January 24, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicare Services
Department of Health and Human Services
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via regulations.gov

RE: [CMS-4180-P] Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses

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) proposed rule focused on Medicare Part D and Medicare Advantage (MA).

Almost half (49.6 percent, or 22.2 million) of adults aged 65 years or older have arthritis, and prevalence rates are expected to increase significantly over the next 20 years. 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.

On balance, Medicare's outpatient prescription drug benefit has been successful in allowing beneficiaries with serious and chronic illnesses to access needed medications. Yet the program must evolve to keep pace with beneficiaries' prescription drug needs. In recent years, access challenges, increased cost-sharing requirements, and plans' use of overly burdensome utilization management tools have held the program back from being even more successful for beneficiaries with chronic diseases like arthritis. Below please find our comments on the proposed rule.

Explanation of Benefits

CMS proposes to require plan sponsors to include information about negotiated drug price changes and lower cost therapeutic alternatives in a beneficiary's explanation of benefits (EOB) as a first step toward achieving a greater degree of drug price transparency in the Part D program. The Arthritis Foundation is supportive of system-wide health care transparency that allows patients to accurately compare costs and

benefits of treatments and therapies. We agree with CMS that lowering prescription drug costs overall is an important element of broader transparency efforts.

In theory, presenting more information about drug price and trend information will empower patients to make informed decisions on care. However, the information must be presented in a way that is understandable to them. Therefore, we are concerned about the proposal to display information on the EOB regarding how the "cumulative percentage by which the negotiated price" for a medication has changed. As currently proposed, we do not believe this information will be useful to patients. A common narrative we hear from our community is that it can be difficult to know the best health care choices to make because of the sheer volume of information and high administrative burdens.

Language in an EOB should be clear, logical, and legible. Phrases such as "negotiated price" will not be readily understandable to patients who already have difficulty making sense of commonly used health care terms. As an example of continued health literacy challenges, in 2018 the Arthritis Foundation conducted a survey that asked patients whether they would feel confident accurately describing a set of common health care topics to a friend. Key results from the survey found:

- Over half of respondents were confident they could define terms such as co-payment or prior authorization;
- About 40 percent of respondents felt comfortable with the phrase step therapy; and
- Only one-third understood the term co-insurance.

The survey results are undoubtedly a wake-up call and underscore the notion that more sophisticated terminology is unlikely to be valuable to patients without intensive education. More broadly, patients are also unable to benefit from price information on an EOB for out of pocket costs they have already incurred.

As an alternative, the Arthritis Foundation proposes CMS include information on the net patient co-payment or co-insurance increase or decrease associated with the prescribed treatment or its lower cost alternatives. This information would allow patients to see how their out of pocket costs are changing over time and would be more relevant than the negotiated price of a beneficiary's medication. The Arthritis Foundation is here as a resource to patient-test any proposed changes to the EOB and ensure terminology is well-defined and presented in the most meaningful way possible.

Step Therapy in Medicare Advantage

CMS proposes requirements for when MA plans may apply utilization management tools such as step therapy for Medicare Part B drugs. The proposed rule reaffirms the CMS memo released last year, which rescinded prior guidance that expressly prohibited the use of step therapy in MA. At that time, the Arthritis Foundation expressed concern over the administration's decision and the potential treatment interruptions that could follow without the institution of sufficient patient safeguards.

Since the 2019 plan year has already begun, we strongly urge CMS to immediately publish guidance to MA plans that outlines patient guardrails under the proposed rule. We further urge CMS to provide

additional details regarding the exceptions processes available to patients. The Arthritis Foundation is supportive of the Restoring the Patient's Voice Act (H.R. 2077 in the 115th Congress), a bipartisan bill that provides for five exceptions in the context of step therapy, and we urge CMS to institute an exceptions process that adheres to the following guardrails:

- When the treatment prescribed is contraindicated or has been ineffective in the treatment of a patient's disease;
- When the treatment under a step therapy protocol is reasonably expected to be ineffective;
- When the treatment may cause an adverse reaction or physical harm to the patient;
- When the treatment is not in the best interest of the patient or could interfere with the patient's ability to complete activities of daily living; and
- When the patient is stable for his or her disease on the medications already selected by a health care provider.

Additionally, while CMS has expressed a commitment to ensure that step therapy would not be permitted to disrupt enrollees' ongoing Part B drug therapies, and that step therapy would only be "applicable to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication," we call on the agency to strengthen the proposed look-back period. While our understanding is that the proposed look-back of 108 days is consistent with existing Part D policy, a 365-day, or full plan year, look-back period for Part B drug therapies is more appropriate for physician-administered drugs. Most Part B drugs approved by the Food and Drug Administration (FDA) that treat osteoarthritis or rheumatoid arthritis (RA), for instance, have dosing frequencies that exceed the 108-day period that has been proposed. Consequently, we are concerned 108 days is an insufficient amount of time to accurately capture medication use as well as whether patients have been stable for an extended period. This is particularly important for enrollees who switch MA plans from year to year, or for other circumstances such as transitioning onto Medicare for the first time.

The proposed rule would also permit MA prescription drug plans to cross-manage between Part B and Part D drug therapies. We are deeply concerned about proposals that would permit plans to require a Part D drug therapy prior to allowing a Part B drug therapy (under the proposal, the reverse would similarly be permitted). The Arthritis Foundation believes decisions on the choice of biologic therapy are best left to shared decision-making between the patient and his or her provider, the latter of whom is in the best position to understand clinical appropriateness of various treatment options based on a patient's medical history and prior adverse events. We further note that policies like indications-based pricing can easily result in unintended consequences: for example, 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.

With respect to Pharmacy and Therapeutics (P&T) Committees and their role in overseeing implementation of these policies, the Arthritis Foundation believes CMS should require plans to have representatives on the committee with strong expertise in inflammatory diseases. We further recommend that the P&T committees add patient representatives or otherwise develop a mechanism for meaningful patient engagement in the process.

Medicare Advantage Appeals Process

If an enrollee is dissatisfied with the plan's coverage determination, the enrollee has a right to appeal. Unfortunately, the current appeals process is not working as intended. A recent report from the Office of the Inspector General (OIG) at HHS studied MA appeal outcomes and audit findings, highlighting a high number of overturned denials upon appeal. The report indicates that some MA enrollees and providers were initially denied services and payments that should have been provided.[1] From 2014-2016, MA plans overturned 75 percent of their own denials (about 216,000 each year). As the report notes:

> "…this is especially concerning because beneficiaries and providers rarely used the appeals process designed to ensure access to care and payment, appealing *only 1 percent* of denials during [the period]." *(emphasis added*)

The Arthritis Foundation calls on the administration to implement the OIG's recommendations to correct any incentives MA plans may have to deny services or payment to patients and providers. We also urge CMS to increase efforts to ensure beneficiaries have access to clear and detailed information about their ability to file an appeal, given that an overwhelming majority of patients are not filing appeals if/when they are denied for the first time.

Pharmacy Price Concessions

CMS proposes to consider passing pharmacy direct and indirect remuneration (DIR) to the point of sale. To the extent this policy would generate savings for patients at the pharmacy counter, the Arthritis Foundation is supportive of the proposal. We look forward to learning more information from CMS regarding how this change will be operationalized.

Electronic Prescribing

CMS proposes to require Medicare Part D plan sponsors implement a real-time benefit tool that would interface with prescribers' electronic prescribing (e-prescribing) or medical records systems with the goal of improving cost-effectiveness of the prescription drug program. The Arthritis Foundation is supportive of this proposal as a strong first step toward ensuring timely, patient-specific, and accurate information is available to prescribers.

We also call attention to the American Medical Association-led prior authorization and utilization management reform principles released in 2017.[2] Importantly, six trade associations came together in a consensus statement around five of these principles in January 2018, including increased e-prescribing.[3] We urge CMS to help guide the incorporation of these principles into health plans across the country.

[1] HHS Office of the Inspector General. https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp
[2] American Medical Association. https://www.arthritis.org/Documents/Sections/Advocate/Regulatory-Letters/AMA-Prior-Authorization-Principles.pdf
[3] American Medical Association. https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf

Prohibition Against Gag Clauses in Pharmacy Contracts

The Arthritis Foundation applauds CMS for incorporating requirements under the Know the Lowest Price Act of 2018, passed by Congress in October 2018, which prohibits Medicare Part D plan sponsors from restricting pharmacies from informing patients when it may be cheaper to pay the cash price for medications rather than through insurance. We also support efforts that would go one step further, requiring by law that a patient be charged the lowest amount (copayment or cash price) at the pharmacy counter.

Part D Out of Pocket Threshold

The Medicare Part D out of pocket limit is expected to increase by over $1,200 in 2020. The so-called "cliff" is a significant financial concern for patients who depend on the Part D program for access to needed medication. The Arthritis Foundation strongly encourages CMS to both act within its authority and work expeditiously with Congress to mitigate this steep increase before the next plan year.

The Arthritis Foundation appreciates the opportunity to comment on the proposed rule and looks forward to continued discussions with the administration 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