January 16, 2018

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Submitted electronically via Regulations.gov

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program

Dear Administrator Verma,

The Coalition of State Rheumatology Organizations, or CSRO, is a group of state or regional professional rheumatology societies formed in order to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our coalition serves the practicing rheumatologist.

Today, we write to express concerns with specific challenges rheumatologists and their patients face with Medicare Advantage and Part D Prescription Drug plans. Through the Alliance of Specialty Medicine, CSRO has provided feedback on additional issues that broadly impact specialists, including rheumatologists. We look forward to working with you to address these issues as part of your broad efforts to put "Patients Over Paperwork."

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

In addition to recommended improvements to the Quality Rating System, including new stars measures, that we endorsed in comments provided by the Alliance of Specialty Medicine, we believe there are other areas where CMS could create meaningful quality improvement incentives and differentiate plans based on quality. For example, quality measures reported by rheumatologists through CMS' physician-focused quality improvement programs, such as the Merit-based Incentive Payment System (MIPS), help to support and improve MA performance under the Quality Rating System. However, there is no clear association between clinician-level measures and stars measures, making it difficult for rheumatologists to demonstrate our unique value to MA plans and the enrollees they cover. Efforts by the Core Quality Measures Collaborative do not address this level of alignment; those efforts simply identify core sets of quality measures that providers can report across payers in their respective quality improvement progams. To address this challenge and promote accountability across programs and provider types, ***we urge CMS to form a technical expert panel (TEP) that would work toward establishing meaningful linkages between clinician-level quality measures and stars measures, where possible.*** This activity

would help CMS with its efforts toward improving measures to further reflect the quality of health outcomes under rated plans. CSRO would be pleased to submit nominees to the TEP to assist the agency with carrying out this work. ***This would be helpful as a precursor to establishing a stars measure that would award points to MA plans that maintain an adequate network of physicians who participate in CMS' Quality Payment Program, including MIPS and alternative payment models (APMs).***

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

In "Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale" ("RFI"), CMS notes that the agency initially believed that market competition would encourage the pass-through of price concessions obtained by sponsors and their PBMs from manufacturers and pharmacies. Thus, when Part D was established, the agency did not establish a requirement to pass through price concessions at the point of sale, due to a concern that such a requirement would undermine the market forces that would encourage pass-throughs. In the RFI, however, the agency states that reality has not matched expectations in this regard; indeed, the agency notes that "only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale." ***Based on our experience treating patients with rheumatologic disease, we can confirm: this is true.*** In recent years, patient cost-sharing has skyrocketed to the point of unaffordability. It begs the question: where are these price concessions going?

Due to significant innovation in the last decade, there are now many effective treatments available for rheumatoid arthritis and other rheumatologic conditions. Previously, a diagnosis meant almost certain disability. Today, due to new treatments, people with well-managed rheumatologic conditions can live long and productive lives. However, these treatments are expensive and not cureative; a patient will likely need the medicine for the remainder of his or her life to avoid or ameloriate the distructive nature of these diseases which lead to disability.

The PBM industry has gone on the offensive in the last year, alleging that they save money for payers, employers, and patients. We know they are not saving money for patients and, from the data CMS produces in the RFI, they are not saving money for Medicare either. Indeed, due to the perverse incentives inherent in the current price concession structure, PBMs are likely contributing to the rising costs for patients and payers on whose behalf they administer prescription benefits. Not a day goes by in the average rheumatologist's office without a patient expressing dismay at his or her ever-rising cost-sharing obligations. Often patients tell us that they have stopped therapy or are rationing their drugs, as a result. To have effective treatments available that patients cannot access is frustrating for physicians and cruel for patients who are suffering pain, missing work, and losing time with family.

In the RFI, CMS solicits comments on requiring sponsors to include some minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. ***We strongly support a pass-through requirement of 100% of price concessions at the point of sale.*** We align ourselves with comments of the Alliance for Transparent and Affordable Prescriptions on this issue.

The impact estimates provided by CMS are encouraging, even without accounting for behavioral changes. CMS estimates that, with a 100% pass-through of manufacturer rebates, beneficiaries would see a monthly premium increase of $43.84 but see a monthly $131.97 reduction in cost-sharing, for an

overall savings of $88.13 per month. In other words: the premium increase would be more than offset by the cost-sharing reduction. Overall, over ten years, beneficiaries would save $56.9 billion with a 100% pass-through. Meanwhile, the government would save $82.1 billion. The effect of passing through pharmacy price concessions is similar for beneficiaries, though the numbers are smaller.

Requiring pass-through of price concessions does not harm the competitive dynamics underpinning Part D; rather, it would provide a consistent structure for all plans to compete within, while benefiting patients and the program. It is difficult to find a proposal that helps beneficiaries without compromising their access to medicines, all while saving the government significant money to boot. We thank CMS for taking this first step toward creating a better program for beneficiaries. We urge the agency to adopt a policy requiring sponsors to include all price concessions at the point of sale for Medicare beneficiaries.

Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

CSRO has long supported the regulatory distinction made by the Food and Drug Administration between biosimilars and traditional generics, and we thank CMS for acknowledging the difference between these two groups of products. Biosimilars are intended to be replicas of innovator biologics, with the goal of providing cost savings for patients in the form of less costly alternatives, where the science supports substitution. As such, we support CMS' proposal to apply the same levels of cost-sharing to biosimilars as applicable to generic drugs for LIS cost-sharing and for non-LIS catastrophic coverage. ***We urge the agency to consider making a similar definitional change to allow biosimilars to be included in the so-called "donut hole" discount program.***

Reducing Provider Burden Associated with Medicare Advantage Medical Record Requests

Rheumatologists receive an inordinate volume of medical record requests, a likely result of the tremendous impact the rheumatic conditions of their enrollees have on rated plans quality ratings and overall costs. *The burden of these requests cannot be overstated*.

Indeed, in a query of multiple rheumatology practices, we have heard from practices that have received hundreds of medical record requests from multiple MA plans within a single calendar year and with due dates of a few days to two weeks, regardless of how many records they need and for what timeframe. These practices tell us that each individual record requested may be hundreds of pages long and take hours to either fax or copy and mail to the auditor. In the aggregate, this is thousands of pages and hundreds of hours lost, which imposes a significant cost and administrative burden on already struggling practices. Moreover, it diverts limited office personnel from more important duties that have a direct impact on patient care.

Some practices tell us that auditors will call their office prior to sending a faxed request, then fax the request, and follow-up with a phone call to ensure the faxed request was received. Within a few days, the auditor will call again to check the status of the request. The excessive and repeated calls tie up phone lines for patients and referring/consulting physicians that have important patient-care questions.

Generally, practices are not always told whether the audits are related to CMS-initiated MA Risk Adjustment Data Validation (RADV) audits or other audits to MA plans are conducting independently to increase their risk score and receive more funding from the federal government.

To address these and other challenges with MA audits, we urge CMS to adopt the recommendations we endorsed in the Alliance of Specialty Medicine's comment letter. Specifically, ***we urge CMS to require MA plans to:***

- ***Follow a standardized process for all medical record requests;***
- ***Clearly identify the nature of their medical record request (e.g., RADV, other purpose) and provide written documentation when requests are mandated as part of CMS-initiated audits;***
- ***Provide reasonable deadlines for medical record submissions, as well as a process for extending the submission deadline for extenuating circumstances;***
- ***Limit the number and volume of medical record requests (e.g., no more than once per year and no more than 20 records per physician); and***
- ***Allow practices to submit medical records through a secure web-portal, on CD/DVD, or by fax, when possible.***
- ***Reimburse practices for completing medical record requests at a rate no less than is set under State law.***

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Thank you for considering our comments, and we look forward to working with you as you implement the QPP in 2018 and future years. Should you have any questions, please contact Judith Gorsuch, JD at jgorsuch@hhs.com, or Emily L. Graham, RHIA, CCS-P at egraham@hhs.com.

Sincerely,

Coalition of State Rheumatology Organizations
Alabama Society for the Rheumatic Diseases
Alaska Rheumatology Alliance
Arkansas Rheumatology Association
Florida Society of Rheumatology
Rheumatology Association of Iowa
Kentuckiana Rheumatology Alliance
Rheumatology Alliance of Louisiana
Massachusetts, Maine, & New Hampshire Rheumatology Association
Michigan Rheumatism Society
Mississippi Arthritis & Rheumatism Society
New Jersey Rheumatology Association
North Carolina Rheumatology Association
Ohio Association of Rheumatology
South Carolina Rheumatism Society
Tennessee Rheumatology Society
Washington Rheumatology Alliance
Wisconsin Rheumatology Association