March 2, 2020

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21224

Submitted via regulations.gov

RE: [CMS-9916-P] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans

Dear Administrator Verma,

The American College of Rheumatology (ACR), representing over 7,700 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the Health and Human Services Notice of Benefit and Payment Parameters for 2021 as published in the Federal Register on February 6, 2020. We welcome the chance to share our concerns about the impact of these policies on our patients.

Rheumatologists provide ongoing care for patients with complex chronic and acute conditions that require specialized expertise. Rheumatologists, rheumatology physician assistants and nurse practitioners, provide face-to-face, primarily non-procedure-based care, and serve patients with severe conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases. Rheumatologists and rheumatology professionals work closely with occupational and physical therapists to maximize the ability of patients to achieve and maintain independence to continue to work and perform everyday activities. Compared to treatment and therapies provided solely by primary care, early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly surgical or interventional procedures.

In today's environment of value-based care, policies should focus on promoting and protecting access to high quality, affordable health care and health insurance. The ACR strongly advocates for health insurance policies that cover necessary treatments for arthritis and rheumatic diseases and include access to a rheumatologist and rheumatology interprofessional team members for both consultative and maintenance care.

We are pleased to see that CMS has placed a focus on increasing consumer transparency, reducing prescription drug costs, reducing regulatory burden, empowering consumers, and
improving affordability. However, we have several concerns regarding the proposals included in the benefit and payment parameters for 2021 proposed rule. Our specific comments are below:

**Price Adjustment Percentage**

CMS is proposing to increase the price adjustment percentage to 1.35. Based on this percentage, and the maximum annual limitation on cost-sharing, the 2021 proposed maximum out-of-pocket cost-sharing limitation will increase to $8,150 for self-only coverage and $16,300 for plans other than self-only. **The ACR reiterates our concern that the increased price adjustment and subsequent maximum out-of-pocket limitations will severely impede our patients’ ability to access the care and treatments they need to manage their rheumatic diseases.** As the out-of-pocket limitations continue to increase year after year, patients are left with the choice of paying the increased costs to manage their condition or forgoing treatment to prevent significant financial hardships.

**Copay Assistance**

CMS is proposing to expand on their current policies by allowing insurers the flexibility to exclude manufacturer copay coupons from being applied toward the patient's out-of-pocket limitation regardless of the availability of a generic product. The current policy enables insurers to exclude the copay assistance to count toward a patient's deductible for treatments that have a generic alternative. The proposed policy expands this exclusion for any treatment regardless of the availability of a generic product. **The ACR strongly urges CMS to withdraw this proposal as it will negatively impact our patients’ ability to access the treatments they need.**

Patients suffering from rheumatic diseases often rely on expensive drugs, such as biologics with no less expensive alternatives, to manage their disease and have a better quality of life. To allow our patients to access these treatments, many rely on manufacturer copay assistance to help defray the high costs associated with their treatments. According to a 2016 study by the USC Schaeffer Center for Health Policy and Economics, 20 percent of brand-name prescriptions use copay coupons to help defray the cost of the treatment. 1 Without the assistance of manufacturer copay coupons, our patients will be forced to delay treatment, ration their medication, forfeit treatment entirely, or experience incredible financial hardships to pay for their treatment.

Additionally, we have seen health plan deductibles and out-of-pocket limits continue to rise. By excluding the copay assistance from counting toward a patient’s out-of-pocket limitation, patients will not be able to meet their deductible as early as they have in the past or they may not

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be able to meet their deductible at all. This will further compound their financial liability and will cause significant barriers to access the treatments they need.

In a national patient survey conducted by the ACR and its Simple Tasks™ public awareness campaign, it was found that 60 percent of respondents reported difficulty affording treatment. In today’s environment of value-based care, we believe policies should focus on promoting and protecting access to high quality, affordable health care, and health insurance. This proposed rule will counter efforts to provide greater access for patients to receive quality care and to receive the right treatment for the right patient at the right time.

In conclusion, the ACR is deeply concerned that the proposed policies to increase the maximum out-of-pocket limitations, coupled with allowing insurers to exclude copay coupons to be applied toward a patient’s out-of-pocket limit, will severely debilitating our patients’ ability to access needed treatments to manage their painful and disabling chronic conditions. We recognize the need for solutions to curb the increasing cost of healthcare; however, we cannot support policies that will sacrifice the health of our patients in the name of cost savings. Please contact Amanda Grimm Wiegrefe, MScHSRA, Director of Regulatory Affairs, at awiegrefe@rheumatology.org or (202) 991-1127, should you have any questions or in need of any additional assistance.

Sincerely,

Ellen Gravallese, MD
President, American College of Rheumatology