February 19, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G-Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Submitted electronically via http://www.regulations.gov

Re: [CMS-9926-P]-Comments on Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020.

Dear Administrator Verma:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to provide input on the Notice of Benefit and Payment Parameters for 2020 Proposed Rule. Rheumatologists provide care for millions of Americans, both adults and children, and are the experts in diagnosing, managing and treating arthritis and rheumatic diseases. These life-long, chronic conditions include rheumatoid arthritis, systemic lupus erythematosus, and vasculitis, among many others. Rheumatic diseases and arthritis are the leading cause of disability in the United States. Early and appropriate treatment by a rheumatologist is vital to controlling disease activity, preventing and slowing progression, improving patient outcomes, and reducing the need for costly downstream procedures and care. Rheumatologists practice in every state, the District of Columbia, and Puerto Rico, and in all communities, both urban and rural. They provide critical care for people with diseases that can be crippling, life changing, and life threatening.

Health policy proposals should promote and protect access to adequate and affordable health insurance. In particular, the ACR recommends that all Americans should be covered by sufficient, affordable, and continuous health insurance that encourages high quality, high value health care. This coverage should include treatment for arthritis and rheumatic diseases, with access to a rheumatologist and rheumatology interprofessional team members for both consultative and maintenance care. We are pleased to see CMS 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 in the rule. Our specific comments are in these subsequent paragraphs:

**Annual premium adjustment percentage**

The proposed premium adjustment percentage will be set at about 1.3 percent, which represents around a 30 percent increase over the 2013 to 2019 period. Additionally, CMS proposes a maximum annual out-of-pocket (OOP) limit on cost-sharing for 2020 of $8,200 for self-only coverage and $16,400 for other than self-only coverage; this proposal represents a 3.8 percent increase in the OOP limit over 2019. We believe the increased premium adjustment change and the increased OOP limit will have a significant impact on patients and result in a higher annual limit on cost-sharing, a higher required contribution from enrollees, higher employer mandate penalties, and reduced access to care. The ACR believes that safe and effective treatments should be accessible to all patients at the lowest possible cost. We support policies rooted in scientific evidence that support shared decision-making between patients and providers and that decrease barriers to patients accessing treatment.

**Prescription Drug Benefit**

*Mid-year Formulary Switching*

CMS proposes that the issuer be permitted to modify its plans’ formularies mid-year to add the generic equivalent drug. The issuer would be permitted to remove the equivalent brand drug(s) from the formulary or move the equivalent brand drug(s) to a different cost-sharing tier on the formulary. The ACR is supportive of switching to a lower cost small molecule generic drug; however, we feel CMS has not made clear that this proposal would only apply to small molecule generic drugs, and not to biologic drugs used to treat many rheumatic diseases and for which biosimilar drugs should not be construed as a generic equivalent (see below). We request clarity from HHS that these proposals apply only to small molecule generic drugs.

*Therapeutic Substitution*

CMS does go on to ask for comments on therapeutic substitution being used to improve the market. The proposal states, “First, the prescription drug market became more efficient after several states passed laws that allowed for generic substitution. Similarly, therapeutic substitution, which consists of substituting chemically different compounds within the same class for one another, could be employed to improve the efficiency of the pharmaceutical market.”

The ACR opposes policies that would permit any kind of prescription therapeutic substitution by insurers or pharmacists, including therapeutic substitution of one biologic or biosimilar for another, unless the insurer or pharmacist is acting in accordance with a collaborative practice agreement with the prescribing physician, nurse practitioner, or physician assistant.
Therapeutic substitution is especially relevant regarding biologic medications and biosimilars. Biosimilars are similar to the innovator biologic product, but do not have the same biochemical structure. Biologics are highly complex medications created in living cells and each product within a class of biologics has unique properties as well as varied safety and efficacy profiles. Biosimilars differ from the original comparator biologic due to the extreme complexity of these medications and unpredictability in the manufacturing process, which may lead to substantial differences in safety and efficacy compared to the innovator biologic. The treating physician or advanced practitioner is most capable of determining when a substitution between biologic drugs is clinically appropriate based on individual patient and disease characteristics as well as comorbid conditions. Allowing entities other than the treating health care team to make therapeutic substitutions between biologics and biosimilars carries a significant risk of disease flares, organ damage and adverse drug reactions.

For the above reasons, the ACR supports a rigorous FDA-approval pathway for interchangeable biosimilars, which includes clinical studies using three switches between a bio-originator and biosimilar. CMS cannot in good faith move forward with a therapeutic substitution policy without the FDA interchangeability guidance being finalized. Also, as CMS notes, there would need to be seamless communication among prescribers, pharmacies, and insurance companies for such a policy to not have an adverse impact on patient care. We are pleased to see CMS acknowledge that many stakeholders are opposed to therapeutic substitution and that there are concerns regarding efficacy, adverse effects, drug interactions, and different indications for drugs within a class, all of which are consistent with our own concerns as stated above. The choice to use large molecule drugs such as biologics and biosimilars in rheumatologic care are complex decisions made between the patient and the rheumatology provider.

Therapeutic substitution of biologics would be completely unacceptable due to the differences between one drug and others in the same drug classes based on FDA-approved indications. There are also differences in safety related to patient conditions (e.g. pregnancy) and comorbidities (e.g. infections), as well as in efficacy for different disease manifestations. For example, while Enbrel and Humira are both TNF inhibitors (the same "therapeutic class") and both are used in psoriatic arthritis, they do not have the same FDA approvals for all conditions treated as part of rheumatologic care, nor do they have the same profile related to patient comorbidities. For example, unlike Humira, Enbrel has not been found to be effective for conditions such as inflammatory eye disease (a condition which causes up to 30,000 new cases of blindness annually) and inflammatory bowel disease, both of which commonly affect people with psoriatic arthritis. It would be unacceptable for a patient given a prescription for Humira for psoriatic arthritis complicated by inflammatory eye or bowel disease to undergo therapeutic substitution of Enbrel for Humira. Similarly, it is common for a patient with psoriatic arthritis to have an excellent response to Enbrel after a poor response to Humira, or vice versa. These varied responses are often unpredictable, and therapeutic substitution would thus place patients at risk for treatment failures and disease progression.
Policies should be based on the best interests of the patient and allow for grandfathering of patients whose disease is well controlled on stable therapy. Grandfathering is especially important for biologics because if a patient stops taking a biologic drug, and then restarts it after a treatment gap, the patient could develop immunogenicity against the drug that could render the drug ineffective or cause side effects. Additionally, we believe 120 days is a more appropriate time frame for enrollee notification if an issuer is going to remove a brand drug from the formulary or move it to a different cost-sharing tier.

**Cost-sharing, Maximum Out-of-Pocket Limits, and Essential Health Benefits**

CMS is also proposing that issuers and self-insured group health plans can exempt certain cost-sharing from the maximum out-of-pocket (OOP) limit if a consumer selects a brand drug when a medically appropriate generic drug is available. Health plans and insurers have systematically shifted costs for specialty drugs onto patients through drug coinsurance programs. This cost shifting, when coupled with the high cost of specialty medications, results in prohibitive OOP for the patient. In response, copay assistance programs are offered by pharmaceutical manufacturers to offset these costs. However, this proposal allows for the exclusion of drug manufacturer coupons to offset the OOP limit when a specific prescription brand drug has a generic equivalent. Again, we ask for clarity on whether this policy applies to small molecule drugs or large molecule drugs.

Copay assistance programs offer coverage of the patient’s drug coinsurance, which, in a conventional benefit design, is also applied to the patient’s annual deductible and OOP maximum. These programs thereby preserve patient access to otherwise unaffordable drugs when OOP expenses are high. They allow patients access to life altering medications without regard to personal financial status. Without such assistance, these medically necessary treatments are out of reach for many patients. Their medical conditions therefore go untreated or undertreated, with resultant permanent joint damage and disability, inability to maintain employment, expensive surgeries, and overall higher health care costs. The ACR acknowledges the potential downsides associated with copay assistance programs, but until such time as inflation in medication costs is controlled and patients have reasonable access to medically necessary therapies, we support the use of copay assistance as a means to provide treatment for otherwise devastating diseases.

If this policy does apply to large molecule drugs, we are very concerned about the following scenario, which certainly could occur if the policy applied to large molecule drugs. There are some rheumatology practice locations where payers often prefer the brand drug (Remicade) over the biosimilar. This proposal could allow the payer to still prefer the brand drug and exclude the copay assistance going toward OOP maximum because it is not the lower cost alternative, based on manufacturer list price. We feel a situation such as this would be disastrous for patients and ask for clarity from CMS on how this policy will work when the brand biologic drug and not the biosimilar is the preferred drug on formulary.
Further, CMS proposes that plans covering both a brand name prescription drug and its generic equivalent could consider the brand name drug not to be an essential health benefit (EHB) if the generic drug is available and medically appropriate for the enrollee. CMS is also soliciting comments on implementing or incentivizing reference-based pricing for prescription drugs where a consumer would pay the difference in cost if they wanted a drug that exceeds the reference price. If this policy is finalized, it would allow group health plans and group health insurers to impose lifetime and annual dollar limits on the brand drugs because they would no longer be considered an EHB. CMS is also considering whether an insurer should be allowed to except the entire amount paid for a brand name drug from the annual limit on cost-sharing. The ACR supports policies that will eliminate excessive patient cost-sharing and OOP costs. We do not believe the current proposals will accomplish patient cost-savings and could be further prohibitive on access to needed treatments. By CMS’ own acknowledgement, these proposals could increase consumer out-of-pocket costs in some instances.

The ACR is dedicated to ensuring that rheumatologists, interprofessional team members, and their patients have access to continuous high-value and high-quality care. The ACR appreciates the work that HHS and CMS does and the opportunity to respond to the Notice of Benefit and Payment Parameters for 2019 Proposed Rule. We look forward to serving as a resource to you and to working with the agency as this rule is finalized. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

Paula Marchetta, MD, MBA
President, American College of Rheumatology