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November 27, 2017

The Honorable Eric D. Hargan
Acting 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

**Re: [CMS-9930-P]-Comments on Notice of Benefit and Payment Parameters for 2019 Proposed Rule**

Dear Acting Administrator Hargan:

The American College of Rheumatology, representing over 9,500 rheumatologists and rheumatology health professionals, appreciates the opportunity to comment on the *Notice of Benefit and Payment Parameters for 2019 Proposed Rule*. Rheumatologists provide face-to-face, primarily non-procedure-based care and serve patients who have serious and frequently chronic conditions that can be difficult to diagnose and treat. These conditions include rheumatoid arthritis, systemic lupus erythematosus and other debilitating diseases. Early and appropriate treatment by rheumatologists slows disease progression, improves patient outcomes, and reduces the need for costly downstream procedures and care that are complicated and made more expensive by advanced disease states.

The following are key issues identified by the ACR relating to the offering of health insurance coverage as outlined in the proposed regulation. We are pleased to see that the Department of Health and Human Services (HHS) is working to reduce fiscal and regulatory burdens to obtaining coverage, and we applaud the agency for considering proposals to help reduce drug costs and promote price transparency. However, regarding state essential health benefit (EHB) flexibilities, we have several concerns about how states will be able to ensure that people living with rheumatic diseases can continue to receive the care they need. We also have concerns regarding network adequacy, standard benefit design, adjustments to the medical loss ratio (MLR), and revisions to the rate review criteria and process. Based on our clinical experience, including discussions with patients, the ACR's rheumatologists offer the following recommendations on what patients need and the additional issues that should be addressed.

**Exchange and Qualified Health Plan Provisions**

***Essential Health Benefits***

HHS is proposing to allow states to select a new EHB-benchmark plan with more flexibility on the components they can select in a benchmark plan, and on a schedule that works for the state, rather than one set by HHS. The proposed rule would also allow EHB-compliant plans to substitute benefits both within and between EHB categories. The ACR strongly cautions against any proposals that weaken or remove the current essential health benefits requirements. We are concerned that these proposals do not ensure states will provide appropriate benefits and continuity of care to people living with rheumatic diseases.

In particular, with these policy changes we feel HHS may be singling out drug coverage, and an unintended consequence could be a state only allowing one drug per class to be covered, a decision that could affect treatment efficacy, access and choice. The decision to choose one biologic over another requires careful clinical evaluation and consideration by a physician and patient. Patient factors that strongly influence this choice include but are not limited to an individual patient's age, gender, diagnosis and comorbid conditions, concomitant medications, specific organ manifestations, antibody status, disease severity and burden, physical or psychological abilities, access to transportation, and ability to tolerate a particular route of administration. Clinical decisions about treatments must be left to the provider, and entities such as insurers or states should not be able to determine the treatment of the patient, nor should they mandate use of one therapy over another.

We understand the desire for flexibility in allowing states to set their own process for soliciting comments on proposed benchmarks, but we are concerned that many states may not have the bandwidth to do so. We urge HHS to create guidance on the public comment process, ensuring transparency and patient engagement. We also believe if states must pick and choose benefits, they will face a significant timing challenge in the choosing of EHBs, creating unpredictability for payers and undue burden on the states. Historically, most states have chosen the default benchmark plan set by HHS. Therefore, we have concerns that that this will create a race to the bottom, wherein states will seek the least acceptable coverage at the lowest cost, further restricting patient access to care. Rheumatologists constitute a specialty that provides ongoing care for patients with complex chronic and acute conditions that can be difficult to diagnose and treat, and having a wide range of benefits available to patients is of utmost importance.

***State-based Exchanges (SBEs)***

HHS seeks to provide incentives for innovation by SBEs, and seeks comment on ways that such efforts can be supported through program flexibilities. One of the greatest barriers to entry for states is the federal platform fee. The ACR believes providing a more predictable fee schedule

would make for a simpler cost benefit analysis. We also caution HHS against any "flexibility" that sacrifices the EHBs, access to care, and quality of care.

***Qualified Health Plan (QHP) Certification Standards***

HHS is proposing to eliminate requirements for SBE-FPs to enforce FFE standards for network adequacy and essential community providers, instead allowing states to establish their own standards. We are particularly concerned about network adequacy standards. This issue is of great importance to people with rheumatic disease, as this is a population that requires regular, ongoing access to both primary and specialty care. Policy changes should protect and promote continuity of care so that patients can keep their doctors, and transparency and accuracy of information about network listings so that patients know which providers are in-network. We caution HHS to consider how having narrow networks or networks that vary wildly between states can jeopardize access to care for patients.

***Standardized Options***

HHS is proposing not to specify standardized options or to provide differential display of standardized options on HealthCare.gov for 2019. Previously, all standardized options included first dollar coverage for many services and we believe this proposal could cause the loss of first dollar coverage and lower deductibles, causing a major access issue.

The ACR believes that consumers need greater access to information, allowing for easier comparisons of health plans offered by different issuers. This includes information that would assist patients in identifying the providers they need among the plan networks that are offered; selecting premiums, benefits and quality improvements that address their specific health care needs; and receiving more consistent cost-sharing requirements among the plans. We urge HHS to consider how this proposal will enable insurers and web brokers more flexibility in the messaging to consumers, potentially negatively affecting consumer choice and removing incentives for issuers to offer coverage with innovative plan designs. As you work to determine this provision, our primary concern is that patients do not experience lapses in coverage.

***Navigator Program***

HHS proposes to provide Exchanges with more flexibility in the operation of Navigator programs, by removing the requirements that each Exchange must have at least two Navigator entities, and that one of these entities must be a community and consumer-focused nonprofit group. Also, HHS proposes to remove the requirement that each Navigator entity maintain a physical presence in the Exchange service area. The ACR has concerns that this policy could reduce the effectiveness of the Navigator programs, and thereby reduce the chance that Americans will maintain continuous coverage for high quality health care services.

**Payment Parameter Provisions**

***Risk Adjustment***

We agree with HHS's proposed amendment to the risk adjustment model by incorporating the most recent prescription drug data to the risk adjustment methodology beginning with the 2019 benefit year. Drug utilization data can be useful in representing missing diagnoses, indicating the severity of an individual's condition and providing more timely and accessible information than medical claims alone. Biologic drugs, like those used to treat rheumatoid arthritis, psoriatic arthritis, lupus and other rheumatic diseases, are breakthrough and important drugs that can prevent disability, save and improve lives, and allow patients to function and remain in the workforce. To date, there are no generic or follow-on substitutes available for many of these drugs. For rheumatology patients, lack of access to these disease-modifying therapies can result in permanent joint damage, leading to disabilities and costly surgeries.

***FFE and SBE-FP User Fees***

HHS proposes to maintain the user fee rates at 3.5 percent of premium for FFEs, and propose to set the user fee for SBE-FPs at 3.0 percent of premium for the 2019 benefit year; an increase from the 2.0 percent established for the 2018 benefit year. As mentioned previously, one of the biggest reservations states have about the SBE-FP model is the uncertainty of the federal platform fee. In the 2018 rule, the fee was set at 2% of the QHP premium for state exchanges using the federal platform. The 2019 proposed rule increases the fee to 3%. The fee changing year over year creates significant budgeting concerns for states, because they must adjust state fees to cover the federal fee. We propose HHS review changes in 5-year increments, so that states may perform more adequate cost benefit analyses and could more confidently pursue the SBE-FP model to reduce administrative costs. Additionally, states that have already established exchanges are unlikely to switch because the largest cost of the exchange is the initial set-up and launch of the exchange.

**Eligibility and Enrollment Provisions**

***Special Enrollment Periods (SEPs)***

The ACR continues to support access to coverage that improves the patient's experience in the health care system. We encourage HHS to ensure any changes in enrollment options do not cause barriers to patients receiving access to continuous insurance coverage and high-quality care and treatments.

***Exemptions***

We agree with the proposed rule adding a new category of hardship exemption for individuals who lack affordable coverage in their area. Because HHS would allow exchanges to use the annual premium for the lowest-cost metal level plan in the individual's rating area, an individual could still

qualify for a hardship exemption if no bronze plan is available, based on the cost of the lowest-cost metal level plan. This proposal would potentially extend coverage to consumers who need it most.

**Market Reform Provisions**

***Rate Review***

HHS proposes to raise the rate increase threshold and revise the review process. Under the proposed rule, HHS would increase the threshold for review of "unreasonable" premium increases from 10 to 15 percent; therefore, any plan with an increase of less than 15% will not be subject to review or the review would be less stringent. The ACR is deeply concerned about any barriers that may limit the ability of patients with arthritis or other rheumatic diseases to obtain affordable, high quality, high value healthcare. Under this scenario, we envision a future with many 14.9% rate increases. Many people already spend more than 10% of their income on insurance premiums[i], and increase of this magnitude could have devastating impacts on patients who live paycheck to paycheck. A married couple earning $50,000 per year could see almost 2% of their paycheck reallocated to health insurance in the first year. This would compound annually as rates continue to climb and could essentially block access to care if consumers can no longer afford to make their copayments or meet their deductibles. We urge HHS to consider the implications this policy may have on coverage affordability and access.

***Medical Loss Ratio (MLR)***

HHS is proposing changing the MLR adjustment process and criteria, reporting requirements, and calculations so that states may adjust the MLR if there is a "reasonable likelihood that an adjustment will help stabilize the individual market in that state." We appreciate that HHS is aiming to increase issuer participation and market competition, but HHS does not provide guidance on states' MLR calculation methodology or how that information will be publicly shared. We request that HHS require states to be transparent in their MLR adjustment process and how any factors will affect the states.

We strongly believe greater transparency will dramatically lower the prices of prescription drugs and help more patients get the treatments they need to effectively manage their chronic conditions. Therefore, the HHS proposal of allowing less detailed reporting of enrollment and issuer profitability would not be conducive to creating a culture of transparency.

***Minimum Essential Coverage (MEC) Designation for CHIP Buy-in Programs***

HHS proposes to categorically designate CHIP buy-in programs that provide identical coverage to the state's Title XXI CHIP program as MEC without going through an application process. We believe this proposal could have serious implications for children suffering from rheumatologic diseases in a CHIP buy-in program. Without clear guidance from HHS, there is no certainty in what will meet the new "substantially resemble" standard, leaving some of the most vulnerable of a

state's population in dangerous medical limbo. The "substantially all" standard is a clear regulation that has been utilized by HHS for some time, and HHS notes that a "substantially resemble" standard would be "less stringent." Notably, the rule states "*we do not propose to codify the 'substantially resemble' standard*". However, this would be a substantive change to an existing regulation, not simply an interpretive rule. Without codifying the change, we believe this action could exceed the discretion of the Secretary and run counter to established practices of administrative rulemaking. Additionally, changes to existing administrative rules must be accompanied by a reasoned analysis for the change in direction. Though the Secretary has deference in the rulemaking process, this current proposal is not accompanied by such analysis. We urge the HHS to withdraw this particular proposal, or at a minimum provide a reasoned analysis for the new standard and codify it in the Code of Federal Regulations.

The ACR is dedicated to ensuring that rheumatologists, rheumatology health professionals, and their patients have access to continuous high-value and high-quality care. The ACR appreciates the work that HHS does and the opportunity to respond to the *Notice of Benefit and Payment Parameters for 2019 Proposed Rule*. We look forward to being 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,

David I. Daikh, MD, PhD
President, American College of Rheumatology

[i] Blumberg, L. J., Holahan, J., & Buettgens, M. (2015, December). How Much Do Marketplace and Other Nongroup Enrollees Spend on Health Care Relative to Their Incomes?. https://www.urban.org/sites/default/files/publication/76446/2000559-How-Much-Do-Marketplace-and-Other-Nongroup-Enrollees-Spend-on-Health-Care-Relative-to-Their-Incomes.pdf