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Specialists in Arthritis Care & Research

2200 Lake Boulevard NE • Atlanta, GA 30319
Phone: (404) 633-3777 • Fax: (404) 633-1870
www.rheumatology.org • info@rheumatology.org

January 22, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244
Submitted electronically via http://www.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:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the *Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule. Reducing high drug costs and improving patients' access to treatments are top priorities for the ACR. We welcome the chance to share our concerns about the impact these proposals will have on our ability to provide quality care to the 54 million Americans living with rheumatic diseases, as well as our recommendations for improving the proposals.

Rheumatologists provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. Rheumatologists, together with members of the rheumatology interprofessional team, primarily provide face-to-face, non-procedure-based care to patients with serious conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other inflammatory arthritides, vasculitis, systemic lupus erythematosus, osteoporosis, and multiple other debilitating diseases. Early and appropriate treatment by rheumatologists and interprofessional team members can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly downstream procedures and care compared to care provided solely by primary care providers.

Lowering Drug Prices and Reducing Out-of-Pocket Costs for Enrollees

While we appreciate the agency's efforts to make prescription medications more affordable, we have serious concerns regarding the decision to allow Medicare Advantage (MA) plans to implement step therapy for Part B drugs and cross-manage Part B and D drug utilization. We believe this policy change significantly threatens patient access to drugs covered under Medicare Part B for the 54 million Americans living with rheumatic diseases. We emphasize that a Part D biologic should not be required before a Part B biologic can be prescribed and that the

choice of biologic should be based on clinical appropriateness and not on cost alone. This policy compromises medical decision making between doctors and patients and prevents timely access to medications that effectively control disease. Additionally, allowing sponsors to implement indication-based formulary designs—i.e. allowing plans to select drugs for their formularies based only on the disease indications they want to use—further takes clinical decision making out of the hands of providers and puts insurance companies in control of patient treatment plans.

Medicare Advantage and Step Therapy for Part B Drugs

Step therapy, also known as fail first protocols, limits therapeutic treatments based on payer preference. This may require a patient to try a treatment other than what the physician believes is best. In the case of patients with rheumatologic diseases, especially severe or complex autoimmune diseases, this can result in irreversible damage. Step therapy frequently disrupts continuity of care by requiring patients to stop an effective therapy and switch to another due to formulary or protocol changes. For rheumatology patients receiving biologic therapy, this stopping and restarting biologic medicines may cause the treatment to fail due to immunogenicity or cause dangerous reactions when the biologic is re-initiated.

CMS states that step therapy as a utilization management tool will better enable MA organizations to ensure that Medicare beneficiaries pay less overall or per unit for Part B drugs. We respectfully disagree. We believe this policy will exacerbate many of the access issues patients currently face with existing utilization management practices. Our patients, like many other patients, rely on very specific treatment regimens that their doctors know is best for them. Step therapy, or "fail-first" policies, can be very detrimental; formularies that prevent patients from getting the right drug first are very concerning. Overall many rheumatology patients with prescription drug plans experience frustrating delays in getting treatment. Those in Part D face increasingly higher cost-sharing and out-of-pocket costs, making their medications unaffordable. Additionally, allowing extra utilization management will increase administrative burden for prescribers, increase overhead costs, and reduce practice efficiency. These impediments to will exacerbate the current US workforce shortage for rheumatology by forcing rheumatologists to stop participating with Medicare in order to maintain practice viability.

Rheumatologists' experience with the commercial market indicates step therapy and the resultant authorization schemes adds significant burden to practices. According to a 2017 AMA survey, 92% of physicians reported that prior authorization caused delays in their patients' care, and 78% reported that prior authorizations sometimes led to treatment abandonment. Prior authorization also creates a burden for physicians who are then required to spend extra time seeking approvals from insurers for medications they have already prescribed[i]. According to the survey, medical practices complete an average of 29.1 prior authorizations per physician per week, which take an average of 14.6 hours to process or the equivalent of nearly two business days—time which could be spent on direct patient care. These requirements further highlight the negative consequences prior authorization has on patient access

We suggest that if a practice agrees to follow an evidence based treatment pathway developed by a specialty society and accepted by CMS, then the practice would be labeled as a trusted entity and be exempt from following Medicare step therapy protocols and prior authorization requirements. This could be done on a disease-by-disease or practice-wide basis.
We applaud CMS for including safeguards intended to protect beneficiaries and ensure timely access to medically necessary Part B drugs. Although we are pleased to see these safeguards, such as step therapy requirements only applying to new starts of medication, the safeguards do not go far enough to protect patients. Further we have grave concerns that there will be a year gap of protections for patients with the rescinding of the September 17, 2012 HPMS memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services for the 2019 plan year and the current proposed rule for the 2020 plan year.. **We urge CMS to immediately publish guidance to plans that lays out, at minimum, the patient safeguards proposed in this rule so that beneficiaries have some protections in 2019.**

CMS' current proposal would require the MA plan to determine whether the enrollee has taken the Part B drug (that would otherwise be subject to step therapy) within the past 108 days. In discussions with CMS staff, we understand that the 108-day period matches existing part D policy and therefore was chosen for this policy in part B. There are many clinical differences in the drugs under Part B compared to those under Part D; therefore, we strongly recommend a 365-day look back period for Part B drugs. For example, the FDA approved dosing frequency for these Part B drugs all exceed 108 days: zoledronic acid for osteoporosis is one year; denosumab for osteoporosis is six months; hyaluronic acid injections for knee osteoarthritis are six months; and rituximab for rheumatoid arthritis is dosed at two infusions repeated every four-six months. There are other similar FDA approved dosing guidelines with a frequency of greater than 108 days for Part B drugs used in the treatment of vasculitis. In addition, various biologics used for rheumatoid arthritis and psoriatic arthritis might need to be held for long intervals due to infection, surgery, or other clinical indications.

The ACR supports more clarity and transparency regarding MA plan notices regarding changes to Part B drug coverage and the requirements for step therapy in order to help put patients in the driver's seat. CMS proposes that MA plans must disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) (when initially adopted or subsequently changed) and Evidence of Coverage (EOC) documents. In the ANOC, we ask that CMS expand on this proposal and require plans to make the step therapy exception process readily available and understandable on its website for providers, patients, and caregivers. We also would appreciate more detail on how CMS will ensure MA plans follow this direction and encourage CMS to increase monitoring of MA plans' usage of utilization management practices overall. Utilization review entities should provide detailed explanations for denials of requests for prior authorization or step therapy override, including whether there was any missing information which resulted in the denial. All utilization review denials should include the clinical rationale for the adverse determination (e.g., national medical specialty society guidelines, peer-reviewed clinical literature, etc.), provide the plan's covered alternative treatment and detail the provider's appeal rights. Further, we encourage CMS to guarantee that a portion of any cost savings be used to reduce OOP expenses for patients and that this be reported transparently on a yearly basis. Our MA patients now have 20% copays on all Part B

drugs, and many have stopped treatment because they cannot afford this expense on their fixed incomes.

We request more details on exceptions and recommend that CMS make the following explicitly clear:

- That the provider determines if a patient "fails" a treatment, not another entity such as the insurance company.
- Exception if the treatment is contraindicated.
- Exception if the provider determines the treatment is likely to be ineffective.
- Exception if the provider determines the treatment is likely to cause a harmful reaction.
- Exception for those whose life could be in jeopardy or physical or sensory function irreparably harmed.
- Exception if the provider and patient believe the treatment is likely to impede the patient's ability to perform daily activities or responsibilities and/or adhere to the treatment plan.
- Preclude any unwritten, implicit step therapy that is handled through a different utilization management process such as prior authorization.

Part D Explanation of Benefits

CMS proposes to amend regulations related to the Part D Explanation of Benefits to require the inclusion of drug pricing information and lower cost therapeutic alternatives in the Explanation of Benefits that Part D plans send members. We agree that this is helpful information and beneficiaries should have access to any possible ways to lower their out of pocket costs, but we do not support forcing a stable patient to switch to another biologic medication for the sake of cost control. This needlessly disrupts continuity of care and puts patients at significant risk for loss of disease control and potentially life-threatening complications. We hope that CMS will monitor plans closely for non-medical switching and will require plans to ensure transparency about any utilization management requirements. The requirements should be directly disclosed in their explanation of coverage during the open enrollment process through plain, clear language about what these requirements mean for patients and what their options are.

E-Prescribing and the Part D Prescription Drug Program

CMS is proposing that each Part D plan adopt a provider (i.e. EHR-integrated) Real Time Benefit Tool (RTBT) of its choosing beginning on or before January 1, 2020 with the idea that the RTBTs have the capability to inform prescribers when lower-cost alternative therapies are available under the beneficiary's prescription drug benefit. This proposal would require the plans to present real-time values for a patient's cost-sharing information, other formulary alternatives, indications-based restrictions, and any utilization management requirements.

The ACR believes this concept and intent of this proposal is good, but we have concerns that if CMS and MA plans require providers to review out-of-pocket (OOP) costs with patients and counsel them on medication choices based on cost, then this may result in treatment choices based solely on cost rather than choosing what is optimal for the patient. Further, the

additional time needed on the part of the physician and staff for this type of non-medical work will increase practice burden and costs. Additionally, as CMS states there is currently no RTBT standard. We are concerned that this lack of standard could result in the sort of cumbersome user interfaces that exist in other stand-alone web-based login sites, such as the current state drug monitoring websites. Such scenarios impede practice workflow and add to the "death by a thousand clicks" environment.

However, we support the spirit of this proposal. It would indeed be most helpful for prescribers to know patients' out of pocket costs while prescribing a medication in the electronic health record in order to further assist patients at the point of care. We suggest that CMS require Part D plans and benefits managers to work with EHR vendors toward this goal, while not placing additional burden on patients and their physicians.

Prohibition Against Gag Clauses in Pharmacy Contracts

We applaud CMS for implementing the provision that restricts Part D sponsors from prohibiting or penalizing a pharmacy from disclosing a lower cash price to an enrollee. Chronic disease patients are often very sophisticated consumers who are accustomed to balancing the cost of everyday necessities with the cost of their prescriptions. When given the appropriate information, they will make choices that save money.

We also propose the inclusion of automated line items on pharmacy receipts that detail the amount of savings, or additional cost, that a patient incurs by utilizing their pharmacy benefit plan. These line items would function much like the savings line items on grocery store receipts that inform customers how much is saved in a shopping trip by using coupons and taking advantage of in-store deals. Similarly, these line items on pharmacy receipts would tell patients in concrete terms how much their pharmacy benefit is saving them. Conversely, it would also tell them how much additional it is costing them if the copay required by utilizing their pharmacy benefit is higher than the cash price of a drug. This automated disclosure would provide transparency at the point of sale and empower patients to make more informed choices about purchasing medications, as well insurance policies.

Pharmacy Price Concessions in the Negotiated Price

We agree that higher negotiated prices lead to higher beneficiary cost-sharing. We support CMS developing policy that would reduce beneficiary out-of-pocket costs and improve price transparency and market competition under the Part D program. CMS has appropriately highlighted that there has been flexibility in how price concessions are categorized: some plans treat them as direct and indirect remuneration (DIR), while others take a different approach. Treating price concessions as DIR creates a premium advantage, which, as CMS notes, may result in plan sponsors sometimes choosing higher negotiated prices in exchange for higher DIR or even preferring a higher net cost drug over a lower-cost option. This practice is unacceptable. We believe there should be contract standards and definitional agreement for money flowing into PBMs. Definitional agreement and consistency are the foundation to most other policy solutions. Therefore, in addition to CMS considering policy to redefine "negotiated

price" we also urge CMS to create a common definition of "rebate," discount," "fee," and any other terms a PBM may use.

In conclusion, we hope that CMS will publish guidance to the plans as soon as possible so that patients will have safeguards for the 2019 plan year. The ACR is dedicated to ensuring that rheumatologists and rheumatology interprofessional team members have the resources they need to work with CMS and provide patients with high-quality 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. The American College of Rheumatology appreciates the work that the agencies do and the opportunity to respond to this proposed rule. We look forward to being a resource to you and to working with the agency. 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

[i] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf