for instance, can involve trying many different therapies over time; one review of biologic therapies for RA found 40 to 50 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 90 percent of the time following an inadequate response.[2]

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

[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.

heart disease to depression. Accessing prescription drugs and treatments should not be one of those challenges. A common narrative we hear from patients is that they cannot always make the best health care choices because of the chronic administrative burdens they face on top of their chronic diseases. Insurance policies are often difficult to understand, and the requirements for protocols like prior authorization and appealing denied claims differ across insurers. Ultimately, administrative barriers and high costs can lead to drug non-adherence, which then leads to 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.

All people, including those with arthritis, deserve a transparent health care system that allows them to make informed decisions. The Arthritis Foundation believes that any effort to increase transparency in health care must focus on all sides of the health care industry since the processes among insurers, pharmacy benefit managers, drug manufacturers, and others are too interconnected to single out only one stakeholder. We encourage HHS to consider the following principles as you develop policies to address high drug costs. People with arthritis should:

1. Expect patient-focused health care requirements that are reasonable;
2. Experience a more seamless, transparent health care system that puts the focus on the patient;
3. Expect to be able to remain on their drug if they are stable; and
4. Not fear that they will be unable to afford or access their medications.

Patient organizations like the Arthritis Foundation are often caught in the middle of policy debates concerning transparency and drug prices. As an example, the public commonly hears from pharmacy benefit managers (PBMs) that there is no correlation between increasing drug prices and manufacturer rebates.[3] Meanwhile, manufacturers suggest that negotiated rebates and discounts are not flowing to patients to tamp down rising out-of-pocket costs.[4] It is vital that all stakeholders come together to address rising drug prices, which directly affect patient access to needed medication.

While a number of proposals in the drug pricing blueprint hold promise for people with arthritis across these important domains, several areas present cause for concern. Below please find our specific comments.

A. Increasing Competition

Biologics have revolutionized the treatment of RA and other inflammatory forms of arthritis by preventing joint damage and preserving function and mobility. The Arthritis Foundation believes that biosimilars hold promise to reduce costs and add to the overall treatment options available to

[3] Visante for PCMA. 2017. *No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories.* https://www.pcmanet.org/wp-content/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL-3.pdf
[4] Berkeley Research Group for PhRMA. 2018. *The pharmaceutical supply chain: gross drug expenditures realized by stakeholders.* https://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf

patients. There are two key factors that could prevent wide-spread adoption of biosimilars: patient and provider trust in their safety and efficacy; and market policies that make it difficult for biosimilars to be offered to patients. Biosimilars educational resources and interchangeability are critical to overcoming these obstacles.

Biosimilar Educational Resources

We were pleased to see the release of educational materials on biosimilars targeting a provider audience last fall by the Food and Drug Administration (FDA). These materials will encourage important conversations between patients and providers about biosimilars. The FDA is now turning its attention to patient materials, which we think will be invaluable. We are glad to be a partner with FDA and offer our resources and knowledge base through this process. In a survey we conducted last year to better understand patients' knowledge and perceptions about biosimilars, we learned that patients view providers and the FDA as critical resources in learning about biosimilars and developing trust in using them. While three-quarters of respondents stated they understood that biosimilars are similar but not identical to branded biologics, most adults expressed a desire to learn more about side-effects, efficacy, safety risks, and insurance coverage associated with RA therapies. Additionally, a plurality of respondents indicated that their health care provider generally walks through the "pros and cons" of therapies before reaching a treatment decision together; policies that support shared decision-making between patients and providers are critically important.

Interchangeability

We strongly encourage FDA to finalize its guidance on interchangeability. We are particularly concerned that in the absence of interchangeability guidance by the agency, interchangeability will instead be dictated by payers. Although we understand that FDA's jurisdiction over this issue rests with the science and not with payer policies, we fear that without additional guidance, biosimilars will be treated as interchangeable in formulary policies based on cost rather than efficacy. Finalizing the interchangeability guidance is a key component of achieving a robust, sustainable biosimilars market. We also support strong investments in research to ensure that switching multiple times between drugs do not pose safety or efficacy issues.

Similarly, the Arthritis Foundation has spent the last few years working diligently to pass state substitution laws for interchangeable biological products, and only 5 states remain without this pathway. We anticipate that once biosimilars are designated as interchangeable, it will automatically trigger wider adoption of biosimilars with these state laws in place. Since biological products are complex treatments requiring careful therapeutic monitoring, we have also emphasized the need for provider communication in substitution legislation. From a survey conducted by the Arthritis Foundation in 2016, over 90 percent of respondents expressed a preference to receive a communication if a substitution for a biosimilar occurs. Having these notification requirements in place will go a long way towards reassuring providers and patients and increasing their comfort level for switching.

B. Better Negotiation

Shifting Drugs from Medical to Pharmacy Benefit
Earlier this year, the president's budget requested authority to move some Medicare Part B drugs to Medicare Part D, and the RFI poses several questions about this policy change. Although the RFI lacks meaningful details about a potential shift of drugs from the medical to the pharmacy benefit, the Arthritis Foundation is concerned about impacts to patient access and out-of-pocket costs due to such a proposal.

HHS already has some evidence at its disposal regarding the negative effects of transitioning Medicare Part B covered drugs to Part D. In a 2005 report to Congress, HHS noted, "The majority of categories of Part B drugs are not good candidates for shifting to Part D because they are provided directly in a physician's office or provider setting, rather than being dispensed to a beneficiary by a pharmacy." The analysis stated that moving drugs from Part B to Part D would increase both the financial risk and administrative complexity for prescription drug plans.[5] A second study conducted for CMS by Acumen found Medicare beneficiaries would be worse off through higher out-of-pocket costs, on average, if Part B to Part D consolidation were to occur.[6]

Setting aside the operational challenges for providers, the Arthritis Foundation is acutely concerned about the impact on patient access to needed medication as both a practical and financial matter under this proposal. We have long been guided by two principles when it comes to access to treatment: patients who are stable on a medication should be able to remain on that medication; and patients should be able to easily access a drug they and their provider decide is best for them based on their disease profile, medical history, and considerations about appropriate delivery mechanisms. As mentioned previously, people with inflammatory forms of arthritis often must try multiple medications before finding one that works for them, and treatments can stop being efficacious over time. Patients should be able to count on the ability to effortlessly switch medications when medically necessary to prevent worsening of disease.

There are other implications we urge HHS to consider. As an example, for some Medicare beneficiaries with RA, a visit to the local pharmacy to pick up an injectable biologic, which is paid for under Part D, may be an appropriate course of treatment especially if his or her joint inflammation or degeneration is mild enough to permit self-administration at home. In many cases, however, disease progression has reached a tipping point where it is neither safe nor practical to use a self-injected medication, and an infusion may be more suitable. Moving these types of medicines from Part B to Part D would almost certainly result in the proliferation of brown-bagging, whereby the onus is on the patient to acquire the specialty medicine at a pharmacy and ensure its care before returning to the provider's office – potentially days later –

[5] Department of Health and Human Services. (2005). *Report to Congress: Transitioning Medicare Part B Covered Drugs to Part D*. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC_PtbtoPtD_2005_4.pdf
[6] Acumen, LLC. (2011). *Estimating the Effects of Consolidating Drugs under Part D or Part B.* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf

and receiving the medication via infusion. These medications are inordinately complex and fragile, requiring careful refrigeration or other safeguards lest they become unusable. Such a scenario places undue burden on Medicare beneficiaries with arthritis who need to adhere to therapy to prevent further disease progression. We urge HHS to avoid creating unnecessary barriers and clinical challenges that would jeopardize the safety of arthritis patients on Medicare by having them transport intravenous medications to their provider.

In addition to practical concerns about patient safety, the Arthritis Foundation is equally troubled by the potential for increased out-of-pocket costs and reduced coverage for people with arthritis if drugs were shifted from the medical to the pharmacy benefit. Under Medicare Part B, most beneficiaries have insurance coverage that limits their out-of-pocket exposure, whether through a supplemental plan such as Medigap or Medicare Advantage. Depending on the scope of the change, moving some drugs into Part D could have the effect of increasing premiums for all beneficiaries and subject many to higher out-of-pocket costs due to the benefit design within the Part D program. For specific perspectives, the Arthritis Foundation polled a consumer panel for feedback on patient experiences accessing needed medication under the Medicare program. One respondent, a 66-year-old RA patient with traditional Medicare and a supplemental plan, noted that at this point in her RA treatment she is limited only to medications that are administered through infusion:

> *"If I were to switch to the injected form of the same drug I have infused, it would cost $6,432 per month under the Part D formulary as it now stands. My current dilemma is my medication appears to be losing its effectiveness, and I have no further infused medications that I haven't already tried or failed. I'm on a fixed income, cannot afford any of the injected medications that are on the Part D formulary, and patients on a government-funded program (such as Medicare or Tri-Care) are not eligible for patient assistance programs from pharmaceutical companies. I'm just lucky that up until now, my infusions have been covered under Part B because I would have had to go without medication. For me, no therapy means continuing, progressive disability."*

This experience is a common refrain we hear from many RA patients. For these reasons, we caution the administration from proposing changes that would shift drugs from the medical to the pharmacy benefit.

Value-Based Payments

Overall, the Arthritis Foundation is pleased to see a continuing emphasis on value-based care and treatment in many of the proposals the administration is considering. As you move forward, we urge you to consider any unintended consequences and work with the patient community early and often.

For instance, due to the complexity of treating arthritis, policies like indications-based pricing can easily result in unintended consequences. As stated previously, a drug that is proven to be

clinically effective in treating RA may not work for a particular patient, whereas a drug that is not clinically indicated to treat that form of RA may be the only drug that works for that patient. Further, there can be a high failure rate of biologic drugs in people with RA. Given these complexities, we offer HHS a few questions for consideration under this proposal:

1. What data will be used to assess clinical effectiveness? Measuring "improvement" in a person with long-standing RA can be difficult and often requires patient-reported assessment. Will patient-reported outcomes (PROs) or other patient-provided information be included?
2. What criteria will be used to evaluate clinical effectiveness? For example, infliximab has a higher failure rate range than rituximab (infliximab has a 27-75 percent failure range versus rituximab which has a 18-49 percent failure range), but rituximab has a higher rate of serious side effects than infliximab (77 percent of people had an adverse reaction on the first infusion of rituximab versus a range of 2-20 percent of people who experienced a side effect on infliximab). How will CMS assess which drug is more clinically effective?
3. How will off-label use of drugs be factored into this proposal?

In addition, the Arthritis Foundation is supportive of comparative effectiveness research (CER) as one of many tools to inform shared decision-making between patients and providers. However, CER does have limitations and should not be used to direct patients toward medications that may be inappropriate given medical history, comorbidities, and other factors.

C. Lowering List Prices

For the current calendar year, it is estimated that Americans will spend more than $380 billion on prescription drugs and the federal government will make about half of all payments through Medicare and other programs. Biologics represent about 80 percent and 20 percent of Medicare Part B and Part D expenditures, respectively.[7] For patients with RA, there are three biologics that command over two-thirds of the market; two are covered under Part D and one under Part B, and recent data suggests between 50,000 and 60,000 patients with RA use these drugs under the Medicare program.[8] Over the 2011 to 2015 period, total spending for these drugs either doubled or tripled while patient out of pocket costs rose steadily as well. These trends are not unique to RA and we appreciate that the administration is seeking to lower list prices overall.

Accuracy of National Spending Data

The Arthritis Foundation agrees that there is value in better understanding the differences between list and net drug prices. Patients often pay co-insurance based on the list price, rather than the negotiated price, of their medications. The Arthritis Foundation urges HHS to consider the following recommendations:

[7] Woollett, G., Love, K., Dixon, T. (March 31, 2017). Avalere. "Five Obstacles to Competition in the United States Biologics Market," para. 2. Retrieved from http://avalere.com/expertise/life-sciences/insights/five-obstacles-to-competition-in-the-united-states-biologics-market
[8] CMS Medicare Drug Spending Dashboard. https://www.cms.gov/Research-Statistics-Data-andSystems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015Medicare.html.

- Co-insurance should be presented to patients as a dollar amount and reflect the negotiated price of a drug, rather than the list price, ensuring that some of the rebates negotiated between manufacturers and pharmacy benefit managers are passed on to patients; and
- Costs for high deductibles or co-insurance should be spread over the course of a year, rather than immediately at the beginning of the year, to significantly reduce hardship burdens on patients.

Copayment Discount Cards

The Arthritis Foundation does not take a position on copay cards, but we do recognize that without them some patients could not afford their medications and some type of financial support is necessary for them. Many patients experience difficulty transitioning onto Medicare and adjusting to new policies, including the prohibition on the use of manufacturer copay cards. In fact, medication access challenges are the top reason people call into the Arthritis Foundation Helpline, and we have the most difficulty remedying this problem for Medicare beneficiaries, for whom manufacturer copay cards are not an option and third-party assistance programs are often depleted by the time the patient needs it.

While copay cards benefit many people with arthritis, PBMs argue that these cards shield patients from the true cost of medications. On the other hand, manufacturers argue PBM practices necessitate them to push list prices higher to ensure drug placement on preferred formulary tiers. Since the copayment card landscape is nuanced and complex, we strongly encourage the administration, to the extent possible, to study the impact these cards and other practices have on drug prices, generic drug use, and overall patient costs within commercial markets. We further urge careful analysis of the potential use of copayment cards in the Medicare program to ensure patients can still adhere to and remain stable on needed medication.

In addition, the blueprint poses questions related to how beneficiaries may be negatively impacted by incentives across the benefits landscape that favor high list prices, and how these incentives could be reset to prioritize lower out-of-pocket costs for patients. One example is a concerning new policy being implemented by PBMs called accumulator adjustment programs, which particularly impact people in high deductible health plans. With an accumulator adjustment program, patients are still allowed to apply the copay card benefits to pay for their medications up to the full limit of the cards, but when that limit is met, the patient is required to pay their full deductible before cost-sharing protections kick in. For some disease states such as RA – where there are no generics or significantly lower cost alternatives – this means transformative medicines to treat RA are put out of reach for patients, negatively impacting adherence, and reducing quality of life. Many of these plan changes have been implemented with little to no notification to the patient, and employers may not fully understand the impact of their choices when they select new insurance benefit designs for their workforce.

Out-of-Pocket Cap

The Arthritis Foundation supports the establishment of a beneficiary out-of-pocket maximum in the Medicare Part D catastrophic phase to reduce spending for beneficiaries who spend the most on drugs. According to a recent analysis, Medicare Part D enrollees spent an average of $1,215 out-of-pocket on prescriptions filled beyond the catastrophic coverage phase, totaling $1.2 billion in aggregate in 2015.[9] In the catastrophic phase, patients are assured a small co-insurance or co-payment for covered drugs for the rest of the year. However, one study found that nearly 60 percent of patients taking specialty drugs for RA reached the catastrophic coverage threshold by the month of May. In other words, most RA patients in the Medicare Part D program spent nearly half the plan year in the catastrophic coverage phase – meaning that the reduced co-insurance rate in this phase of coverage (today about 5%) can translate into significant out-of-pocket costs.[10] We are supportive of legislation to eliminate patient cost-sharing above the Medicare Part D annual threshold. The absence of a limit on out-of-pocket spending exposes patients to overly burdensome costs – especially for people with arthritis that require high-priced drugs such as biologics to treat and prevent progression of their disease.

Rebate Pass-Through

The Arthritis Foundation supports the administration's proposal to require Medicare Part D sponsors to pass through savings and apply rebates at the point of sale. If implemented appropriately, such a move would allow Medicare beneficiaries to benefit from the discounts negotiated between manufacturers and sponsors, drive greater transparency, and protect patients from paying a larger share of their drug costs. We look forward to additional guidance from the administration on this matter. Relatedly, we encourage HHS to explore requiring more detailed information about the contractual arrangements between payers and manufacturers, which include rebates at the individual drug level. This additional data could drive the development and testing of new innovative models of care through the Center for Medicare and Medicaid Innovation.

D. Lowering Out-of-Pocket Costs

Gag Clauses

The Arthritis Foundation applauds HHS for efforts to implement a federal preemption of contracted pharmacy gag clause laws. As you know, a clawback occurs when a patient pays a co-payment set by their pharmacy benefit manager that is larger than the actual cash cost of a drug. As a result, individuals sometimes pay more for covered prescriptions than they would otherwise have paid if they had bought the drug without using an insurance plan. Patients often do so unknowingly because of contract provisions preventing a pharmacist from telling a patient o the consequences of their payment options. These contract provisions are known as gag orders.

[9] Kaiser Family Foundation. (2018). *No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending*. https://www.kff.org/report-section/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/

[10] Trish, E., Xu, J., & Joyce, G. (2016). Medicare Beneficiaries Face Growing Out-Of-Pocket Burden for Specialty Drugs While in Catastrophic Coverage Phase. Health Affairs (Project Hope), 35(9), 1564–1571. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5573178/.

We support efforts to prohibit gag orders and allow pharmacists to disclose all possible payment options to patients so they pay the lowest possible price for their medications. We also support legislation that goes one step further, requiring by law that a patient be charged the lowest amount (copayment or cash price) at the pharmacy counter.

E. Additional Feedback

Drug Formulary Issues
Insurance plans sometimes change the available benefits of a policy and coverage of medications, imposing new utilization management practices, increasing cost sharing obligations, and making other changes that can have a negative impact on an insured. These types of mid-year formulary changes can adversely impact people with arthritis. The Arthritis Foundation remains opposed to this practice and is active at the state level supporting legislation that keeps insurance coverage consistent and affordable during a plan year.

Further, we applaud HHS for turning down the proposal in the Massachusetts 1115 waiver amendment that would potentially limit access to medications by imposing a closed formulary with as few as a single drug per therapeutic class in the state's Medicaid program. Patient with arthritis need uninterrupted access to maintain or treat their disease and the proposal could have negatively impacted treatment and health outcomes for Medicaid enrollees.

Center for Medicare and Medicaid Innovation (CMMI)
We believe CMMI would be a valuable and appropriate vehicle to develop and test some of the proposals outlined in the blueprint before scaling up to the broader Medicare and Medicaid populations. Many of the goals within the blueprint are in line with CMMI's mission, and the Center is increasingly prioritizing patient engagement as part of their process.

Last fall, the Arthritis Foundation submitted comments to CMMI as part of the "new directions" RFI.[11] In our comments, we emphasized the need for appropriate safeguards to ensure patient access to care is not jeopardized as new models are developed, citing the need for small-scale testing, which would be a welcome return to the original intent of CMMI. Similarly, as seen in the episode payment models and the Part B drug payment model, we reiterate that CMMI must 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. One 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. Patient advocacy groups and other stakeholders are

[11] Arthritis Foundation. (2018). *CMMI New Directions RFI.* https://www.arthritis.org/Documents/Sections/Advocate/Regulatory-Letters/AF-Comments-CMMI-RFI-New-Direction.pdf

crucial partners in the design, implementation, and evaluation of models and we urge HHS to consult with these organizations early and often about the development of any new proposals.

People with arthritis live with uncertainty every day and count on comprehensive health care to appropriately manage their disease. The Arthritis Foundation appreciates the opportunity to provide comments on the RFI and the administration's concerns about drug pricing and affordability. We look forward to working with you and offering the patient perspective as you develop any proposals. If you have any questions or would like to discuss these comments further, please contact Vincent Pacileo, Director of Federal Affairs, at vpacileo@arthritis.org or 202-843-0114.

Sincerely,

Anna Hyde
Vice President, Advocacy and Access
Arthritis Foundation